WALLACH

BIOVAC 500

SMOKE EVACUATOR

INSTRUCTION MANUAL

REF 909105 and 909105-05

Wallach Surgical Devices
95 Corporate Drive
Trumbull, CT 06611 U.S.A.
Phone: (203) 799-2000
Fax: (203) 799-2002

INTRODUCTION

The Wallach BIOVAC 500 Smoke Evacuator is a simple-to-operate electrical device designed to remove smoke particulate (smoke plume) generated as a by-product of certain medical procedures, such as electrosurgery and electrocautery. It is intended for use in short term procedures performed in a physician's office. As with all such devices, there are instructions and precautions. Please read the manual and become familiar with your equipment prior to use.

WARNING

READ INSTRUCTIONS FOR USE BEFORE USING THIS PRODUCT.

- **Do not use this device in the presence of potentially explosive anesthetic gases.**
- **This device is a BF type device. Type BF equipment is a type B equipment with an F type applied part. Type B is a piece of equipment providing a particular degree of protection against electric shock, particularly regarding:**
  -Allowable leakage current
  -Reliability of the protective earth connection.
  F-type isolated (floating) applied part. Applied part isolated from all other parts of the equipment to such a degree that the patient leakage current allowable in single fault condition is not exceeded when a voltage equal to 1.1 times the highest rated mains voltage is applied between the applied part and earth.
- **Always use a three-prong, grounded electrical outlet to prevent the possibility of electrical shock.**

CAUTION

- **Do not use an electrical extension cord. However, a UL-approved power strip (such as those used on accessory carts) of sufficient current rating is acceptable.**
- **The Sterile Disposable Tubing (REF 920002) is for <u>single patient use only</u>. Due to possible cross contamination, it is to be used for one patient, then discarded per local, state, or federal regulations regarding medical waste disposal.**
- **The maximum allowable continued use of a single filter assembly (REF 909094) is 30 minutes (see FILTER ASSEMBLY). Filter efficiency and effectiveness are dramatically decreased, rendering it ineffective, if used for a longer period.**
- **Only Wallach Surgical Devices is authorized to service or repair the unit. Do not attempt to disassemble or service the device, other than changing a fuse. Unplug the unit before changing the fuse.**
- **Do not allow fluids of any kind to enter the device, either from spills on the cabinet, or through the vacuum hose. This may create an electrical hazard.**

BIOVAC SMOKE EVACUATOR COMPONENTS

The Wallach BIOVAC 500 Smoke Evacuator consists of two components: a) the Motor Cabinet, with its electric motor and controls, and b) the Smoke Plume Filter Assembly and a STERILE single use Disposable Smoke Evacuation Tubing.

MOTOR CABINET

The Motor Cabinet contains a high power motor/blower which is controlled by two switches: a) the Power ON-OFF switch (labeled POWER), and b) the Air Flow Control Switch (labeled SUCTION ADJUST), which adjusts the amount of air being moved. There are no electrical user-serviceable components within the cabinet.

Prior to your first use, connect a Filter Assembly and Disposable Smoke Evacuator Tubing, and operate the Smoke Evacuator through the range of suction available. You will notice that the sound level increases as the suction range is increased. Although the cabinet is sound-insulated, it is the nature of high efficiency blower motors to produce elevated sound levels. Some experimentation will lead you to the correct setting.

FILTER ASSEMBLY

The non-sterile Filter Assembly utilizes two filter devices to clean the collected air. Within the length of the four-foot hose is a smoke scrubbing, odor removing material that will compress as the Smoke Evacuator is operated. This compression will eventually restrict the flow of air in the tube, thus limiting the amount of time that the Smoke Evacuator can be in continuous use (using the same Filter Assembly). The expected maximum operating time limit for the filter is 30 minutes, which far exceeds the typical time needed for one electrocautery or electrosurgery procedure. Should the device continue running beyond this operational range, the unit may become warm to the touch and the filter will be ineffective.

The second filter element, a viral, bacterial, particulate filter, is positioned in the filter assembly at the connecting end of the hose (connecting to the Motor Console). It efficiently removes potentially harmful microbes as small as .02 microns.

Filter Assembly and Disposable Smoke Evacuator Tubing must be disposed of per your local, state or federal guidelines for the disposal of medical waste.

Both are available from your local Wallach distributor. For the name of the nearest distributor, call (203)-799-2000 and request customer service.

OPERATING INSTRUCTIONS

A powerful motor/blower within the Motor Cabinet creates a vacuum which removes the smoke plume from the operating site via a specially constructed hose and filter assembly. This Filter Assembly traps odorous particulate along its 2.4 m length by means of filter material inserted in the hose passage, and by a final stage micron filter at the connecting end.

1) Set the unit in an upright position on a solid structure with a smooth level surface.

2) Be certain the Wallach BIOVAC 500 Smoke Evacuator is turned "OFF". Now plug the cord into a grounded electrical receptacle.

3) Open a fresh Filter Assembly package. Attach the square filter housing of the hose assembly to the smoke collection port in the center of the top cover. Attach the sterilized disposable filter tubing.

4) If tubing is to be connected to a speculum

5) Attach the distal end of the tubing to the speculum. One Filter Assembly has a maximum limit of 30 minutes of continuous operation.

6) Turn the unit ON by depressing the POWER switch, and regulate the SUCTION ADJUST knob control to suit the condition, keeping in mind that the sound level increases as the vacuum increases. Test the unit prior to each patient use to insure that the BIOVAC 500 Smoke Evacuator is drawing air, and to acquaint your patient with the sound of the motor.

7) When the procedure is complete, turn OFF the unit, remove the Disposable Tubing and dispose of as per local, state, and federal regulations for handling medical waste.

Note: Do not operate this device without a Filter Assembly in place.

SPECIFICATIONS

Electrical requirements:	120VAC, 50/60 Hz, 7.9A,	240V AC, 50/60 Hz, 5.0A
Electrical Fuses	Two TIOAL250V	Two T5AL250V
Power Cord Length	2.28 meters	
Power Plug	Hospital Grade	
Sound Level From One	Meter: 65 DBA at low speed	
Air Flow Range	3.0 CFM to 6.5 CFM	
Filtration	99.99% Effective to .02 Micron	
Filter Assembly	Non-Sterile	
Disposable Tubing & Straw	Sterile	
Filter/Tubing/Straw Length:	3.35 meters	
Dimensions	30.5cm (L) x 25.4cm (W) x 30.5cm H (including handle and feet)	
Weight	8 kg	
Country of Origin:	U.S.A.	

MAINTENANCE

After each use, the unit must be cleaned and disinfected. To sanitize the unit, wipe down with a disinfectant.

While the finish on the instrument cabinet will resist scuffing and the chemical attack of most acids and alkalis, any liquids spilled on the cabinet should be wiped up immediately.

WARRANTY

The Wallach BIOVAC Smoke Evacuator is supported by a one-year warranty from date of purchase covering any failure of the device due to defective workmanship or components, when used in compliance with the product's intended use.

The warranty remains valid within the time period, provided only Wallach supplied filter sets and components are used with the device.

Only Wallach Surgical Devices is authorized to service or repair this unit. Do not disassemble the device. There are no user-serviceable components within the housing.

Two extremely accessible electrical fuses are located on the rear of the Cabinet (see SPECIFICATIONS).

SERVICE/REPAIR

Only Wallach Surgical Devices is authorized to service or repair this unit. If repair is attempted outside the factory, the warranty will be considered void. Wallach Surgical Devices is not responsible for any injury resulting from repairs made by other individuals or organizations not certified by Wallach Surgical Devices. If a repair is needed, carefully package the Biovac in a protective carton. Equipment must be sanitized before it is returned. Items that are not sanitized will be returned to the customer freight collect. All shipments must be made via pre-paid parcel post or U.S. Mail. C.O.D. packages will not be accepted.

Return carton to:

Wallach Surgical Devices
95 Corporate Drive
Trumbull, CT 06611 U.S.A.
Phone: (203) 799-2000
Fax: (203) 799-2002

ACCESSORIES

REORDER NUMBER (REF)	DESCRIPTION	RECOMMENDED REPLACEMENT
920002	Sterile Disposable Tubing	Every procedure
909094	Single Filter Assembly	After 30 minutes of continuous use
109639	Electrical Fuses	as needed
109641	Replacement Power Cord	as needed

TROUBLE SHOOTING/FUNCTIONAL TESTING

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
Motor does not run	1. Unit not plugged in 2. ON switch not activated 3. Fuses blown/defective 4. Defective motor	1. Plug in power cord 2. Activate switch to "1" 3. Replace (be sure unit is unplugged) 4. Return to WSD
On/off switch is not illuminated	1. Unit not plugged in 2. Fuses blown/defective 3. Defective switch	1. Plug in power cord 2. Replace be sure unit is unplugged 3. Return to WSD

MAINTENANCE SCHEDULE

Disinfect Unit	After every use
Check power cord for fray	Prior to each use
Operate (see instructions)	Once yearly

EXPLANATION OF SYMBOLS

TYPE BF EQUIPMENT = Type of equipment is a type B equipment with an F type applied part. **Type B** equipment is a piece of equipment providing a particular degree of protection against electric shock, particularly regarding:

-Allowable leakage current

-Reliability of the protective earth connection.

Type F = isolated (floating) applied part

Applied part isolated from all other parts of the equipment to such a degree that the patient leakage current allowable in single fault condition is not exceeded when a voltage equal to 1.1 times the highest rated mains voltage is applied between the applied part and earth.

Alternating Current Symbol = AC current

See Instructions for Use

Shock Hazard Warning

For Professional Use Only

REF Reorder Number

SN Serial Number