

OPERATION AND MAINTENANCE INSTRUCTION MANUAL

AEU-6000-70V & AEU-6000 Implant/Endodontic Dental Systems



Aseptic

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CLASSIFICATIONS:

- Class I Equipment
- Type B Equipment
- Ordinary Equipment - degree of protection against ingress of water

ETL CLASSIFIED



CONFORMS TO UL STD 60601-1;
CERTIFIED TO CSA STD C22.2 NO. 601.1



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INTENDED PURPOSE AND INTENDED USERS:

Intended Purpose:

Intended Use	The AEU-6000 & AEU-6000-70V are intended to provide drilling during dental implant or root canal procedures.
Indications for Use	The AEU-6000 & AEU-6000-70V are drive systems used in dentistry for replacement of missing or damaged teeth with implants or by preservation of function through root canal therapy.
Contraindications	None known.

Intended Users:

The AEU-6000 and AEU-6000-70V are prescription devices that are used by healthcare professionals in the field of dentistry.

Intended Patient Population:

There are no restrictions on age group, sex, weight range, health, or other conditions on the patient population.

EXPECTED SERVICE LIFE:

Seven years.

ESSENTIAL PERFORMANCE:

This device does not have ESSENTIAL PERFORMANCE as defined in IEC 60601-1.

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

INFORMATION CONCERNING THE ACCURACY AND PRECISION OF THIS PRODUCT MAY BE OBTAINED UPON REQUEST BY CONTACTING ASEPTICO AT THE ADDRESS SHOWN ON THIS PAGE.

Your new Aseptico AEU-6000-70V & AEU-6000 Systems are two of the finest dual-function implant/endodontic motor systems available to the dental profession. The systems combine a powerful brushless 40,000 RPM motor with a wide range of handpiece ratios and precision torque controls to make the perfect dental systems for both implant and endodontic applications. The AEU-6000-70V is equipped with a multi-function foot control and the AEU-6000 comes with a basic On/Off foot switch.

Congratulations!

This System is engineered to provide many years of reliable service. Please read the instructions provided in this manual to receive the best and longest service from your Aseptico equipment.

Separate manuals may be provided to cover the operation and maintenance of handpieces or other accessories for your unit.

PACKAGE CONTENTS:

- Electronic Control Console, P/N 120351
- AE-230M-40 40K Brushless Micromotor
- Motor Holder, P/N 461561, with Attaching Bracket, P/N 461816
- AE-70V2 Variable Speed Foot Control (AEU-6000-70V only)
- AE-7PM On/Off Foot Control (AEU-6000 only)
- AE-23 Autoclavable Irrigation Tubing Set
- AE-23-PUMP Peristaltic Pump Tubing Set (10 Pieces)
- AHP-07K Cannula Clip Set w/ Y-connector
- Irrigation Bag Hanger Rod, P/N 461541
- Power Cord

PURCHASED SEPARATELY:

- AHP-85MB-X or AHP-85MB-CX 20:1 Mont Blanc® Reduction Contra-Angle Handpiece
- AHP-85-SS Saeshin 20:1 Contra Non-Optic Reducer Dental Handpiece
- AHP-85MK or AHP-85MK-FO 20:1 Eco Line® Reduction Contra-Angle Handpiece
- AHP-85P-I 20:1 Impulsion® Reduction Contra-Angle Handpiece
- AHP-64 1:1 Straight Handpiece
- AHP-64MKI 1:1 Eco Line® Straight Handpiece with Internal Irrigation
- AHP-77W 1:2 Speed Increasing Handpiece
- AHP-65TI 1:3 Speed Increasing Handpiece
- AHP-72MK 1:5 Speed Increasing Contra-Angle Handpiece
- AHP-88MN 8:1 Reduction Latch-Head Contra Angle Handpiece
- AHP-88MNP 8:1 Reduction Push-Button Head Contra Angle Handpiece
- Replacement AE-23 Autoclavable Irrigation Tubing Set
- Replacement AE-23-PUMP Peristaltic Pump Tubing (10 Pieces)
- Replacement AE-23-BOT Autoclavable Irrigation Tubing Set for Bottles
- MC-6000 Memory Card

Mont Blanc® and Impulsion® are registered trademarks of Anthogyr. Eco Line® is a registered trademark of MK Dent. The above Dental Handpieces are not sold or distributed with the system in the EU. Handpieces are sourced locally through the handpiece manufacturers distribution channels. For recommended handpiece manufacturer and part number, contact Aseptico.

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

WARNING: Injury or death may result if ignored.

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

NOTE: Important additional information and hints.



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 of this product.

WARNING: Inspect the system components including the power cord, motor, motor cable, and irrigation tubing for damage or material degradation before each use. If system components do not operate as expected at startup, replace or send for repair. Do not use the device if it appears damaged or defective.

WARNING: The Systems are supplied Non-Sterile! Before first use, and before each patient use thereafter, sterilize specified components as recommended in the Sterilization and Maintenance section.

CAUTION: Do not soak or submerge the motor in any liquid.

CAUTION: Use of cleaning or disinfection solutions may damage the tubing set. Follow the pre-cleaning and sterilization procedures provided for the tubing set.

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

CAUTION: Federal law restricts this device to sale by or on the order of a dentist.

CAUTION: Use of other dental accessories or sub-assemblies from third-party manufacturers not specified by Aseptico may damage the equipment and/or lead to a safety hazard due to device malfunction.

CAUTION: All repairs are to be performed by authorized Aseptico service personnel only.

WARNING: Always follow these guidelines when operating the unit:

- Never touch drills, burs, files, or other handpiece tips when they are still rotating.
- Handpieces should only be attached when the motor has stopped running.

WARNING: All handpieces have inherent inefficiencies that can lead to torque variations. Routine calibration is recommended, even if using the same handpiece or whenever a handpiece is changed. If further verification of torque accuracy is desired, then it is suggested that a torque wrench be used.

WARNING: Always comply with the handpiece and implant/file manufacturers' instructions regarding maximum speeds, torques, forward and reverse directions, and use of all instrumentation, drills, burs, etc., used in endodontics, implantology, and other oral surgery applications.

- CAUTION:** The irrigation supply system is designed for use with a saline solution or sterile water. For implants, use only suitable irrigants as recommended by the manufacturer's instructions.
- CAUTION:** Connect mains power cable to a properly grounded outlet only.
- CAUTION:** The motor is sensitive to shock and may be damaged if dropped or impacted against a hard surface.
- CAUTION:** Do not oil or lubricate the motor.
- CAUTION:** Do not bend motor cord sharply.
- WARNING:** Do not disassemble or alter the System motor, console, or foot switch.
- CAUTION:** Use only appliance cord Type C13, 10A per IEC / EN 60320-1. Note: North America, Denmark, Australia, and New Zealand may require hospital grade plugs. Consult local codes.
- WARNING:** Never use damaged or worn files as they may separate in the root canal.
- CAUTION:** Never connect or disconnect the bag spike to the irrigation bag over the console. Water spilled onto the console can damage the unit.
- WARNING:** Use of a rubber dam is required during endodontic pulp removal to prevent ingestion or aspiration of materials or broken files.
- WARNING:** Using a different 20:1 handpiece from that indicated on the System display can cause significant under- or over-torque.
- WARNING:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- WARNING:** Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the unit, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- WARNING:** Turn the power off and unplug the unit before changing the fuses.
- NOTE:** Report any malfunction or deterioration in the characteristics and/or performance of this device, as well as any inadequacy in its labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in their state of health (e.g. Serious Adverse Event) immediately to the manufacturer and the regulatory authority where the incident occurred.

ELECTROMAGNETIC COMPATIBILITY: This equipment meets all requirements for safety and performance, related to Electromagnetic Compatibility Standard IEC 60601-1-2:2014.

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

SETTING UP THE UNIT:

1. Unpack the Console.
2. The autoclavable Motor Cradle can be attached to either side of the Console or placed flat on any adjacent tabletop surface or tray. To install the Cradle, mount the Cradle Bracket into the holes provided on the bottom of the Chassis with the two screws provided (see Figure 1). Align the slot on the bottom of the Cradle with the mounting rail on the Bracket and snap into place.
3. Attach the remote power cord to the back of the console (see Figure 2) and plug into a hospital-grade grounded electrical receptacle.

Confirm that the type of cord plug cap is correct for the country of usage and carries the proper certification markings.

4. Connect the AE-230M-40 Motor/Cord to the receptacle on the lower right front of the console (Figure 3) by aligning the red dot on the cord connector with the arrow at the top of the receptacle, then gently pushing the connector straight in to lock into place. Remove cord by pushing inward slightly on the strain relief, then grasping connector body near the red dot and pulling the connector straight out of receptacle.

Fig.1 - Motor Cradle Bracket Installation

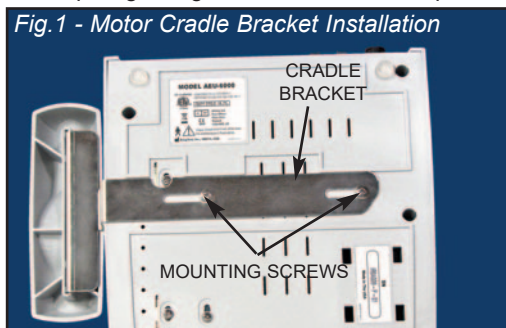


Fig.2 - Console Back

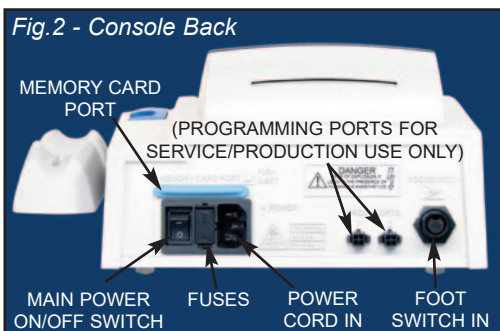
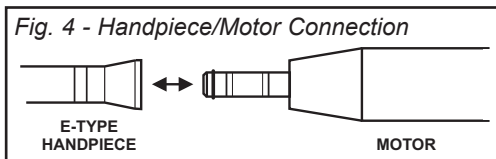


Fig.3 - Setup



5. Attach the appropriate "E-Type" handpiece to the motor as shown in Figure 4.

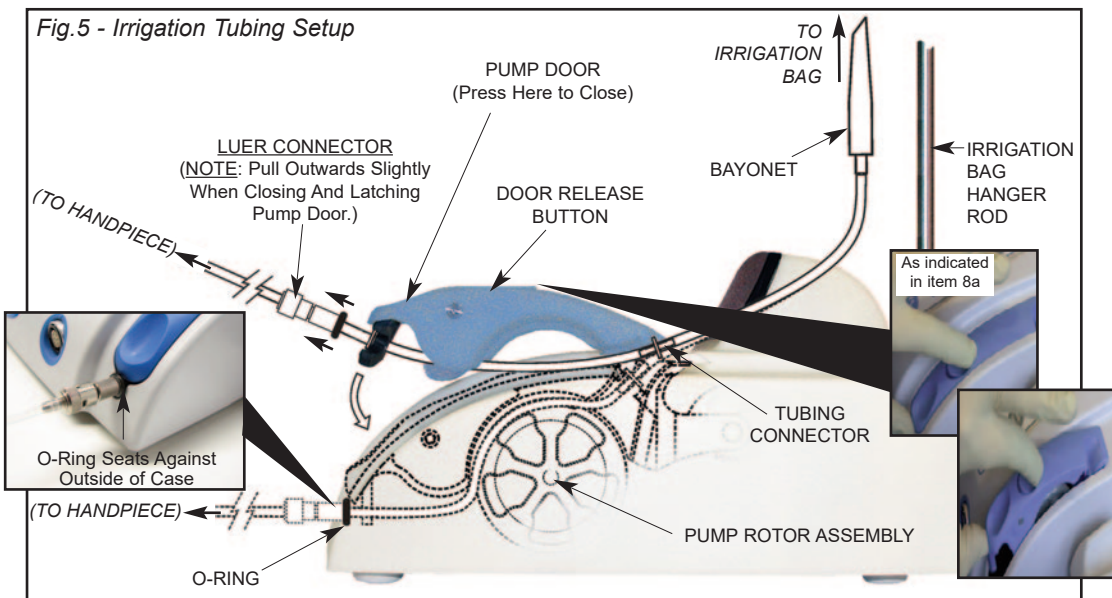


6. Insert bag hanger rod into socket on the top of the unit. Note keyway in slot.
7. Attach the supplied foot control to the connector on the back of unit marked "Footswitch" (see Figure 2). Refer to page 15 for foot control descriptions and operation.
8. Install irrigation tubing set into pump door as described below (see Figure 5):

CAUTION: Never connect or disconnect the bag spike to the irrigation bag over the console. Water spilled onto the console can damage the unit.

CAUTION: The pump door is designed to exclusively operate with Aseptico's autoclavable irrigation tubing set (refer to "Package Contents" section). The use of other brands may result in damage to the irrigation pump system unit.

- a. While pressing and holding the pump door latch release button, gently lift the door open from the lip just above the button.
- b. Install Pump Tubing Assembly into pump door as shown in Figure 5. Install tubing connector into the slot located on the back end of pump door. Then, pull the Luer connector toward the front end of door and slide connector into the slot located on the front of the pump door.
- c. Grasp Luer connector and gently pull outwards, then close and latch the pump door. Slowly release tension on the Luer connector and allow the O-Ring to seat against the outside of the case as shown in Figure 5. Ensure that the tubing is not pinched.
- d. Route the remaining length of tubing to the handpiece and connect to the irrigation accessory tubing provided with the handpiece. Secure the tubing to the motor cord with clip set provided.
- e. Remove the protective cover from the irrigation bag and insert the bayonet into the I.V. port. Hang the bag from the hanger rod.



CONTROL PANEL FUNCTIONS:

1. Main Power Switch:

Located on back of console (see Figure 2). Controls main power On/Off to the console. When first turned On, the System will allow the user to select either Mont Blanc, Eco Line, Impulsion, or AHP-85-SS type 20:1 handpiece settings:

Select 20:1 Handpiece:	
1>MontBlanc	2>Next
1>Eco Line	2>Next
1>Impulsion	2>Next
1>AHP-85-SS	2>Next

Press Preset Button #1 to select or #2 to view next handpiece. The System will confirm the type of handpiece selected and then briefly display the software version and date. The System will then initialize with Implant Preset-1 active. **Note:** The System will only ask for the 20:1 handpiece selection above when: the unit is turned On for the first time; after factory settings are

⚠ WARNING

Using a different handpiece than indicated on the display can cause significant under- or over-torque.

recalled; or after the unit is reprogrammed with the memory card. Otherwise, the last settings used will initialize.

2 Control Panel 'Standby' Button:

Turns control panel on/off. Reactivates System from Sleep Mode.



a. Press the Standby button to turn console key pad and display On or Off. When console is turned On, display should light up and show the default startup screen. If the console was turned Off using the Standby button, press the Standby button again or press the foot pedal to wake up the System and return it to the last state used.

3 Calibration (CAL):

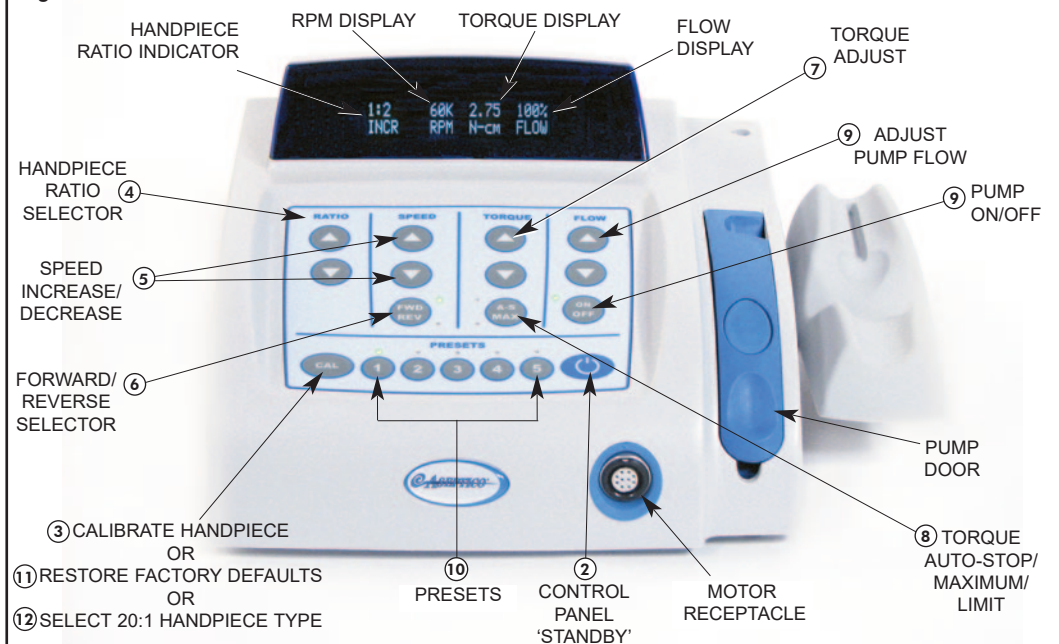
Activates the integrated program for calibrating the handpiece.



a. Press and release CAL button.

The System will run the selected handpiece through a series of calibration tests. Follow the prompts provided on the display (refer to paragraph 9, page 11 for complete calibration instructions).

Fig.6 - Console Control Panel



- 4 **Handpiece Ratio Selector:**
*Allows user to select ratio of hand-piece.
 Ensures accurate display of speed
 and torque levels.*

a. Press the handpiece Ratio selector Up/Down buttons until the Handpiece Ratio Indicator matches the ratio indicated on the handpiece being used. The available ratios are 1:5, 1:3, 1:2, 1:1, 20:1, and 8:1. The relative speed ranges with a 40K motor are shown in Figure 7.



Fig.7

SPEED RANGES		
1:5	5,000 - 200,000	RPM
1:3	3,000 - 120,000	RPM
1:2	2,000 - 80,000	RPM
1:1	1,000 - 40,000	RPM
20:1	15 - 2,000	RPM
8:1*	42 - 5,000	RPM

* 42 - 1,400 RPM if Endo ASR active.

Note: Handpiece ratio selection automatically determines which system Presets are used. When the 1:5, 1:3, 1:2, 1:1, and 20:1 ratios are selected, the system automatically switches the Presets to Implant operating parameters; when the 8:1 ratio is selected, the system automatically switches the Presets to Endodontic operating parameters.

Note: Prior to calibrating a handpiece on the System, the user must preselect the ratio of the handpiece via the Ratio Up/Down buttons. The System can then perform a “Free-Run” calibration on both increaser and reduction handpieces.

- 5 **Speed:**
Allows user to select desired speed (RPM) for motor/handpiece.

a. Press the Speed Up button to increase speed or the Speed Down button to decrease speed.



Note: For display accuracy, the Ratio Selector must match the ratio of the

handpiece being used.

- 6 **Forward/Reverse (FWD/REV):**
Sets the rotational direction of the handpiece.



a. The green LED next to the FWD/REV button illuminates when forward rotation is selected. The amber LED indicates reverse rotation. An audible beep will also indicate reverse rotation.

- 7 **Torque Adjustment:**

Allows the user to select torque limits in Newton•centimeter increments or gram-centimeter increments, depending upon handpiece ratio selected.



a. Press the Torque Adjustment Up/Down buttons until the desired torque level is indicated on the Display. **Note:** This feature is not available when in “MAX” Mode - see paragraph 8 for details. **Note:** When using an Impulsion 20:1 Handpiece, the maximum available torque will be 32 N-cm when the Pump is ON, or 40 N-cm when the Pump is OFF. When using a Mont Blanc, Eco Line, or AHP-85-SS 20:1 handpiece, the maximum available torque will always be 50 N-cm., regardless of pump setting.

- 8 **Torque Modes (A-S/MAX):**
Allows the user to select from one of four torque control modes: Auto-Stop, Auto-Stop-Reverse, Maximum, or Torque Limiting, depending upon which handpiece ratio is selected.



a. **Auto-Stop Torque Mode (20:1 and 1:1 handpiece ratios)** - The user can specify an Auto-Stop torque mode by depressing the Auto Stop (A-S/MAX) button until the green LED illuminates, then selecting the desired torque level via the Torque Up/Down buttons. The handpiece will stop operating one second after the Auto-Stop torque limit is reached. A warning tone will sound when the actual torque level reaches 75% of the specified Auto-Stop limit.

CONTROL PANEL FUNCTIONS - Cont'd:

b. Auto-Stop-Reverse Torque Mode (8:1 handpiece ratio) - The user can specify an Auto-Stop-Reverse torque mode by depressing the (A-S/MAX) button until the green LED illuminates, then selecting the desired torque level via the Torque Up/Down buttons. The System will automatically alternate between forward and reverse rotation in an attempt to free the instrument. Whenever the System is operating in this mode, "ASR" will be indicated on the Display directly below the Ratio Indicator.

c. MAX Torque Mode (1:1, 20:1, and 8:1 handpiece ratios) - Depressing the MAX (A-S/MAX) button until the amber LED illuminates will set the torque to its maximum level. The handpiece will only operate up to this specified torque level. No incremental adjustments are allowed when in "MAX" mode.

NOTE: MAX Mode is only available with 1:1 and reduction handpieces.

d. Torque Limit Mode (Available with all handpiece ratios)- Depressing the Torque Modes Button (A-S/MAX) until neither LED is lit will limit torque to the value set via the torque Up/Down buttons. The handpiece will slow down when a load greater than the torque limit is applied. Once the load is removed, the handpiece will return to target speed. The Torque Limit Mode is the only Mode available for increaser handpieces.

9 Irrigation Pump Controls (FLOW):

Allows user to turn pump On/Off and select Flow rate.

a. Depress the pump On/Off button to activate/deactivate the pump. The green LED will illuminate when activated.

b. Flow rate can be adjusted in 10% increments, from 10% to 100%, by pressing the Flow Up/Down buttons.

c. Irrigant will flow when the footswitch is depressed.



Note:The irrigation pump can provide irrigant to the handpiece at a maximum flow rate of 140 ml/min.

10 PRESETS 1 - 5:

Allows the user to store and quickly access up to



5 different configurations. Each preset can be reprogrammed by the user with different operating parameters. Green LEDs indicate which preset is active.

a. For the 1:5, 1:3, 1:2, 1:1, and 20:1 ratio selections, Preset buttons 1 - 5 are preprogrammed at the factory for the following **Implant** parameters:

Preset 1:

- 1:2 Handpiece
- 60,000 RPM, FWD
- 1.67 N•cm Torque, Torque Limit
- Pump On, 100% Flow

Preset 2:

- 20:1 Handpiece
- 1,200 RPM, FWD
- MAX Torque
- Pump On, 80% Flow

Preset 3:

- 20:1 Handpiece
- 800 RPM, FWD
- MAX Torque
- Pump On, 80% Flow

Preset 4:

- 20:1 Handpiece
- 15 RPM, FWD
- 25 N•cm Torque, Auto Stop
- Pump On, 30% Flow

Preset 5:

- 20:1 Handpiece
- 15 RPM, FWD
- 32 N•cm Torque, Auto Stop
- Pump Off

b. For the 8:1 ratio selection, Preset buttons 1 - 5 are preprogrammed with the following settings:

Preset 1:

- 8:1 Handpiece
- 300 RPM, FWD
- 700 g•cm Torque, Auto Stop Reverse
- Pump Off

Preset 2:

- 8:1 Handpiece
- 300 RPM, FWD
- 500 g•cm Torque, Auto Stop Reverse
- Pump Off

Preset 3:

- 8:1 Handpiece
- 300 RPM, FWD
- 300 g•cm Torque, Auto Stop Reverse
- Pump Off

Preset 4:

- 8:1 Handpiece
- 500 RPM, FWD
- 500 g•cm Torque, Auto Stop Reverse
- Pump Off

Preset 5:

- 8:1 Handpiece
- 500 RPM, FWD
- 300 g•cm Torque, Auto Stop Reverse
- Pump Off

Press desired Preset button once to select; Hold button down to save new customized settings (refer to paragraph 12, page 13 for complete instructions on changing and saving Presets.)

11 Restoring Factory Defaults:

Allows user to restore the factory default settings to the System.

a. Turn Main Power Switch on back of console to 'OFF' (O) position.

b. Wait two seconds for the Display and LEDs to turn off, then turn Power Switch back 'ON' (—). As the "Aseptic" startup marquee scrolls across the Display, press and hold the Calibration (CAL) button.



c. The following prompt will be displayed:

Recall Factory Setup? Press 1> Yes 3> No

- 1) To restore factory defaults, press Preset Button #1 (Yes). The following prompt will then ask the user to confirm the recall:

Are You Sure? Press 1> Yes 3> No

To confirm the restore, press Preset Button #1, or, to abort the restore, press Preset Button #3. A beep will sound once the defaults are loaded into the System. The startup screen will then redisplay.

- 2) To keep all current or customized settings without loading the factory defaults, press Preset Button #3 (No). The System startup screen will redisplay.

IMPORTANT: All user customized Presets will be lost whenever the above factory default settings are restored or whenever the unit has been reprogrammed with new software.

12 Select 20:1 Handpiece Type:

Allows user to select the 20:1 handpiece used.

a. Repeat Steps 11a and 11b above under "**Restoring Factory Defaults**", then at Step 11c, press Preset Button #3 (**No**) at the "Recall Factory Setup" prompt.

b. The following prompt will display:

Select 20:1 Handpiece:
1>MontBlanc 2>Next
1>Eco Line 2>Next
1>Impulsion 2>Next
1>AHP-85-SS 2>Next

- 1) Press Preset Button #1 to select or #2 to view next handpiece. The System will then confirm the type of handpiece selected.

The System will briefly display the software version and date, then initialize with Implant Preset-1 active. **Note:** When a 20:1 handpiece is selected, the System display will indicate "MB" (Mont Blanc), "ECO" (Eco Line), "IMP" (Impulsion), or "SS" (AHP-85-SS) beneath the ratio.

OPERATION:

GETTING STARTED: After the unit has been set up and the user has become familiar with the System's control panel functions, there are two different modes that can be used to begin operation:

- **Manual Mode** - By default, the unit is always in manual mode. At any time, the user can adjust the torque, speed, irrigation flow, and other parameters, using the control panel keypad. *Refer to Manual Mode instructions on this page.*
- **Preset Mode** - The System provides ten Presets, five in Implant Mode and five in Endodontic Mode, that can be used to quickly retrieve preferred operating settings. Selecting these Presets saves time when preparing for different procedures. *Refer to Presets on page 14.*

The system automatically switches between the **Implant** and **Endodontic** presets, depending upon which handpiece ratios are selected with the control panel "Ratio" buttons:

a. Implant Mode - The system uses these presets whenever the 1:5, 1:3, 1:2, 1:1, or 20:1 handpiece ratios are selected. A display prompt confirms the mode switch:

Switching to Implant Mode

b. Endodontic Mode - The system uses these presets whenever the 8:1 handpiece ratio is selected. A display prompt confirms the mode switch:

Switching to Endo Mode

Start-Up:

1. Turn the main power switch on the back of console to the 'ON' position. The display on the console will turn on and the default Start-Up Screen will be displayed for a few seconds. The Start-Up Screen displays the current software version of the unit. (This

version number will change with each software upgrade.) Following the Start-Up Screen display, the settings for Preset 1 will initialize and display when: the main power to the console is turned 'ON' for the first time, the software is updated, or the factory defaults are restored. Otherwise, the settings that were last used will initialize.

Depressing the blue Standby button on the keypad will enable/disable the "Standby" mode, which turns the display On/Off and places the unit into a temporary "Power Save" mode. Pressing the Standby button a second time or pressing the foot pedal will reactivate the unit. **NOTE:** The Preset LEDs blink consecutively when the unit is in Standby Mode.

Manual Mode:

1. Select the handpiece ratio that matches the handpiece being used. *For more information, refer to paragraph (4), page 7.*
2. Insert a file, bur, or drill into the handpiece.
3. Calibrate the attached handpiece to ensure more precise measurements. *Refer to paragraph 9, page 11 for complete calibration instructions.*
4. Set the desired speed (RPM) for the handpiece using the "SPEED" control buttons.
5. Set the desired torque for the handpiece using the "TORQUE" control buttons:
 - a. **Auto-Stop and Auto-Stop Reverse Torque Modes** - When using the 20:1 or 1:1 ratio, the user can specify an Auto-Stop torque limit by depressing the Auto-Stop button (A-S/MAX) until the green LED illuminates, then selecting the desired torque level. The handpiece will stop operating one second after the user reaches the Auto-Stop torque limit. The handpiece will resume operation once the foot switch is released and reapplied.

When using the 8:1 (Endo) ratio, the user can specify an Auto-Stop-Reverse torque mode by depressing the (A-S/MAX) button until the green LED illuminates, then selecting the desired torque level via the Torque Up/Down buttons. The rotation of the handpiece will automatically alternate between forward and reverse in order to free the instrument when the selected torque is reached. Whenever the System is operating in this mode, "ASR" will be indicated on the Display directly below the Ratio Indicator. Auto-Stop-Reverse is the suggested mode for endodontic procedures.

In Implant Mode, torque warning tones warn the user when the handpiece torque level reaches 75% of the Auto-Stop limit. Auto-Stop is the suggested mode when tapping and threading implants.

b. MAX Torque Mode - When using the 1:1, 20:1, or 8:1 ratios, depressing the MAX (A-S/MAX) button until the amber LED illuminates will set the torque limit to its maximum level. The handpiece will only operate up to this manufacturer-specified torque level. The handpiece will stop and then restart once the load is removed.

CAUTION: Because of the unrestrained torque characteristics inherent in MAX Torque Mode operation, it is recommended that MAX Mode be used only when doing an osteotomy. It is also recommended that the user perform a complete calibration of the handpiece before operating in MAX Mode and/or adhere to the torque recommendations of the handpiece manufacturer.

c. Torque Limit Mode - When using any of the available ratios, depressing the Torque Modes (A-S/MAX) button until neither the green nor amber LED is lit will enable Torque Limiting. In this mode, the handpiece will only operate up to the torque limit set via the Torque Up/Down

buttons. The handpiece will slow down when a load greater than the torque limit is applied. Once the load is removed, the handpiece will return to target speed. This is the only Torque Mode available for increaser handpieces.

6. Turn irrigation pump 'ON' (green LED illuminates) and select the irrigation flow rate for the handpiece using the "FLOW" Up/Down buttons (or press and hold the Teal colored pad on the variable-speed foot control).
7. Select the desired forward or reverse direction for the handpiece using the "FWD/REV" button (or press the yellow pad on the variable-speed foot control). The green/amber LED will illuminate.
8. Depress footswitch to activate the motor/handpiece and irrigation pump. If using the On/Off footswitch or the variable-speed footswitch in ENDO Mode, releasing the footswitch will instantly stop the motor/handpiece and pump. If using the variable-speed footswitch in IMPLANT Mode, the motor/handpiece speed will decrease gradually as the footswitch is slowly released and the pump will stop when fully released.

9. Calibration of Handpiece - NOTE:

Because the mechanical condition of a handpiece can affect the efficiency of the handpiece/motor, it is recommended to routinely calibrate the handpiece, even if using the same handpiece, or whenever a handpiece is changed.

"Free Run" Calibration:

Performed on both increaser and reduction type handpieces. Follow the steps below to perform the "Free Run" calibration:

- a. Preselect ratio of the handpiece, using the Ratio Up/Down buttons on the console keypad. **NOTE:** This step must be performed prior to calibrating each handpiece.

OPERATION - *Cont'd:*

- b. Insert a file, bur, or drill into the handpiece.
- c. Press and release the Calibration (CAL) button to activate the integrated "Free Run" Calibration program. Follow the prompts on the display:

Add Handpiece To Motor
Press 1> Next 3> Exit

By pressing Preset Button #1, the System will automatically perform the "Free Run" Calibration test. **NOTE:** Pressing Preset Button #3 at any time during the calibration process will exit the procedure, however, no calibration settings will be saved into the System.

Free Run In Progress
Please Wait ...

If the handpiece fails the "Free Run" test, the following message will be displayed:

Calibration Failed!
Press 1> Retry 3> Exit

Press Preset Button #1 to retry or Button #3 to exit the test. **NOTE:** Repeated failures can indicate a damaged or defective handpiece or motor - Exit test and inspect and/or repair handpiece/motor before next use.

If the handpiece passes the "Free Run" Calibration test, the following message will be displayed:

Calibration Successful!
The Result is Saved

This concludes Calibration testing.

OPERATION - Presets:



The five preset memory buttons are preprogrammed at the factory with the default **Implant and Endodontic Presets** shown in Charts 1 & 2, on page 14.

10. Selecting Preset Modes:

The system automatically switches between the **Implant** and **Endodontic** Presets, depending upon which handpiece ratios are selected with the control panel "Ratio" buttons:

a. Implant Presets - The system uses Implant operating parameters whenever the 1:5, 1:3, 1:2, 1:1, or 20:1 handpiece ratios are used. A display prompt confirms the preset switch:

Switching to Implant Mode

b. Endodontic Presets - The system uses Endo operating parameters whenever the 8:1 handpiece ratio is used. A display prompt confirms the preset switch:

Switching to Endo Mode

11. Activating the Preset:

a. While in either Preset mode, press the desired preset button and the display will show the System operating parameters for that Preset. The LED located above the Preset button will illuminate, indicating which Preset is activated and ready to use.

12. Changing Presets:

All five Preset memory buttons can be changed by the user with new settings at any time, in either Preset mode. These

new settings will overwrite the existing settings, including the factory defaults.

Step 1:

Adjust each of the Ratio, Speed, Torque, Flow, Rotation Direction, and Pump On/Off settings to the desired values via the control panel buttons (refer to Control Panel Function descriptions on pages 7 & 8).

Step 2:

Press and hold any of the Preset buttons #1 through #5, to save the new, modified settings into that particular button.

a. The following prompt will be displayed:

Save To Preset (#)?
Press 1> Yes 3> No

1) To save the new values to that Preset, press Preset Button #1 (Yes). The following prompt then confirms that the settings were saved:

Preset (#)
Setting Saved

2) To keep the original values and ignore the new settings, press Preset Button #3 (No). The screen will redisplay the original values.

Repeat Steps 1 & 2 above to change settings in any of the other Presets.

Important: All factory default settings will be permanently overwritten when Presets are changed. To restore factory defaults, refer to instructions in paragraph 11 on page 9; to reprogram the unit with updated software, refer to instructions on page 17.

Chart 1 - Implant Default Presets

PRESET	RATIO	SPEED (RPM)	DIRECTION	TORQUE	FLOW
1	1:2	60,000	FWD	1.67 N•cm, Torque Limit	100%
2	20:1	1,200	FWD	MAX	80%
3	20:1	800	FWD	MAX	80%
4	20:1	15	FWD	25 N•cm, Auto Stop	30%
5	20:1	15	FWD	32 N•cm, Auto Stop	Off

Chart 2 - Endodontic Default Presets

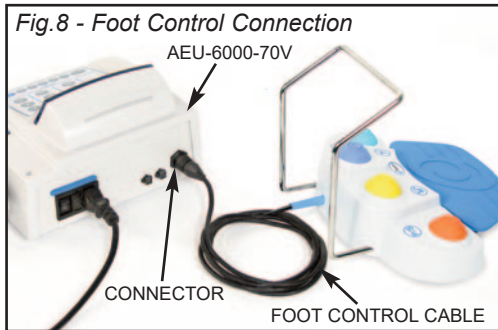
PRESET	RATIO	SPEED (RPM)	DIRECTION	TORQUE	FLOW
1	8:1	300	FWD	700 g-cm, Auto Stop Reverse	Off
2	8:1	300	FWD	500 g-cm, Auto Stop Reverse	Off
3	8:1	300	FWD	300 g-cm, Auto Stop Reverse	Off
4	8:1	500	FWD	500 g-cm, Auto Stop Reverse	Off
5	8:1	500	FWD	300 g-cm, Auto Stop Reverse	Off

VARIABLE-SPEED FOOT CONTROL OPERATION


The AE-70V2 Variable-Speed Foot Control comes as standard equipment on the AEU-6000-70V System and as an option on the AEU-6000 System. The AE-70V2 can control motor speed, direction, torque, and turn the pump On/Off. It can also select presets.

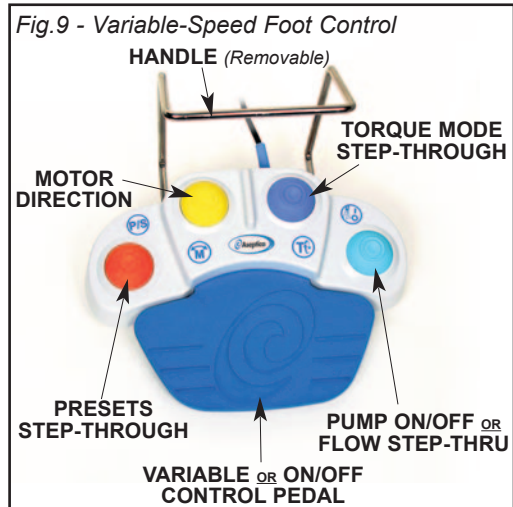
Installation:



1. Attach the Foot Control cable to the connector on the back of the Console (see Figure 8). Note keyway on connector. Turn locking sleeve clockwise to secure cable to connector. The AEU-6000-70V will automatically detect the Foot Control and allow dual functionality through either the Foot Control or key pad.



Foot Pad Functions (See Figure 9):

2. The 'M' pad (Upper left - Yellow) performs the same function as the Motor direction button on the console. Each press of the pad changes the direction of motor rotation. When the Motor is in reverse, the reverse warning tone will sound. 



3. The 'T' pad (Upper right - Lavender) increases the current torque setting each time the pad is pressed, up to a maximum five times consecutively. When the pad is pressed the sixth time, the unit will cycle the torque back down to its first (lowest) setting. For example, in **Endo Mode**, repeated pressing of the pad will increase the torque from 40 g-cm, through the 60, 80, 100, 120, and 140 g-cm settings, then automatically recycle back to 40 when the pad is pressed the sixth time. (**NOTE:** In **Endo Mode**, torque is measured in g-cm; in **Implant Mode**, it is measured in N-cm. Actual incremental values are dependent upon handpiece ratio selected.) 
4. The 'P/S' pad (Lower left - Orange) cycles through System Presets 1 - 5. Each press of the pad selects the next Preset. 

5. The **Pump On/Off** pad (Lower right – Teal) turns the pump On and Off, just like the console button. Press and release the pad to turn the pump On or Off (a beep will sound). To adjust pump flow, use either the Variable-Speed Foot Control or the Up/Down Control Panel Buttons. When adjusting flow with the Foot Control, press and hold Teal pad to cycle through the Flow settings in 10% increments, from 10% to 100%. A beep will sound with each incremental change.



6. The center **Variable Pedal** operates in either 'Variable' or 'On/Off' Mode:
- a. Variable Mode** - Pedal automatically operates in this mode whenever the System is in **Implant Mode** (1:5, 1:3, 1:2, 1:1, and 20:1 handpiece ratios selected). Motor speed is proportional to how far the pedal is depressed. Depress pedal slowly to gradually increase speed; release slowly to gradually decrease speed.
- b. ON/OFF Mode** - Pedal automatically operates in this mode whenever the System is in **Endo Mode** (8:1 handpiece ratio selected). The motor runs only at 'set' speed. Foot pedal will switch the motor 'On/Off' when depressed/released approximately halfway.

NOTE: The **Variable Pedal** can also be used to reactivate the System from Standby mode. Press the pedal briefly to wake up the System and return it to the last state used.

Handle Installation/Removal:

7. The Foot Control Handle may be installed to allow the user to reposition or move the Foot Control more easily.
- a.** Grasp vertical guide rods and carefully push handle straight into base (see Figure 10). To remove, pull rods straight out.

Fig.10 - Handle Installation/Removal



AE-7PM FOOT CONTROL

(AEU-6000 only)

Fig. 11

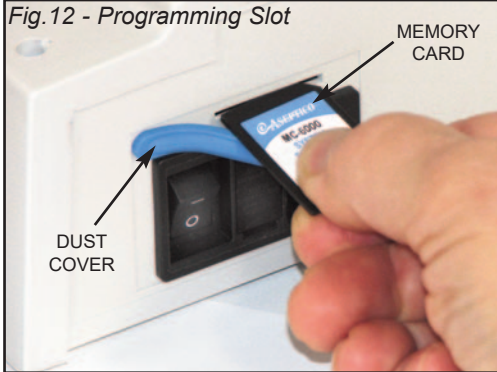


The AE-7PM Foot Control is provided as standard equipment on the AEU-6000 System. The AE-7PM is used to turn the motor and pump (when activated) On/Off. The AE-70V2 Variable-Speed Foot Control is available on the AEU-6000 System as an option.

AE-7PM Installation:

Attach the Foot Control cable to the connector on the back of the Console. Note keyway on connector. Turn locking sleeve clockwise to secure cable to connector.

REPROGRAMMING THE UNIT



The System has the ability to load software updates and enhance the functionality of the System. A card slot, labeled "Memory Card Port", is provided on the back of the unit (see Figure 12). This Port accepts memory cards very similar to those used in common consumer devices. These cards, available from Aseptico, enable a user to update software or replace existing software that might have been accidentally erased or corrupted. Contact Aseptico for more information on card usage and availability. To reprogram a unit, follow the Steps below:

Programming Steps:

1. Turn 'Off' the Main Power Switch on the back panel.
2. Grasp the right-hand end of the rubber dust cover for the Memory Card Port and pry open the cover to expose the card slot.
3. Insert the new memory card in the slot with label facing upward (card terminals should face downward). Carefully and slowly press card inward until a 'click' is felt. Release card.
4. Turn the Main Power Switch (on the back panel) 'On'.
5. The Display will show the following message:

**Memory Card Detected.
Re-program? 1> Yes 3> No**

 - Press the Preset '1' key (Yes) on the Control Panel.
6. The Display will then show the following message:

**Presets Will Be Erased!
Continue? 1> Yes 3> No**

 - Press the Preset '1' key (Yes) on the Control Panel.
7. The Display will show the following message:

Programming...

 - A status bar will indicate the progress of the programming.
8. When the programming is complete, the Display will show the following message:

**Programming Successful.
Eject Card.**

 - Press the card inward slightly, then release it to eject it. When the card is ejected, the System will reset with normal power-up screen displayed.
9. Remove the memory card and store it in a safe place. Close the rubber dust cover on the Memory Card Port.

In the event that the programming procedure is interrupted, the unit will display the following message:

Programming Failed

 Then:

**Console Software Error.
Re-program unit.**

Re-start the programming procedure from Step #1 (Remember to turn main power 'Off' before reprogramming).

STERILIZATION:



WARNING - Sterilize the motor and irrigation tubing before first use and between each patient use.

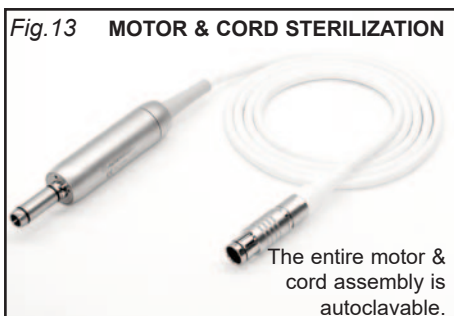
WARNING - Use of a sterilization method or temperatures other than what are prescribed may damage the motor or present a risk of cross-contamination between patients.

CAUTION - Do not soak or submerge the motor in any liquid.

CAUTION - Use of cleaning or disinfection solutions may damage the tubing set. Follow the Pre-cleaning and sterilization procedures provided for the tubing set.

Motor & Cord Assembly:

The entire AE-230M-40 motor and cord assembly is fully autoclavable. Loosely coil the motor cord when autoclaving. Avoid sharply bending the cord when autoclaving.



Pre-clean Motor

- 1) Brush off any visible signs of debris from the motor and cord.
- 2) Thoroughly clean the device with a moist cloth or towel to remove any remaining signs of debris.

Pre-clean Irrigation Tubing Set

Before sterilization, run clean water through the tubing for 30 seconds to expel any stagnant water and clear with air.

Inspection

While pre-cleaning, inspect the motor, cable, and irrigation tubing for damage or material degradation. Do not use the device if it appears damaged or defective.

To Sterilize:

Select one of the following sterilization methods:

Gravity Packaged

- Place in a pouch suitable for steam sterilization and seal it.
- Temperature: 132°C (270°F)
- Time: 15 minutes
- Dry Time: 30 minutes

Pre-vacuum Packaged

- Place in a pouch suitable for steam sterilization and seal it.
- Preconditioning Pulses: 4
- Temperature: 132°C (270°F)
- Time: 4 minutes
- Dry Time: 40 minutes

Gravity Not Packaged (Flash) - For immediate use only.

- Temperature: 132°C (270°F)
- Time: 15 minutes
- No dry time is required for flash sterilization.


NOTE: Call Aseptico Inc. at 425-487-3157 for any questions or clarifications on this sterilization procedure.

MAINTENANCE & CLEANING:

HANDPIECES - Thorough cleaning and lubrication of handpieces after each use and before sterilization is very important to ensure proper operation and service life of the handpiece. Follow the instructions provided with the handpiece for complete maintenance instructions.

MOTOR - IMPORTANT! Protect motor from excess oil draining from handpiece. After lubricating and before autoclaving, stand handpiece by its base on a paper towel and allow excess oil to drain (see Figure 14).




 **WARNING**

- Do not attempt to disassemble the motor or motor connector.
- Do not oil or lubricate the motor.
- Do not attach a handpiece to the motor while the motor is running.
- Do not bend motor cord sharply.
- The motor is sensitive to shock. Do not drop or impact motor against a hard surface.

Failure to comply with any of the above instructions may void your warranty.

CONSOLE - The exterior of the console may be cleaned by wiping with a soft cloth moistened with a mild detergent or a 10% bleach solution (1 part household bleach to 9 parts water).

Note: The motor cradle may be cleaned with the console or may be removed and sterilized according to one of the methods in the Sterilization section.

 **CAUTION:** Use of other cleaning or disinfecting solutions may damage the console and may void the warranty.

FOOT CONTROL - The exterior of the foot control may be cleaned by wiping with a soft cloth moistened with mild detergent or disinfecting solution. When cleaning, remove handle from foot control and wipe clean with disinfectant, then reinstall handle.

SPECIFICATIONS:

Console Dimensions: 8.6"W x 9.2"L x 4.8"H
(22 cm x 23 cm x 12 cm)

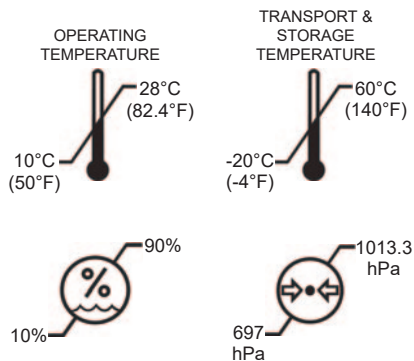
Console Weight: 3.9 lbs (1.8 kg)

Power: 100-240V ~
1.0 - 0.6 A
50-60 HZ

Fuses: 1.6A, 250V, Slo Blow Type

NOTE: The appliance inlet is the mains disconnect means.

Environmental Conditions:




Non-condensing

Altitude 0 to 3048 meters (0 to 10,000 feet)


TROUBLESHOOTING:

Problem:	Correction:
Console does not light when on:	<ul style="list-style-type: none"> • Check console to power connection. • If Preset LEDs are blinking, press Standby button on Control Panel to exit Sleep Mode. • Check fuse. If blown, replace with 1.6A/250V slo-blow fuse.
Console lights when turned on, but handpiece does not turn:	<ul style="list-style-type: none"> • Check motor plug connection. • Check foot switch connection. • Depress foot switch. • Increase RPM. • Increase Torque setting • Check that bur/file/drill is properly seated in the handpiece and the collet is closed.
No water flow from pump to handpiece:	<ul style="list-style-type: none"> • Check that pump is on and flow level is sufficient. • Check that water container seal is completely punctured. • Make sure the irrigation tubing is properly installed in pump door and flow is in the correct direction.
Motor slowing down or sluggish:	<ul style="list-style-type: none"> • Check for dirty, under-lubricated handpiece. • Check if handpiece lubricant is draining into motor. After lubricating and before autoclaving, stand handpiece on its base to let excess lubricant drain out.
Improper display:	<ul style="list-style-type: none"> • Verify that ratio setting matches handpiece ratio. • Turn power switch off, wait 5 seconds, then turn back on to reset.
Irrigation Tube Leaks:	<ul style="list-style-type: none"> • Replace worn tube section located under the pump door with a new section from the extra tube set provided with this system.
Cannot remove motor/cord from unit:	<ul style="list-style-type: none"> • Grasp the strain relief directly behind the cord connector and gently push inward. Then, grasp the connector body near the red dot and pull the connector straight out of the motor receptacle.

CHANGING THE FUSE:



WARNING



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

NOTE: The AEU-6000-70V & AEU-6000 feature auto-sensing, global voltage compatibility. The fuse indicated is correct for 100V-240V 50/60 Hz line voltage.

1. Remove the Fuse Holder from the Power Inlet connector (see Figure 15).
2. Replace the fuses in the Fuse holder.

Replacement Fuses:

1.6A, 250V slo-blow fuse
(Fuse size: 5 x 20mm)

3. Reinstall the Fuse Holder.



Fig.15 - Fuses

DISPOSAL OF PRODUCT:

- Prior to return for service or disposal, your device must not be contaminated and must have been completely reprocessed (Cleaning / Disinfection / Sterilization).
- Follow your local and country specific laws, directives, standards and guidelines for disposal of medical device, waste electrical equipment, and packaging.

SYMBOL DEFINITIONS:



Consult Instructions For Use



Type B Applied Part



Footswitch



Not for General Waste. Separate collection for waste electric and electronic equipment (WEEE) is required.



Manufacturer



Country of Manufacture - USA



Fuse Rating



Motor Direction



Torque Step Through



Temperature Limitation



Part Number



Serial Number



UDI - Unique Device Identifier



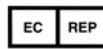
MD - Medical Device



Model Number



Fragile: Handle with Care



Authorized European Representative



UK-REP - United Kingdom Representative



Standby Switch



Dangerous Voltage



Alternating current



Protection Against Dripping Water



Protective Earth (Ground)



Preset Step Through



Pump On/Off



Atmospheric Pressure Limitation



Humidity Limitation



Caution



Sterilize At 132°C (270°F)



Keep Dry or Keep Away From Rain



Rx Dental Use Only

WARRANTY

Aseptico Inc. warrants its new products against defects in material and workmanship under normal and proper use, care, and maintenance for a period of two (2) years from date of original invoice. This two (2) year warranty does NOT apply nor is it extended to products that are not manufactured by Aseptico. These products may be covered by a separate limited warranty provided by the particular manufacturer, and all claims and questions regarding the same are to be directed to the particular manufacturer.

Expendable components, such as batteries, fuses, light bulbs, and tubing sets installed on Aseptico products are specifically excluded and have no warranty. Consumable goods are warranted for the stated expiration date of such goods.

Repair or replacement of any product(s) or part(s) under this warranty does not extend the term of this warranty, and such product(s) or part(s) shall remain covered by the unexpired portion of the warranty period, or for ninety (90) days from the date of return to Aseptico, whichever is later. This limited warranty applies only to the initial or first installation of the product or part.

During the specific warranty periods set forth above, Aseptico will, at its option, repair or replace the product(s) or particular part(s) that are found to be defective in either material or workmanship 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 Return Material Authorization (RMA) instructions, usually directing that the product be returned for service, shipping prepaid by the buyer or end user, to Aseptico or its designated and authorized warranty service center.

This warranty shall not apply to products (1) that have been subjected to neglect, abuse, misuse, improper installation, inadequate maintenance, or damage due to improper use of cleaning materials or chemicals, or non-compliance with Aseptico's storage, installation, operation, maintenance or environmental requirements; (2) that have undergone any modification or repair not previously authorized by Aseptico in writing, or service, repair or modification by or from any facility other than an authorized Aseptico service center or technician, or that use non-authorized software or spare or replacement parts; or (3) that fail due to reasonable and normal use or wear and tear, or materials made, furnished or specified by the buyer or end user.

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. Under no circumstances will Aseptico be liable or responsible for special, compensatory, incidental, consequential or punitive damages, lost profits, lost sales, or loss of use or loss of business opportunity by or through the use of the product. Aseptico's sole and maximum liability with respect to the product, other than its obligations set forth above, shall be the total purchase price paid for the product.



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