

Smoke Shark™ III

Surgical Smoke Evacuator

Operator's Manual



Bovie®

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DIAGRAM / CONTENTS

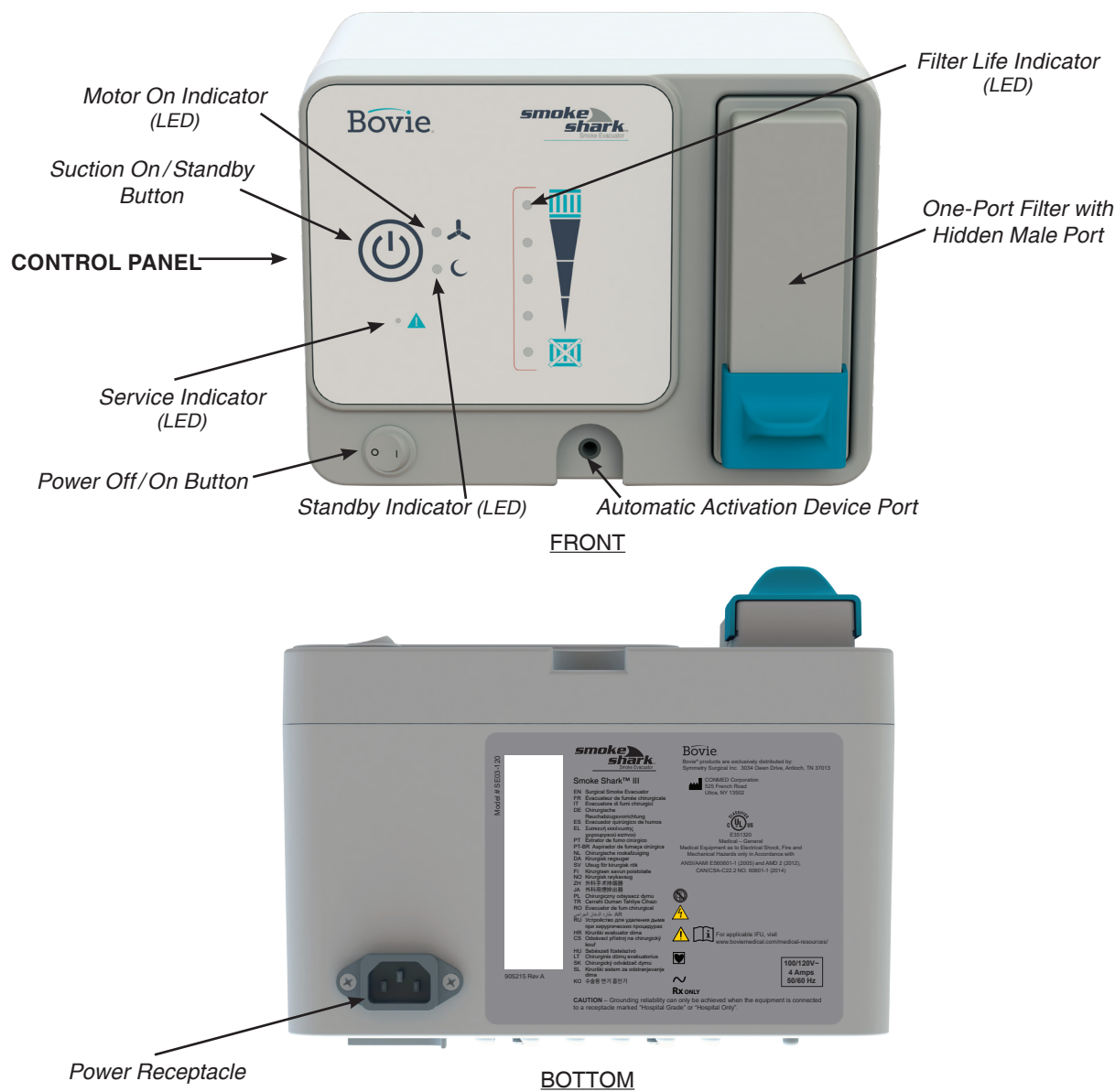


Figure 1



GLOSSARY

Name	Description
AMP	Ampere, unit of electric current
Automatic Activation Device	Device used to remotely operate the <i>Bovie® Smoke Shark Surgical Smoke Evacuator</i> to control the suction on/standby modes in conjunction with ESU activation, saving filter life.
CISPR	International Special Committee on Radio Interference
EMC	Electromagnetic Compatibility
ESD	Electrostatic Discharge
Filter	Completely enclosed device where surgical smoke is processed through four (4) stages of filtration.
Filter Life Indicator	A visual status indication of the life of filter in use.
Grounded Electrical Outlet	An electrical outlet, which in addition to the current-carrying contacts, has a third contact that serves for connection to a grounding conductor. Devices and equipment that are to benefit from this safety feature must have an appropriate three-prong plug that is inserted into this outlet. There are other possible arrangements for such outlets, including the use of lateral grounding contacts that make contact with metallic strips on the side of the plug. Also called by various other names, including grounding outlet, ground outlet, grounded receptacle, grounding receptacle, grounded socket, safety outlet, or three-prong outlet.
IEC	International Electrotechnical Commission
LED	Light-emitting diode (LED) is a two-lead semiconductor light source that emits light when activated.
Power Cord	A cable used to connect the <i>Surgical Smoke Evacuator</i> to a grounded electrical outlet.
Suction On/Standby Button	Button to shift between two modes of suction control: on and standby.
<i>Bovie® Smoke Shark Surgical Smoke Evacuator.</i>	Device with one or more filters designed to evacuate surgical smoke and aerosol from the operative site, filter out the contaminants, and return filtered air to the operating room.
VAC	Volts Alternating Current

DESCRIPTION / INTRODUCTION: SECTION 1.0

1.1 Introduction

The *Bovie® Smoke Shark Surgical Smoke Evacuator* is intended to evacuate and filter surgical smoke and aerosols created by the interface of surgical tools with tissue (examples: lasers, electrosurgery systems, desiccators and ultrasonic devices).

The *Bovie® Smoke Shark Surgical Smoke Evacuator* has been designed to provide appropriate suctioning, using a motor on/off button, to manage surgical smoke instruments. The ultra-quiet motor is used to draw the surgical smoke from the surgical site through the vacuum tubing and into the filter where the surgical smoke is processed through four (4) stages of filtration. A single, completely enclosed, disposable filter is used to simplify installation and removal during filter changes to protect healthcare personnel from potential contamination during filter changes.

1. The first stage filtration utilizes a pre-filter to trap and remove gross particulate and casual fluid.
2. The second stage filtration is an ULPA grade (Ultra Low Penetration Air) filter with a high-tech patented design that captures particulates and micro-organisms from 0.1 to 0.2 microns at 99.999% efficiency.
3. The third stage filtration uses the highest grade virgin activated carbon. The activated carbon is known to remove toxic organic gases and may provide optimal odor removal.
4. The fourth stage filtration is a woven fiberglass filtration media used to reduce the amount of activated carbon fines from migrating out of the filters.

1.2 Inspection

The *Bovie® Smoke Shark Surgical Smoke Evacuator* was thoroughly tested and inspected prior to shipment. Please inspect the *Bovie® Smoke Shark Surgical Smoke Evacuator* before using to ensure all items have been received and that no damage occurred during transit. If items are missing or damage is evident, please contact Customer/Technical Services.

Items Included:

- Operator's Manual
- Filter
- Power Cord
- Automatic Activation Device
- Wall Mounting Kit

1.3 Operational Information

The operational information contained in this section is intended for customer review of technical specifications. The information pertains to the use of the products both domestically and internationally:

1. Both the 100/120 VAC, 50/60 Hz and 220/240 VAC, 50/60 Hz *Bovie® Smoke Shark Surgical Smoke Evacuators* comply with IEC60601-1 electrical specifications.
2. Type of protection against electrical shock (ANSI/AAMI ES 60601-1, Clause 6.1): Class I
3. Degree of protection against electric shock (ANSI/AAMI ES 60601-1, Clause 6.2): Type CF Applied Part
4. Degree of protection against ingress of water (ANSI/AAMI ES 60601-1, Clause 6.3): IPX0
5. Method of sterilization or disinfection recommended (ANSI/AAMI ES 60601-1, Clause 6.4):
Unplug Bovie® Smoke Shark Surgical Smoke Evacuator. Wipe Bovie® Smoke Shark Surgical Smoke Evacuator with a damp cloth containing mild disinfectant solution or soapy water. Wipe dry with a clean cloth. Do not steam sterilize.
6. Degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide (ANSI/AAMI ES 60601-1, Clause 6.5): Not Suitable
7. Mode of operation (ANSI/AAMI ES 60601-1, Clause 6.6): Continuous

DESCRIPTION / INTRODUCTION: SECTION 1.0

8. The fuses are to be serviced by an authorized technician. Please call Technical Services.
100/120 VAC, 50/60 Hz use 4 AMP 250 Volt Fuse (Slo-Blo)
220/240 VAC, 50/60 Hz use 2 AMP 250 Volt Fuse (Slo-Blo)
9. The *Bovie® Smoke Shark Surgical Smoke Evacuator* requires special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed according to EMC information found in this manual.
10. To isolate the *Bovie® Smoke Shark Surgical Smoke Evacuator* from supply mains, unplug the Power Cord from the power receptacle on the *Bovie® Smoke Shark Surgical Smoke Evacuator* or receptacle in the wall. Position the equipment to allow for ease of unplugging the Power Cord.
11. The *Bovie® Smoke Shark Surgical Smoke Evacuator* and all filters are not intended for contact with patients.
12. Type CF applied part – Pen-type (tubing) device for attachment to surgical cutting tool; no electrical connection to unit.

1.4 Cautions and Warnings

All Cautions and Warnings should be read and understood before using the *Bovie® Smoke Shark Surgical Smoke Evacuator*.

Attention: Consult Instructions Before Use.



1.4.1 WARNINGS:

The warranty on the *Bovie® Smoke Shark Surgical Smoke Evacuator* is void if any of the following warnings are disregarded.

- Read this manual thoroughly and be familiar with its contents prior to using the *Bovie® Smoke Shark Surgical Smoke Evacuator*.
- Confirm operational set-up of the *Bovie® Smoke Shark Surgical Smoke Evacuator* prior to a surgical procedure.
- Disconnect the *Bovie® Smoke Shark Surgical Smoke Evacuator* from the grounded electrical outlet prior to inspecting *Bovie® Smoke Shark Surgical Smoke Evacuator* components.
- The *Bovie® Smoke Shark Surgical Smoke Evacuator* is only intended and suitable for the applications mentioned in the operating instructions.
- The *Bovie® Smoke Shark Surgical Smoke Evacuator* produces a strong vacuum. Position the inlet end of the wand or tubing to prevent patient injury and to prevent suction of surgical materials and specimens.
- To prevent patient injury, the tubing or wand should not come into direct contact with tissue.
- The filter and single-use accessories are completely disposable. Please dispose according to your local codes or regulations and facility policy.
- Route Power Cord to prevent a tripping hazard or crimping of cords, which could cause unreliable operation or electric shock.
- Position Automatic Activation Device and any other attached accessories to prevent a tripping hazard or crimping of cords, which could cause unreliable operation.
- Do not operate the *Bovie® Smoke Shark Surgical Smoke Evacuator* in the presence of flammable or explosive gases.
- The *Bovie® Smoke Shark Surgical Smoke Evacuator* is intended for use by healthcare professionals only.

DESCRIPTION / INTRODUCTION: SECTION 1.0

- The *Bovie® Smoke Shark Surgical Smoke Evacuator* may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as re-orienting or relocating the *Bovie® Smoke Shark Surgical Smoke Evacuator* or shielding the location.
- The use of accessories other than those specified by the manufacturer as replacement parts for internal components may result in increased emissions or decreased immunity of the *Bovie® Smoke Shark Surgical Smoke Evacuator*.
- Refer routine servicing to Symmetry Surgical. See Customer/Technical Services contact information.
- Changes or modifications not expressly approved by the manufacturer could void the warranty.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

1.4.2 CAUTIONS:

- United States Federal Law restricts the *Bovie® Smoke Shark Surgical Smoke Evacuator* to sale by or on the order of a physician.
- Using any other filter or accessory not specified by the manufacturer may cause damage and/or cause the *Bovie® Smoke Shark Surgical Smoke Evacuator* to be inoperable, voiding the warranty.
- Care must be exercised in the installation of tubing and adapters. Failure to follow the procedures outlined in this manual may result in overheating of the motor and may void the warranty.
- The *Bovie® Smoke Shark Surgical Smoke Evacuator* is not intended for evacuation of fluid. Failure to avoid fluid aspiration could cause filter blockage, electrical damage, decreased efficiency, and possible internal contamination.
- The filter should be changed according to the Filter Life Indicator. The filter should not be used for more than the filter life specified. Failure to change the filter may result in decreased efficiency and possible internal contamination.
- Care must be exercised in the installation and removal of filter and tubing. Filter and tubing are used to capture potentially hazardous materials. Failure to follow the procedures outlined in this manual may result in possible internal contamination.
- Do not block the tubing during operation. An occlusion or significant restriction may cause the motor to overheat and the *Bovie® Smoke Shark Surgical Smoke Evacuator* to stop working.
- Installation of the *Bovie® Smoke Shark Surgical Smoke Evacuator* must be performed such that the intake and exhaust vents located on the rear of the system are not obstructed. Failure to properly install the *Bovie® Smoke Shark Surgical Smoke Evacuator* may cause reduced performance, damage, and/or cause the *Bovie® Smoke Shark Surgical Smoke Evacuator* to be inoperable, voiding the warranty.
- The ambient temperature during operation must be kept between 50°F to 104°F (10°C to 40°C).
- The relative humidity during operation must be kept between 10% to 75%.
- An atmospheric pressure range during operation must be kept between 700 hPa to 1,060 hPa.
- Storage environmental ambient temperature should be kept between 14°F to 140°F (-10°C to 60°C).
- Storage environmental relative humidity should be kept between 10% to 75%.
- There are no user serviceable components in the *Bovie® Smoke Shark Surgical Smoke Evacuator*. Refer to Symmetry Surgical Customer/Technical Services for routine servicing.
- Use only with the Power Cord provided and always plug into a grounded electrical outlet.

DESCRIPTION / INTRODUCTION: SECTION 1.0

Symbol	Description / Meaning	Symbol	Description / Meaning
	DANGER HIGH VOLTAGE CAUTION - ELECTRICAL SHOCK HAZARD. DO NOT REMOVE COVER. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL.		MARKING OF EEE (ELECTRICAL AND ELECTRONIC EQUIPMENT). FOLLOW LOCAL REQUIREMENTS FOR PROPER DISPOSAL.
	DANGER CAUTION - RISK OF EXPLOSION IF USED IN THE PRESENCE OF FLAMMABLE ANESTHETICS.		CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN
	WARNING		CONSULT INSTRUCTIONS/ DIRECTIONS FOR USE
	CAUTION		MEDICAL DEVICE
	TYPE CF APPLIED PART		NOT MADE WITH NATURAL RUBBER LATEX
	ALTERNATING CURRENT		CE MARK
	PROTECTIVE EARTH, (GROUND)		AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY FOR CE MARKED DEVICES.
	DENOTES THE DATE THE EQUIPMENT WAS MANUFACTURED		SERIAL NUMBER
	DENOTES THE MANUFACTURER OF THE DEVICE		DO NOT USE IF PACKAGE IS DAMAGED
	NON-IONIZING RADIATION		SERVICE INDICATOR CONTACT CUSTOMER/TECHNICAL SERVICES

2.1 Control Panel (see Figure 1, Diagram/Contents)

The Control Panel contains the following LED indicators: Motor On, Standby, Filter Life, and Service. Read all instructions before operating the *Bovie® Smoke Shark Surgical Smoke Evacuator* or installing accessories. Failure to do so may result in damage to the *Bovie® Smoke Shark Surgical Smoke Evacuator* and/or personal injury.

POWER OFF/ON

To power up the *Bovie® Smoke Shark Surgical Smoke Evacuator*, connect the supplied Power Cord to a grounded electrical outlet and the power receptacle at the bottom of the *Bovie® Smoke Shark Surgical Smoke Evacuator*. Flip the Power Off/On Button to “ON” to apply power to the unit. Once power has been applied, the Standby Indicator LED illuminates the color amber. Turn the *Bovie® Smoke Shark Surgical Smoke Evacuator* main power off by either flipping the Power Off/On Button to “OFF” or by unplugging the Power Cord from either the power receptacle on the *Bovie® Smoke Shark Surgical Smoke Evacuator* or the grounded electrical outlet.

SUCTION ON / STANDBY BUTTON

Press the Suction On/Standby Button to shift between two (2) modes: On or Standby. The Suction On LED illuminates the color green indicating active suction and the Standby LED illuminates the color amber when in standby.

Filter LIFE INDICATOR

The Filter Life Indicator on the Control Panel provides a visual indication of the status of the filter life of the filter in use.

Install an unused filter into the *Bovie® Smoke Shark Surgical Smoke Evacuator* as per the installation instructions (section 2.3). When the Motor On LED is illuminated, the Filter Life Indicator will light up the uppermost green LED indicating 100% Filter Life. The indicator will progress through subsequent colors, from green LEDs to amber LED as time elapses, and finally to red to indicate the filter has expired and requires replacement. When the maximum filter life is expended: The unit will cease operation in one (1) hour or when the unit is manually powered off, whichever occurs first. The smoke evacuator will not resume functionality until a new filter is installed. The filter has a 6 hour lifetime which is automatically tracked by the *Bovie® Smoke Shark Surgical Smoke Evacuator*.

2.2 Set-Up and Operation

1. Mount the *Bovie® Smoke Shark Surgical Smoke Evacuator* using the wall mounting kit (SE03-M). Secure the wall mounting kit to the wall by drilling two 3/8” diameter holes in wall, installing the provided hardware into the holes, and secure mounting plate to the provided hardware. The *Bovie® Smoke Shark Surgical Smoke Evacuator* can be secured to the wall mounting kit (SE03-M) by sliding the two screws protruding from the rear of the *Bovie® Smoke Shark Surgical Smoke Evacuator* (Figure 2.) into the grooves found on the mounting kit (SE03-M).
2. Attach the Power Cord to the power receptacle on the bottom of the *Bovie® Smoke Shark Surgical Smoke Evacuator* and into a grounded electrical outlet. Route Power Cord to prevent a tripping hazard or crimping of cords, which could cause unreliable operation or electric shock.



Figure 2

OPERATING INSTRUCTIONS: SECTION 2.0

3. Install the filter (see filter installation instructions, section 2.3).
4. The Automatic Activation Device may also be installed by plugging it into the Automatic Activation Device port located on the front of the *Bovie® Smoke Shark Surgical Smoke Evacuator*. See section 2.4 for instructions.
5. Ensure that any smoke evacuation capture accessory is fully installed in the filter port.
6. Route any other attached accessories to prevent a tripping hazard or crimping of cords, which could cause unreliable operation.
7. Activate the *Bovie® Smoke Shark Surgical Smoke Evacuator* by one of the following:
 - Pressing the Suction On/Standby Button on the Control Panel of the smoke evacuator.
 - Utilizing the automatic activation accessory provided with the unit. This device will synchronize the activation of the smoke evacuation unit with the activation of the desiccator device.
8. Deactivate the *Bovie® Smoke Shark Surgical Smoke Evacuator* by one of the following:
 - Pressing the Suction On/Standby Button on the Control Panel of the smoke evacuator.
 - Releasing the pencil button on the desiccator device if an automatic activation device is being used.
9. Replace the filter when the Filter Life Indicator flashes the color red (0% life remaining). Failure to change the filter will affect the performance of the *Bovie® Smoke Shark Surgical Smoke Evacuator*.

2.3 Filter Instructions

Bovie® P/N:	SF06
Configuration:	Wall Mounted
Bovie® SF06 Filter:	4-Stage Filtration In One Casing, (Pre-Filter, ULPA, Carbon, Post-Filter)
Filter(s):	ULPA
Particle Size, µm:	0.1 to 0.2 Microns At 99.999% Efficiency
Filter Life:	6 hours, Automatic Factory Set Filter Sensor
Filter Life Indicator:	Time Replacement

Filter Installation Instructions:

Note: Before installing or removing any filter, be sure that the *Bovie® Smoke Shark Surgical Smoke Evacuator* is placed in the Standby mode by pressing the Suction On/Standby Button.

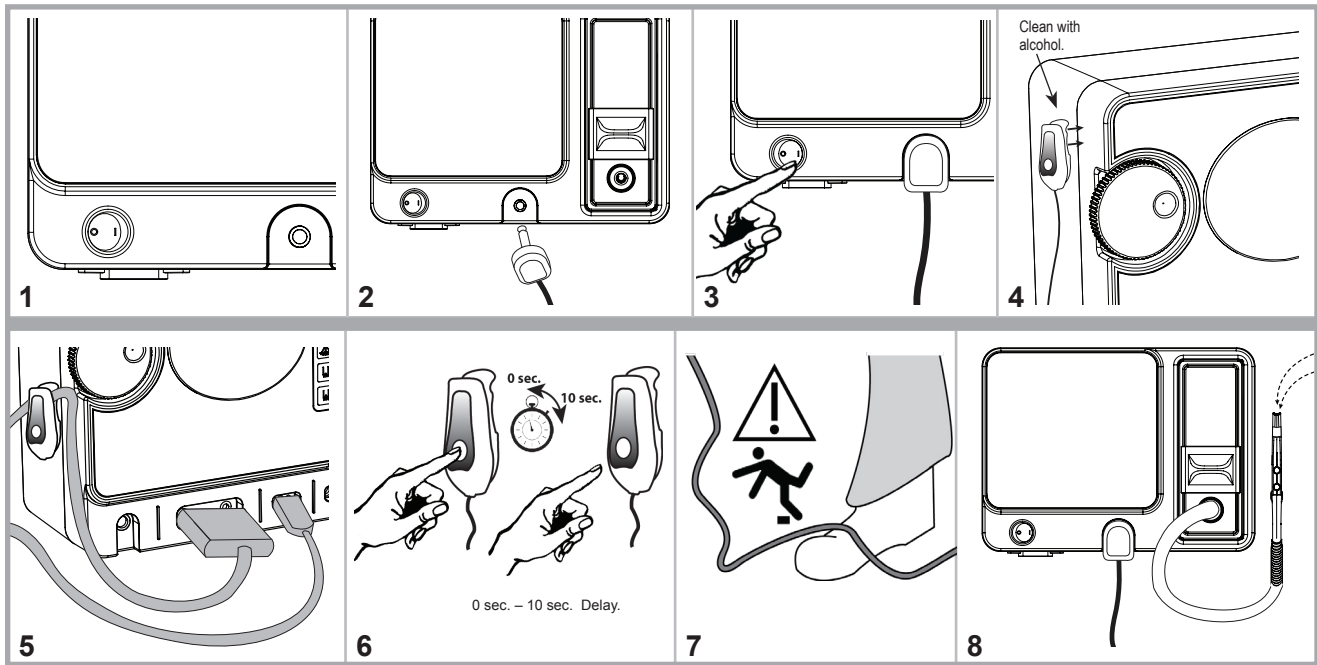
1. Remove the filter from the shipping box and discard any protective wrapping.
2. Inspect the filter for damage, which may have occurred during shipping and storage. Do not install any filter with visible signs of structural damage.
3. Insert the filter into the filter chamber and ensure the filter is installed completely against the bottom of the filter chamber.

Filter Removal Instructions:

1. After the filter life has expired, turn the *Bovie® Smoke Shark Surgical Smoke Evacuator* to the Standby mode by pressing the Suction On/Standby Button.
2. Remove all accessories attached to the filter.
3. Remove the Filter from the *Bovie® Smoke Shark Surgical Smoke Evacuator*. Dispose according to your local codes or regulations and facility policy (Section 3.2).
4. Clean the *Bovie® Smoke Shark Surgical Smoke Evacuator* with a mild disinfectant prior to re-use and follow the indicated instructions for maintenance and installation of a new filter (Section 3.2).

OPERATING INSTRUCTIONS: SECTION 2.0

2.4 Automatic Activation Device Instructions



2.5 Performance References*

Performance		
Model Name/ Number		Bovie® Smoke Shark III / SE03-120 & SE03-220
Maximum Flow Setting (LPM-U.S.)		
Standard Hose I.D.		9.5 mm, 3/8"
SharkSkin Adapter		45 LPM
Dimensions (H x W x D)	inches	10 x 7 x 7.5
Dimensions (H x W x D)	centimeters	25.4 x 17.8 x 19.1
Weight	lbs	7.0
Weight	kg	3.2
Noise Level, dBA	maximum	55 dBA (120 V), 62 dBA (220 V)
Voltage Available		100/120 VAC, 220/240 VAC
Frequency, auto sensed		50/60 Hz
Remote Control Activation:		Yes (optional)
Safety Features:		UL Classified, CE Marked, Fuse Protection
Display:		LED, Filter Status, Suction On/Off, Service Required

*For reference purposes only

OPERATING INSTRUCTIONS: SECTION 2.0

2.6 Electromagnetic Compatibility Information per IEC 60601-1-2

Table 1

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The <i>Bovie® Smoke Shark Surgical Smoke Evacuator</i> is intended for use in the electromagnetic environment specified below. The customer or user of the <i>Bovie® Smoke Shark Surgical Smoke Evacuator</i> should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The <i>Bovie® Smoke Shark Surgical Smoke Evacuator</i> uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The <i>Bovie® Smoke Shark Surgical Smoke Evacuator</i> is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	Not applicable.
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Class A	Not applicable.

OPERATING INSTRUCTIONS: SECTION 2.0

Table 2

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The <i>Bovie® Smoke Shark Surgical Smoke Evacuator</i> is intended for use in the electromagnetic environment specified below. The customer or user of the <i>Bovie® Smoke Shark Surgical Smoke Evacuator</i> should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electromagnetic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines. IEC 61000-4-11	$<5\% U_T$ ($>95\%$ dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $<5\% U_T$ ($>95\%$ dip in U_T) for 5 sec	$<5\% U_T$ ($>95\%$ dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $<5\% U_T$ ($>95\%$ dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the <i>Bovie® Smoke Shark Surgical Smoke Evacuator</i> requires continued operation during power main interruptions, it is recommended the <i>Bovie® Smoke Shark Surgical Smoke Evacuator</i> be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

OPERATING INSTRUCTIONS: SECTION 2.0

Table 3

Guidance and Manufacturer's Declaration - Electromagnetic Emissions			
The <i>Bovie® Smoke Shark Surgical Smoke Evacuator</i> is intended for use in the electromagnetic environment specified below. The customer or user of the <i>Bovie® Smoke Shark Surgical Smoke Evacuator</i> should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the <i>Bovie® Smoke Shark Surgical Smoke Evacuator</i> including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 3 Vrms	d = 1.7 √P 80 MHz to 800 MHz
			d = 2.3 √P 800 MHz to 2.5 GHz
			d = [3.5/V1} √P
Conducted RF IEC 61000-4-6	150 kHz to 80 MHz		Where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and D is the recommended separation distance in meters (M).
			Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.
			Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structure, objects and people.			
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy.			
To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the <i>Bovie® Smoke Shark Surgical Smoke Evacuator</i> is used exceeds the applicable RF compliance level above, the <i>Bovie® Smoke Shark Surgical Smoke Evacuator</i> should be observed to verify normal operation.			
If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the <i>Bovie® Smoke Shark Surgical Smoke Evacuator</i> .			
Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 4

**Recommended Separation Distance Between
Portable and Mobile RF Communications Equipment and
the *Bovie® Smoke Shark Surgical Smoke Evacuator* @ 3 Vrms**

The *Bovie® Smoke Shark Surgical Smoke Evacuator* is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled.

The customer or the user of the *Bovie® Smoke Shark Surgical Smoke Evacuator* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *Bovie® Smoke Shark Surgical Smoke Evacuator* as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz	80 kHz to 800 MHz	800 kHz to 2.5 GHz
	$d = \left[\begin{matrix} 3.5 \\ - \\ v_1 \end{matrix} \right] \sqrt{P}$	$d = \left[\begin{matrix} 3.5 \\ - \\ E_1 \end{matrix} \right] \sqrt{P}$	$d = \left[\begin{matrix} 3.5 \\ - \\ E_1 \end{matrix} \right] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.34	0.34	0.74
1	1.7	1.7	2.3
10	3.7	3.7	7.4
100	11.7	11.7	23.3
For transmitters rated at a maximum output power not listed above, the recommended separation Distance (D) in Meters (M) can be estimated using the equation applicable to the frequency of the transmitter, where (P) is the maximum output rating of the transmitter in Watts (W) according to the transmitter manufacturer.			
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structure, objects, and people.			

3.1 General Maintenance Information

It is recommended that periodic inspection and performance testing be completed by a qualified facility biomedical technician to ensure continued safe and effective operation.

3.2 Cleaning

- Unplug the *Bovie® Smoke Shark Surgical Smoke Evacuator*.
- Wipe *Bovie® Smoke Shark Surgical Smoke Evacuator* with a damp cloth containing mild disinfectant solution or soapy water.
- Wipe *Bovie® Smoke Shark Surgical Smoke Evacuator* with a dry clean cloth.
- Do not steam sterilize.

3.3 Periodic Inspection

The *Bovie® Smoke Shark Surgical Smoke Evacuator* should be visually inspected at least once per year. The inspection should include checks for:

- Damage to the Power Cord or Power Inlet Module.
- Obvious external or internal damage to the *Bovie® Smoke Shark Surgical Smoke Evacuator*.

FUSES

Two 4 AMP fuses for 100/120 *Bovie® Smoke Shark Surgical Smoke Evacuators* or two 2 AMP fuses for 220/240 *Bovie® Smoke Shark Surgical Smoke Evacuators* are located within the housing of the system. The fuses electrically protect both the *Bovie® Smoke Shark Surgical Smoke Evacuator* and the operator from damage or injury. If the *Bovie® Smoke Shark Surgical Smoke Evacuator* is overheated or if there is an electrical surge, fuses will break and the *Bovie® Smoke Shark Surgical Smoke Evacuator* will not operate. No parts are user serviceable. When the Service LED Light Indicator illuminates, please contact Customer/Technical Services.

3.4 Troubleshooting

PROBLEM	POTENTIAL CAUSE	CORRECTIVE ACTION
1. <i>Bovie® Smoke Shark Surgical Smoke Evacuator</i> is on but suction is minimal or none.	1. Filter is not seated completely.	1. Re-install the filter, press firmly into place.
	2. Filter is clogged.	2. Replace the filter with the manufacturer's filter. (SF06)
	3. Vacuum tubing is clogged.	3. Replace vacuum tubing with manufacturer's products.
	4. Motor is obstructed.	4. Call Symmetry Surgical Customer Service.
2. <i>Bovie® Smoke Shark Surgical Smoke Evacuator</i> does not function even though Suction On/Standby Button is depressed.	1. Not plugged into an electrical outlet.	1. Check the grounded electrical outlet connection and the power receptacle located at the bottom of the <i>Bovie® Smoke Shark Surgical Smoke Evacuator</i> .
	2. Fuses are blown.	2. Call Symmetry Surgical Customer Service.
	3. Electronic <i>Bovie® Smoke Shark Surgical Smoke Evacuator</i> failure.	3. Call Symmetry Surgical Customer Service.
	4. Filter Life has expired or invalid filter installed.	4. Replace the filter.

Report complaints involving this device to bovie.complaint@symmetrysurgical.com or to your local distributor.

4.1 Product Return

For the quickest response to your service needs, please follow these procedures:

Step 1: Write down *Bovie® Smoke Shark Surgical Smoke Evacuator* model name and serial number.

Step 2: Call Customer/Technical Services: 800.251.3000 (United States) or +1 615.964.5532 (International) and describe the problem.

Step 3: If the problem cannot be resolved over the phone and the *Bovie® Smoke Shark Surgical Smoke Evacuator* must be returned for repair, a Return Material Authorization (RMA) number must be obtained from Customer Service before returning the *Bovie® Smoke Shark Surgical Smoke Evacuator*.

Step 4: Use the original packaging material to return your *Bovie® Smoke Shark Surgical Smoke Evacuator* whenever possible. If you do not have the original packaging material, ask Customer Service for advice on how to pack for return shipment.

Step 5: Freight for all returned products should be prepaid by the facility returning the product. A Ship To address will be supplied by Customer Service.

4.2 Ordering Information

To reorder, obtain replacement parts, or to return *Bovie® Smoke Shark Surgical Smoke Evacuator*, call Customer Service or contact your authorized Distributor/Sales Representative.

Available accessories:

- Replacement filters (SF06)
- Replacement Automatic Activation Device (SERS2)
- Tubing (Various)
- Reducer Fittings (Various)
- Electrosurgical Pencil Adapter (SS95)

5.1 Terms & Warranty

SPECIFICATIONS

Specifications are subject to change without notice.

SHIPMENT OF ORDER

Symmetry Surgical, Inc. will try to accommodate individual customer requests for shipping method. Symmetry Surgical, Inc. reserves the right to decide shipping method on prepaid orders. Care is exercised in the checking and packaging of all merchandise to avoid error, but should discrepancies arise, claims should be made within 24 hours after delivery.

Symmetry Surgical, Inc.'s responsibility ceases with the safe delivery to the carrier at our dock. If the merchandise is damaged in transit, a claim must be made to the carrier involved. Symmetry Surgical, Inc. will assist customers in pursuing these claims.

RETURN OF MATERIAL

All returned merchandise must have a pre-authorized Return Material Authorization (RMA) from Symmetry Surgical, Inc. and be marked with that RMA number prior to returning. Transportation costs must be prepaid by the shipper and all risk of loss and damage of goods are the responsibility of the shipper. Unauthorized returns will be refused. Include a copy of the packing papers and/or invoice with the return. Exchange will be of an equivalent dollar value of returned merchandise less a restocking and handling fee of new, unused, unopened equipment or disposables.

EXCEPTIONS

- Defective merchandise may be returned for replacement only.
Please contact Symmetry Surgical Customer Service before shipping back merchandise.
- Incorrectly shipped merchandise is exempt from restocking fees.
Please contact Symmetry Surgical Customer Service before shipping back merchandise.

WARRANTY

Symmetry Surgical, Inc. warrants that the Bovie® Smoke Shark Surgical Smoke Evacuator manufactured by Symmetry Surgical, Inc. shall be free from defects in material and workmanship. Products are warranted only to the extent that Symmetry Surgical, Inc. will replace without charge any Bovie® Smoke Shark Surgical Smoke Evacuator proven to have defects within two (2) years of the date of delivery of Surgical Smoke Evacuator and provided Symmetry Surgical, Inc. has been given the opportunity to inspect the Surgical Smoke Evacuator alleged to be defective and the installation or use thereof. No warranty is included for incidental or consequential damages of any nature arising from any defect. The warranty above is the only warranty made by Symmetry Surgical, Inc. and is expressly in lieu of all other warranties, expressed or implied, including, without limitation, the warranties of merchantability and fitness for a particular purpose. All warranties implied by any course of dealing or usage between parties are expressly excluded.

TERMS & WARRANTY: SECTION 5.0

Limitation of Liability for Damages. Symmetry Surgical, Inc. is not liable for indirect, special, incidental or consequential damages of any kind, arising from any theory, including breach of warranty, breach of contract, negligence, tort or any other legal theory. Such damages include but are not limited to, loss of profits or revenues, loss of use of the Product or any associated equipment, cost of capital, cost of any substitute Product, facilities or services, down-time costs, lost reputation, or claims of customers for such damages. Notwithstanding anything to the contrary herein, the total limit of Symmetry Surgical, Inc.'s liability under any theory for one or more claims shall not exceed, in the aggregate, the amount paid to Symmetry Surgical, Inc. for the Product that is the subject of such claim. Purchase and use of the Product associated with this IFU constitutes acceptance of this provision and all others in the IFU.

Entire Agreement and Amendment. All exhibits and schedules attached hereto and referenced herein are made a part of this Agreement. This Agreement constitutes the entire agreement between the parties concerning the subject matter of this Agreement and supersedes all prior negotiations and agreements between the parties concerning the subject matter of this Agreement. The terms of any purchase order, invoice, or similar document used to implement this Agreement shall be subject to and shall not modify this Agreement. This Agreement may only be amended by a written agreement signed by both parties.

Warranties. All warranties provided by Symmetry Surgical, Inc. with respect to any Product sold are as described in the package inserts or instructions for use available with the Product or on the www.symmetrysurgical.com or www.boviemedical.com websites. **OTHER THAN AS SET FORTH IN THE PREVIOUS SENTENCE, THERE IS NO IMPLIED OR EXPRESS WARRANTY ON THE PRODUCTS, INCLUDING THOSE OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.** Using any filter not distributed by Symmetry Surgical, Inc. may cause damage to the Surgical Smoke Evacuator and will void all warranties.

Governing Law, Venue and Jurisdiction. Any dispute arising from or related in any way to this IFU, the product(s) associated with it or described herein shall be governed by and construed in all respects in accordance with the laws of the state of Tennessee in the United States of America. All claims or differences or other disputes, which arise out of or in connection with this IFU, the product(s) related to it or otherwise shall be settled, litigated, or resolved by the state or federal courts in Antioch, Tennessee (or those serving Antioch, Tennessee), and the parties hereby submit to the exclusive jurisdiction of such courts over any dispute. *All proceedings shall be held in English. Each party will bear its own costs in such proceedings.*

For a period of two (2) years following the date of delivery, **Symmetry Surgical, Inc.** warrants the SmokeShark *Surgical Smoke Evacuator* against any defects in material or workmanship. **Symmetry Surgical, Inc.** will repair or replace (at **Symmetry Surgical's** option) the same without charge, provided that routine maintenance as specified in this manual has been performed using replacement parts approved by **Symmetry Surgical, Inc.**

This warranty is void if the product is used in a manner or for purposes other than intended.

Bovie®



The revision level of this manual is specified by the highest revision letter found on either the inside front cover or enclosed errata pages (if any).

Manual Number 905214 Rev A 07/2020

Unit Serial Number _____



E351320

Medical – General

Medical Equipment as to Electrical Shock, Fire and Mechanical Hazards only in Accordance with ANSI/AAMI ES60601-1 (2005) and AMD 1 (2012), CAN/CSA-C22.2 NO. 60601-1 (2014)
