AEU-1000BSB-70V

Dental Implant Motor System



*Shown with optional equipment purchased separately

OPERATION AND MAINTENANCE MANUAL



! SAFETY PRECAUTIONS

Blue Sky Bio, LLC 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.

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: The system is supplied non-sterile! Before first use, and before each patient use thereafter, sterilize specified components as recommended in the Cleaning, Maintenance and Sterilization section.
- ▲ 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.
- ▲ **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 is the sole responsibility of the user.
- ▲ **CAUTION:** All repairs are to be performed by authorized service personnel only.
- ▲ **CAUTION:** Always follow these guidelines when operating the unit:
 - Never touch drills, burs, files, or other handpiece tips when they are still rotating.
 - The handpiece should only be attached when the motor has stopped running.
- ▲ WARNING: Do not install where there is a risk of an explosion. The system is not intended for operation in the presence of flammable anesthetics or gases.
- ▲ 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.
- ▲ WARNING: Do not disassemble or alter the system motor, console, or foot switch. No modification of the unit is allowed.
- ▲ 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:** Do not use this device in conjunction with an electric scalpel or on patients with pacemakers.
- ▲ 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:** It is recommended to always have the patient wear a rubber dam during implant procedures.
- ▲ WARNING: Using a different handpiece model from those recommended can cause significant under- or over-torque.
- ▲ WARNING: Using the incorrect ratio setting can cause significant under- or over-torque and under- or over-speeds.
- ▲ WARNING: Do not position the unit so that the power cord is inaccessible for disconnection during use.
- ▲ 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.



NOTE: Report any malfunction or deterioration in the characteristics and/or performance of this device, as well as any inadequacy in it's labelling or 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.

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.

Information concerning the accuracy and precision of this product may be obtained upon request by contacting Blue Sky Bio, LLC at the web address shown below.

Distributed by:



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INTENDED PURPOSE & INTENDED USERS

Intended Purpose:

Intended Use	The AEU-1000BSB-70V is intended to provide drilling during dental implant procedures.
Indications for Use	The AEU-1000BSB-70V is a drive system used in dentistry for replacement of missing or damaged teeth with implants.
Contraindications	None known.

Intended Users:

The AEU-1000BSB-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

7 years

ESSENTIAL PERFORMANCE

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

Congratulations!

Your new Blue Sky Bio AEU-1000BSB-70V system is one of the finest and most affordable dental implant motor systems available to the dental profession.

Features include:

- Powerful brushless 40,000 RPM motor for use with: AHP-85MB-X, AHP-85MB-CX 20:1 reduction handpiece, AHP-64 1:1 handpiece, AHP-85SS handpiece, or AHP-85-MK handpiece.
- · Large, easy-to-read touch screen display.
- 8 programmable presets.
- · Multi-function foot controller
- Water-resistant cabinet design helps prevent liquid spills from entering the internal electronics and allows easy clean-up.
- Vibration isolated peristaltic pump motor provides extremely quiet operation.
- Large 1000ml saline bag capacity.
- · Made in the USA.

This system is engineered to provide many years of reliable service. Please read the instructions provided in this manual to ensure the optimum service from your Blue Sky Bio 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 120399-04)
- AE-230A-40 Autoclavable 40K Brushless Micromotor
- Autoclavable Motor Holder (P/N 461561)
- AE-70V2BSB Multi-function Foot Controller
- AE-24 Autoclavable Irrigation Tubing Set
- AE-24-PUMP Peristaltic Pump Tubing Set (10 pieces)
- Irrigation Bag Hanger Rod (P/N 461541)
- Hospital-grade Power Cord (P/N 840079)

PURCHASED SEPARATELY

- AHP-85MB-X or AHP-85-SS 20:1 Reduction Contra-Angle Handpiece
- AHP-85MK 20:1 Eco Line Reduction Contra-Angle Handpiece
- AHP-64 1:1 Straight Handpiece
- Replacement AE-24 Autoclavable Irrigation Tubing Set
- Replacement AE-24-PUMP Peristaltic Pump Tubing (10 Pieces)
- Replacement AE-24-BOT Autoclavable Irrigation Tubing Set for use with Bottles

Mont Blanc® is a registered trademark 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.

PACKAGE CONTENTS



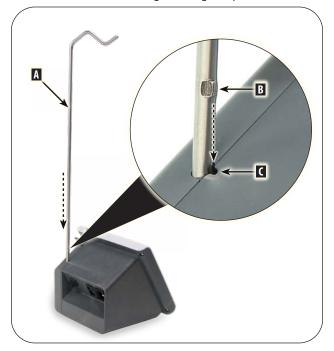
SYSTEM SETUP

This section provides step-by-step instructions for setting up the unit.



The handpiece, motor/cord assembly, and irrigation tubing set must be sterilized before each procedure as instructed in the Maintenance and Sterilization section (page 10).

- Unpack the unit and identify each of the components shown to the left (page 4).
- Insert the bag hanger A into the hole on top of the console.
 Make sure that the tab B on the hanger fully enters into the slot C on the console, locking the hanger in position.



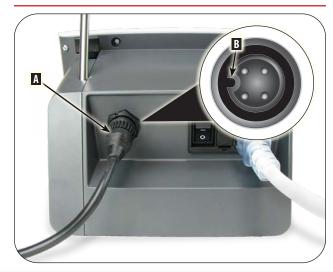
3. Plug the power cord **A** into the power inlet on the back of the console, then plug the other end of the power cord into a hospital-grade, grounded electrical outlet.



4. Connect the foot controller plug **\(\mathbb{\Omega} \)** to the socket on the back of the console.



The foot controller plug is "keyed" to the socket and can only be inserted in one position, with the notch **B** pointing to the left. Hold the plug against the socket and rotate it until you feel the plug enter the socket, then turn the locking sleeve clockwise until it clicks to secure the connection.



5. Connect the motor plug **\(\Displayer\)** to the socket on the front of the console.



The motor plug is "keyed" to the socket and can only be inserted in one position, with the larger tab pointing up. Hold the plug against the socket and <u>gently</u> rotate it until you feel the plug enter the socket, then turn the locking sleeve clockwise to secure the connection.



6. Install an AHP-85MB-X, AHP-85MB-CX 20:1 handpiece **A**, AHP-64 1:1 handpiece, AHP-85SS or AHP-85-MK (handpieces purchased separately) onto the motor **B**.

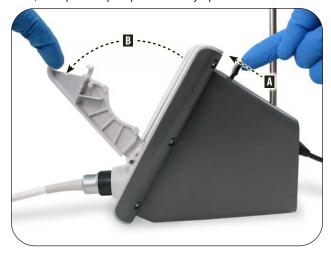


SYSTEM SETUP (Continued)

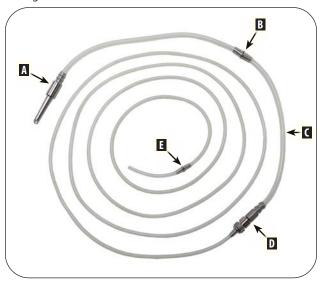
7. Place the motor-handpiece onto the cradle A.



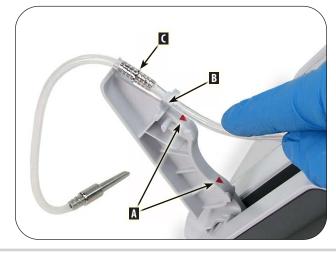
8. Pull the lever **a** on top of the console to release the pump door, then pull the pump door **b** fully open.



9. While installing the irrigation tubing it will be helpful to be able to identify the bayonet (1), large tubing connector (2), peristaltic tube segment (3), Luer connector (1), and the small tubing connector (3).



10. Two red arrows **A** on the pump door show the direction to install the irrigation tubing. Start by threading the peristaltic tube segment through the top slot **B** in the pump door. The large tubing connector **C** should be above the slot, as shown.



11. Pull the tube down through the top slot until the large tubing connector A seats securely into the slot.



12. Following the next red arrow on the pump door, thread the peristaltic tube segment through the bottom slot **A** on the pump door.



13. With one hand, pull the irrigation tube firmly from the bottom of the pump door ⚠. Use the other hand to guide the irrigation tube into the notch ☒ on the console while closing the pump door ☒.



14. Attach the small end of the irrigation tube A to the handpiece irrigation fitting, following the instructions that came with your handpiece. Attach the irrigation tube to the motor cable at evenly spaced intervals using the AHP-03 clips provided in the AE-24 tubing set bag.



15. Hang a saline bag (1000ml max.) from the hanger with the saline port pointing towards the rear of the console. Swing the bag away from the console to prevent dripping on the console, then spike the saline bag with the bayonet **A**. Wipe up any spills on the console immediately.



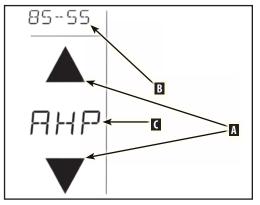
16. Press the power switch **A** on the rear of the console to the on (I) position to turn the unit on.



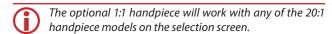
Handpiece Selection Screen

17. The *handpiece selection screen* is displayed the first time the unit is powered on. Cycle between ▲ and ▼ buttons ⚠ to select the 20:1 handpiece model that you will be using. When the *code* for your handpiece model is displayed in the top segment of the screen ☒ press the "AHP" segment of the screen ☒ to confirm your selection and activate the unit.

HANDPIECE MODEL	CODE DISPLAYED
AHP-85-SS (20:1)	85-SS
AHP-85MK (20:1)	85-MK
AHP-85MB-X (20:1)	85-MB



If you switch to a different handpiece model, you must activate the factory restore (pg. 9). After the presets have been reloaded, the handpiece selection screen will appear.



18. To switch to the 1:1 handpiece setting, press the speed selection buttons ⚠. Once there, press the ratio selection buttons ⚠ to change from 20:1 to 1:1.





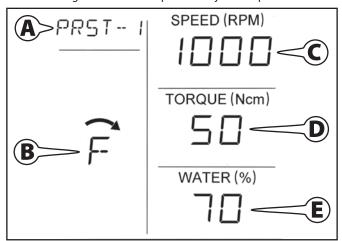
19. Calibrating the handpiece takes about 20 seconds and should be done every time you turn the unit on or change handpieces. See *Calibrating the Handpiece* on page 9, after becoming familiar with the layout of the control panel.

CONTROL PANEL

This section describes the functions of the touch-screen.

Home Screen

The home screen displays the name of the active preset and the current settings for each of the preset's adjustable parameters.



PRESET — This segment of the screen displays the name of the current preset. Press here repeatedly to select presets sequentially. Below is a table of the factory settings for each preset.

PRESET	DIRECTION	SPEED	RATIO	TORQUE	WATER
PRST-1: Osteotomy	FORWARD	1000	20:1	50 (Max)	70
PRST-2: Implant Placement	FORWARD	30	20:1	25	0
PRST-3: Reverse	REVERSE	30	20:1	30	0
PRST-4: Straight Handpiece	FORWARD	2000	1:1	3 (Max)	0
PRST-5: Osteotomy	FORWARD	1000	20:1	50 (Max)	70
PRST-6: Implant Placement	FORWARD	30	20:1	25	0
PRST-7: Reverse	REVERSE	30	20:1	30	0
PRST-8: Straight Handpiece	FORWARD	2000	1:1	3 (Max)	0

- **B MOTOR DIRECTION** This segment of the screen displays the current motor rotation direction. Press here to alternate between forward (F) and reverse (R).
- © SPEED/RATIO This segment of the screen displays both the current speed <u>and</u> ratio settings. Press here to open the speed/ratio adjustment screen.
 - <u>SPEED SETTING</u>: Press the ▲ and ▼ buttons to adjust the speed setting in the following ranges, according to the ratio setting:

RATIO SETTING	SPEED RANGE	SPEED DISPLAYED
20:1	15-2,000	15-2000
1:1	1,000-40,000	1E3-40E3



RATIO INDICATOR: If 1:1 ratio is selected, the SPEED (RPM) will be displayed as a number ending in "E3." Replace "E3" with "000" to calculate the speed of a 1:1 handpiece (e.g. 40E3 = 40,000 RPM). If 20:1 ratio is selected, SPEED (RPM) is displayed as a whole number.

• <u>RATIO SETTING</u>: Press the number that appears *between* the

 ▲ and ▼ buttons to select the ratio setting:

NUMBER DISPLAYED	HANDPIECE RATIO SETTING
20	20:1
1	1:1

Press anywhere on the right side of the screen to return to the home screen.

TORQUE — This segment of the screen displays the current torque setting. Press here to open the torque adjustment screen, then press the ▲ and ▼ buttons to adjust the torque setting in the following ranges, according to the ratio setting:

RATIO SETTING	TORQUE RANGE
20:1	5-50
1:1	1–3

Press anywhere on the right side of the screen to return to the home screen.



The speed and ratio settings determine whether the system is in "Torque-Limit" mode or "Torque Auto-Stop" mode. See the table below for details.

TORQUE-LIMIT MODE		
When speed setting is ≥ 500 RPM	20:1 ratio	
When speed setting is ≥10,000 RPM	1:1 ratio	

A torque warning tone will beep when the handpiece torque reaches 75% of the torque setting. The handpiece will slow down when a load greater than the torque setting is reached. The handpiece will resume speed once the load is removed.

TORQUE AUTO-STOP MODE		
When speed setting is <500 RPM	20:1 ratio	
When speed setting is <10,000 RPM	1:1 ratio	

A torque warning tone will beep when the handpiece torque reaches 75% of the torque setting. The handpiece will stop one second after the handpiece reaches the torque setting. The handpiece will resume operation once the footpedal is released and reapplied.



Pressing the Torque screen segment (1) also activates the Factory Restore, Handpiece Selection and Calibration screens, as described in the sections below.

E WATER — This segment of the screen displays the current irrigation flow setting. Press here to open the flow adjustment screen, then press the ▲ and ▼ buttons to adjust the flow setting (0–100%). A setting of 0% turns irrigation off. Press anywhere on the right side of the screen to return to the home screen.

Customizing Presets

The Preset segment **(A)** of the screen will flash if you have made any manual adjustments to the settings of the current preset:

To <u>clear</u> all manual adjustments made to the current preset, simply **press and release** the flashing Preset segment A of the screen.

To <u>save</u> all manual adjustments and customize the current preset, *press and hold* the flashing Preset segment (A) of the screen until you hear a beep. The blank tables on page 14 can be used to write down your customized preset settings.

Factory Restore

To **restore** all presets to their factory settings:

- 1. Press the Torque segment (D) of the home screen.
- Press and hold the "CAL" button that appears between the ▲ and ▼ buttons until you hear a beep.
- 3. Press and hold the flashing "RECALL" button that appears in the Preset segment (A) of the screen until you hear another beep. The factory settings have been restored for all presets (all user customized presets have been erased).
- **4.** The Handpiece Selection Screen will then appear. Follow *Handpiece Selection Screen* instructions in the *System Setup* guide to select your handpiece. Once done, the home screen will then appear.
- **5.** To <u>cancel</u> the factory restore procedure, press anywhere on the right side of the screen before completing step 3 above.

Calibrating Handpieces

Because the mechanical condition of motors and handpieces changes over time, it is recommended that you calibrate handpieces every time you power up the unit and **especially** when you change handpiece models:

- Confirm that the correct handpiece ratio and handpiece model are selected in the settings. NOTE: For AHP-64 handpieces, use the AHP-85MB-X handpiece model setting and the 1:1 ratio setting.
- 2. Insert a drill, bur or file into the handpiece.
- **3.** Position the handpiece in the cradle so that the drill/bur/file can rotate freely without touching anything.
- **4.** Press the Torque segment **(D)** of the home screen.
- 5. Press the "CAL" button that appears between the ▲ and ▼ buttons to start the calibration process. The CAL button will flash and the motor will run through several speed changes, then stop.

6. If calibration is successful, the CAL button will stop flashing when the motor stops.



If the CAL button <u>continues to flash</u> after the motor stops, calibration has failed. Press TORQUE (N-CM) and the Preset area (upper left) to try calibrating again. Repeated failures can indicate a dirty, damaged or defective handpiece and/ or a motor in need of repair or replacement.

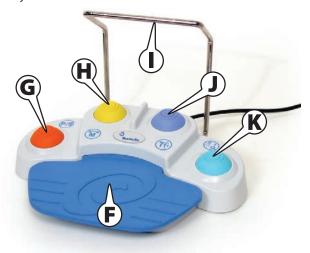
Press anywhere on the right side of the screen to return to the home screen.

OPERATION

This section explains how to operate the unit using the foot controller.

AE-70V2BSB Foot Controller

The AE-70V2BSB foot controller provides multiple-function control of the system.



- (F) VARIABLE SPEED PEDAL This pedal activates the motor and irrigation pump simultaneously. The motor speed varies (up to the current speed setting) in proportion to how far down you press the pedal. The irrigation pump activates at the current water setting, regardless of how far down the pedal is pressed.
- **G PRESET** Press repeatedly to step through each of the presets sequentially. This provides the same function as pressing the Preset segment (A) (page 8) on the touch screen.



MOTOR DIRECTION — Press to alternate between forward and reverse. This provides the same function as pressing the Motor Direction icon (B) (page 8) on the touch screen.



(I) **HANDLE** — Use to manually position the foot controller. Install the handle by inserting the handle prongs into the holes on the rear of the foot controller.



- J TORQUE STEP-INCREASE For 20:1 handpieces, press to increase the torque setting in 2 Ncm steps for a maximum of 5 consecutive steps (or until the maximum torque setting is reached). On the sixth press (or the press after the maximum torque setting is reached), the torque setting will return to the original, lowest setting.
- WATER ON-OFF / STEP-INCREASE Press to switch the irrigation pump on-off. When the pump is switched off, the Water segment (E) (page 8) of the screen will display "——" instead of 0%. Press and hold this button to step through the water settings in +10% increments; the steps occur at 1-second intervals with a beep sounding to signal each step.

MAINTENANCE AND STERILIZATION

Failure to adhere to the following instructions or blatant misuse of the device and/or related components will be considered abuse of the device and will void the warranty.



Call Blue Sky Bio at 1-718-376-0422 with any questions on sterilization procedures.

Console and Foot Controller

Clean the exterior of the console and foot controller by wiping with a soft cloth moistened with mild detergent or 10% bleach solution (1-part bleach to 9-parts water). Use of solvents or other solutions may cause damage and void the warranty.

Handpiece

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 cleaning, maintenance and sterilization instructions.

Motor & Cord Assembly / Irrigation Tubing



CAUTION: Do not allow oil from the handpiece to drain into the motor. After lubricating and before sterilizing the handpiece, stand it on a paper towel to allow excess oil to drain out of the handpiece.

CAUTION: The motor is sensitive to shock. Do not drop or impact the motor against a hard surface.



WARNING: Do not oil or lubricate the motor.

WARNING: Do not attach a handpiece to the motor while the motor is running.

WARNING: Do not bend the motor cord sharply.

WARNING: Do not attempt to disassemble the motor or motor connector.

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

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

CAUTION: Do not use ultrasonic cleaners.

CAUTION: Do not use cold sterilization or dry heat.

STERILIZATION

1. Inspection

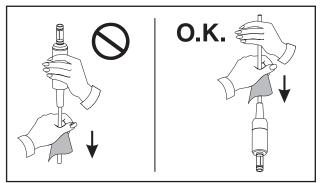
While precleaning, inspect the motor, cable, and irrigation tubing for damage or material degradation. Do not use the device if it appears damaged or defective.

2. 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.

3. Pre-Clean Motor

- **A.** Brush off debris from the motor and cord.
- **B.** Thoroughly clean the motor and cord with a moist cloth or towel to remove any remaining signs of debris. Avoid pulling the cord away from the motor. Always wipe towards the motor.



4. Install the provided autoclaving plug **A** onto the end of the motor cord connector.



- Loosely coil the motor cord. Avoid sharp bending of the cord.
- **6.** Sterilize the motor and cord assembly and irrigation tubing set using one of the <u>STERILIZATION METHODS</u>.

STERILIZATION METHODS:

Wrapped Sterilization — Place in an appropriately sized sterilization pouch and seal.

Standard autoclaving (Gravity displacement method)

A. Time: 15 min

B. Temperature: 132° C (270° F)C. Dry time: 30 minutes

Pre-vacuum (Dynamic air removal method)

A. Time: 4 minutes

B. Temperature: 132° C (270° F)C. Dry time: 40 minutes

Flash Sterilization — For immediate use only.

Unwrapped standard autoclaving (Gravity displacement method)

A. Time: 15 minutes

B. Temperature: 132° C (270° F)

C. Dry time: No dry time is required for flash sterilization.

MESSAGES

System Messages

 When the system is powered on, the software part number and version will be displayed briefly on the console screen.

Error Messages

NONE

Fault Messages

NONE

WASTE DISPOSAL

Dispose of all medical waste products, residues, etc. in accordance with your local, state and country laws. Dispose of the AEU-1000BSB-70V and accessories at the end-of-life in accordance with your local, state and country laws.

CONTRAINDICATIONS

None known

ADVERSE REACTIONS

None known

TROUBLESHOOTING

Console does not light up when turned on:

- · Check power cord connection.
- Check fuse. If blown, see Fuse Replacement (page 13)

Console lights up when turned on, but handpiece does not operate:

- · Check motor plug connection.
- · Check foot controller connection.
- Depress the main foot controller switch.
- · Increase the speed setting.
- · Increase the torque setting.
- · Check that the connector pins in the plug socket are not bent.
- Check that the rotary tool is properly seated in the handpiece and that the latch/collet is closed.

No water flow from pump to handpiece:

- Check that the water setting is 10% or above.
- · 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:

- Check for dirty, under-lubricated handpiece.
- · Verify that the ratio setting matches the handpiece.
- · Check if handpiece lubricant is draining into motor.

Display error:

· Switch off power, wait 5 seconds, then switch back on to reset.

Pump leaking:

 Replace the peristaltic pump segment of the irrigation line with a new one from the extra tube set provided.

WARRANTY

Blue Sky Bio, LLC warrants this product against defects in material or workmanship for a period of two (2) years, 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. Blue Sky Bio'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. Blue Sky Bio shall be the sole arbiter of such action.

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

Accidental misuse, inappropriate installation, or failure to perform directed maintenance voids the warranty. Deliberately defacing, modifying, or removing the serial number voids the warranty.

Blue Sky Bio 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.

FUSE REPLACEMENT



WARNING

4

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



The system features 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 socket by prying it out using two small blade screwdrivers, one on the top **A** and the other on the bottom **B** of the fuse holder.



- Replace both fuses in the fuse holder with the same type and rating: 5 x 20mm, 1.6A, 250V slow-blow.
- 3. Reinstall the fuse holder.

SPECIFICATIONS

CONSOLE DIMENSIONS: 19.6 cm W x 18.0 cm D x 16.0 cm H (7.72" W x 7.09" D x 6.30" H)

CONSOLE WEIGHT: 1.41 kg (3.11 lbs)

POWER SOURCE: 100-240V, 50-60Hz

CURRENT RATING: 100V/2A, 240V/2A

ENVIRONMENTAL CONDITIONS:

Operating Temperature: 10°C to 28°C (50°F to 82.4°F)

Transport/Storage Temperature: –20°C to 60°C (–4°F to 140°F)

Relative Humidity: 10 to 90% non-condensing **Altitude:** 0 to 3,000 meters (0 to 9,842 feet)

Classifications:

- · Class 1 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.
- IPX1 Footswitch





Manufacturer

Aseptico Inc
8333 216 St SE

Woodinville, WA, 98072 USA



Tower Business Centre, 2nd Fir, Tower Street, Swatar, BKR 4013 Malta



MEDICAL ELECTRICAL EQUIPMENT WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1:2007 (R)2012, CAN/CSA C22.2 No. 60601-1:14 and IEC 80601-2-60:2012

S	MBOL DESCRIPTIONS
i	Consult Instructions For Use
<u> </u>	Type B Equipment
\triangle	Caution
\sim	Alternating Current
250V 250V 510-840 1.6A	Fuse Rating
4	Dangerous Voltage
M	Motor Direction
(P/S)	Preset Step Through
TÛ	Torque Step Through
	Pump On-Off/Step Through
X	Not for General Waste. Separate collection for waste electric and electronic equipment (WEEE) is required.
<u></u>	Footswitch
***	Manufacturer
IPX1	Ingress of Water - Classification-Footswitch
	Protective Earth (Ground)
	Temperature Limitation
∳•	Atmospheric Pressure Limitation
<u>%</u>	Humidity Limitation
132°C	Sterilize at 132°C (270°F)
SN	Serial Number
REF	Part Number
10	ON-OFF Switch
(i)	Important information
UDI	Unique Device Identifier

#	Model Number
W SA	Country of manufacture, USA
MD	Medical Device
R Dental Use Only	Rx Dental Use Only
EC REP	Authorized European Representative
UK REP	Authorized United Kingdom Representative

CUSTOM PRESETS

Use the blank tables below to write down your custom preset settings:

PRESET	DIRECTION	SPEED	RATIO	TORQUE	WATER
PRST-1					
PRST-2					
PRST-3					
PRST-4					
PRST-5					
PRST-6					
PRST-7					
PRST-8					

PRESET	DIRECTION	SPEED	RATIO	TORQUE	WATER
PRST-1					
PRST-2					
PRST-3					
PRST-4					
PRST-5					
PRST-6					
PRST-7					
PRST-8					

PRESET	DIRECTION	SPEED	RATIO	TORQUE	WATER
PRST-1					
PRST-2					
PRST-3					
PRST-4					
PRST-5					
PRST-6					
PRST-7					
PRST-8					

PRESET	DIRECTION	SPEED	RATIO	TORQUE	WATER
PRST-1					
PRST-2					
PRST-3					
PRST-4					
PRST-5					
PRST-6					
PRST-7					
PRST-8					



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