Bovie®

# smoke shark™

## Smoke Evacuator

# Operator's Manual




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For a period of two (2) years following the date of delivery, Bovie Medical Corporation warrants the Smoke Shark II against any defects in material or workmanship. Bovie Medical Corporation will repair or replace (at Bovie Medical Corporation's option) the same without charge, provided that routine maintenance as specified in this manual has been performed using replacement parts approved by Bovie Medical Corporation. This warranty is void if the product is used in a manner or for purposes other than intended.



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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:902958REVA
Bovie® P/N: 23088

MEDICAL – GENERAL MEDICAL EQUIPMENT
AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH UL 60601-1, ANSI/AAMI ES60601-1 (2005, 3rd ed.),
CAN/CSA C22.2 NO. 601.1, AND CAN/CSA-C22.2 No. 60601-1 (2008)
9D93

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.

EC REP
Emergo Europe
Molenstraat 15
NL-2513 BH The Hague
The Netherlands

CE

# Table of Contents & List of Illustrations

# System Description
# Section 1.0

## 1.1 Introduction

Bovie® Smoke Shark II Smoke Evacuation Systems are intended to evacuate and filter surgical smoke plume and aerosols created by the interface surgical tools with tissue, examples being lasers, electrosurgery systems, and ultrasonic devices.

The Smoke Shark II Smoke Evacuation Systems have been designed with a high suction, high flow rate vacuum motor. The ultra-quiet motor is used to draw the surgical smoke from the surgical site through the vacuum tubing and into the Bovie® SF35 Filter where the surgical smoke is processed by a series of filters. A single disposable filter is used to simplify the installation and removal during filter changes. The filter is completely enclosed to protect the healthcare personnel from potential contamination during filter changes. One Bovie® SF35 Filter contains four different stages within to capture the smoke plume.

The first stage filtration is a prefilter whose function is to trap and remove gross particulate and casual fluid.

The second stage filtration is ULPA grade (Ultra Low Penetration Air) filter whose high-tech patented (U.S. Patent #5874052) design captures particulates and micro-organisms from .1 to .2 microns at an efficiency of 99.999%.

The third stage filtration uses the highest grade virgin activated carbon, especially designed for Bovie Medical Corporation for the removal and adsorption of odors and toxic gases produced by burning tissues. These harmful gases may constitute a health hazard to healthcare professionals who are subjected to prolonged exposure. The activated carbon used in the Smoke Shark II Smoke Evacuation Systems preferentially removes toxic organic gases rather than water vapor and provides optimal odor removal.

The fourth stage filtration is an expanded foam used to trap activated carbon fines from migrating out of the filter.

The electronic controls on the face panel of the Smoke Shark II Smoke Evacuation System has been designed “user friendly” and facilitate unit set up and operation. Please refer to Section 2.0 for Operating Instructions.

## 1.2 Inspection

The Smoke Shark II Smoke Evacuator has been thoroughly tested and inspected before shipment from the factory. Please check the unit before using it to insure that no damage has occurred in transit. If damage is evident, please contact Bovie Medical Corporation Customer Service at 1.800.537.2790 (US Only) or +1.727.384.2323 (International)

In addition, please compare the accessories you receive with the standard accessories list below. If an item is missing, please notify Bovie Medical Corporation Customer Service.

Standard Accessories:
- Operator's Manual
- Power Cord
- Pneumatic Footswitch

Please contact Bovie Medical Corporation Customer Service to purchase the following accessories:
- Replacement Filters
- Remote Activation Device
- Hoses, Tubing, Laparoscopic Kits, Adapters, Wands & Other Accessories

## 1.3 Operational Information

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

1. The Bovie® Smoke Shark II Smoke Evacuation System(s) complies with IEC60601.1 electrical specifications in the following systems:
   *100/120 VAC 50/60 Hz, 220/240 VAC 50/60 Hz*

2. Type of protection against electrical shock (UL 60601-1, Clause 5.1): Class I

3. Degree of protection against electric shock (UL 60601-1, Clause 5.2); Type CF Applied Part

4. Degree of protection against ingress of water (UL 60601-1, Clause 5.3): IPX1

5. Method of sterilization or disinfection recommended by Bovie Medical Corporation (UL 60601-1, Clause 5.4):
   *Unplug Unit. Wipe unit 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 (UL 60601-1, Clause 5.5): Not Suitable

7. Mode of operation (UL 60601-1, Clause 5.6): Continuous

8. Upon request, Bovie Medical Corporation will provide the following:
   *Service and Repair Instructions, including Circuit Diagrams and Parts List*

9. The fuses on the circuit board are to be serviced by an authorized Bovie Medical Corporation technician as follows:
   *100/120 VAC, 50/60 Hz - use* T10AH250V *Fuse (10 Amp 250 Volt [Slo-Blo]), (F1, F2)*
   *220/240 VAC, 50/60 Hz - use T8.0AH250V Fuse (8 Amp 250 Volt [Slo-blo]), (F1, F2)*

10. The fuses on the motor circuit are to be serviced by an authorized Bovie Medical Corporation technician as follows:
*220/240 VAC, 50/60 Hz – use F3.15AH250V Fuse (3,15 Amp 250 Volt [Fast-Acting]), (F3)*

11. This equipment needs special precautions regarding ElectroMagnetic Compatibility and needs to be installed according to EMC information found in this manual.

12. This equipment utilizes mobile RF communications equipment that can affect medical electrical equipment.

13. This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at their expense.

14. This equipment operates in the following radio frequency specifications:

    RX modulation: Pulse-width coded, AM 100% modulation
    TX Frequencies: Manchester encoded,
    A = fc =/- 423.75kHz, B = fc +/- 484.29kHz
    Low bit: transition A to B
    High bit: transition B to A

15. To isolate equipment from supply mains, unplug the power cord from the appliance inlet on the unit or receptacle in the wall. Position the equipment to allow for ease of unplugging power cord.

16. Potential Equalization Conductor: Terminal located on back panel for connection of potential equalization. Conductor complies with requirements per IEC 60601-1 (2005).

The Smoke Shark II Smoke Evacuation System(s) and all filters are not intended for contact with patients.

## 1.4 Cautions and Warnings

Please note that all Cautions and Warnings should be read and understood before any use of this equipment.

Please note that all Cautions and Warnings should be read and understood before any use of this equipment.

### 1.4.1 WARNINGS:

- Read this manual thoroughly, and be familiar with its contents prior to using this equipment.
- Test this equipment prior to a surgical procedure. This product was thoroughly tested at the factory before shipment.
- Disconnect the unit from the electrical outlet prior to inspecting system components.
- The Smoke Shark II system is only intended and suitable for the applications that are mentioned in the operating instructions.
- The smoke evacuator produces a strong vacuum. Adjust the airflow and the position of the inlet end of the wand or tubing to prevent patient injury and to prevent suction of surgical materials and surgical specimens.
- If the smoke evacuator is activated while the airflow is set to a high speed, it may produce a sudden, strong suction action. Check the airflow setting before activating the smoke evacuator to prevent patient injury and to prevent suction of surgical materials and surgical specimens.
- To maximize patient safety, the tubing or wand should not come into direct contact with tissue. Otherwise, patient injury may result.
- The Bovie® Smoke Shark II filters and single-use accessories are completely disposable. Please dispose of according to your local codes or regulations and hospital policy. These filters may be disposed of or incinerated, whichever is appropriate for your institution.
- Care should be taken to route the power cord, foot pedal, smoke evacuation tubing, and Remote Activation Device cable as to not cause a tripping hazard or crimping of cords.
- Do not operate this device in the presence of flammable or explosive gases.
- To avoid risk of Electric Shock, this equipment must only be connected to a supply mains with protective earth.
- This equipment is intended for use by healthcare professionals only. This equipment 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 Smoke Shark II or shielding the location.
- The use of ACCESSORIES other than those specified by Bovie Medical Corporation, or sold by Bovie® may result in increased emissions or decreased effectiveness of the Smoke Shark II.

- This equipment should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Smoke Shark II should be observed to verify normal operation in the configuration in which it will be used.

- Refer routine servicing to qualified biomedical technical personnel.

- Changes or modifications not expressly approved by Bovie Medical Corporation could void the user's authority to operate the equipment.

The warranty on this product is void if any of these warnings are disregarded.

### 1.4.2 CAUTIONS:

- Federal law (United States of America) restricts this device to be used by, or on the order of a physician.

- Do not block either the tubing or the filter. If either becomes occluded or significantly restricted, the motor/blower may overheat and cause the unit to fail.

- Using any other filter or accessory not supplied by Bovie Medical Corporation may cause damage and/or cause the system to be inoperable and may void the warranty.

- Care must be exercised in the installation of hoses, adapters and suction canisters. Failure to follow the procedures outlined in this manual may result in overheating of the motor and may void the unit warranty.

- This device is not intended for evacuation of fluid. If fluid is expected to be aspirated to the Bovie® SF35 Filter, fluid collection devices must be installed with the vacuum hose assembly. Failure to install a fluid collection device could cause filter blockage and electrical damage.

- The Bovie® SF35 should be changed according to the life of the filter. The Bovie® SF35 Filter, used with the Smoke Shark II Smoke Evacuation System(s), should not be used for more the time specified for each filter. Failure to change the filter may result in decreased efficiency and contamination of the electric motor, vacuum pump, and sound absorbing media within the unit.

- Do not block either the tubing or the filter during operation. An occlusion or significant restric tion may cause the motor to overheat and the unit to stop working.

- The installation of this equipment must be performed such that the intake and exhaust vents located on the bottom of the system are not obstructed. Failure to properly install the unit may cause reduced performance, damage and/or cause the system to be inoperable and may void 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 of 700 hPA to 1,060 hPa.
- Storage environmental ambient temperature 14°F to140°F (-10°C to 60°C).
- Storage environmental relative humidity 10% to 75%.

**There are no user serviceable components in the Smoke Shark II Smoke Evacuation System(s). Refer service to qualified service personnel.**

**Use only with the power cord provided and always plug into a grounded outlet.**

| SYMBOL | DESCRIPTION/MEANING |
|---|---|
|  | WARNING:<br>DANGEROUS VOLTAGE. |
|  | WARNING. |
|  | TYPE CF APPLIED PART. |
| IPX1 | PROTECTION AGAINST INGRESS OF WATER AS DETAILED IN IEC 60529. |
|  | ALTERNATING CURRENT. |
|  | PROTECTIVE EARTH, (GROUND). |
|  | EQUIPOTENTIALITY. |
|  | DENOTES THE DATE THE EQUIPMENT WAS MANUFACTURED. |
|  | DENOTES THE MANUFACTURER OF THE DEVICE. |
|  | NON-IONIZING RADIATION. |
|  | MANDATORY:<br>REFER TO INSTRUCTION MANUAL/GUIDE. |
|  | DO NOT RESTERILIZE. |
|  | SINGLE USE ONLY. |
|  | DO NOT USE IF PACKAGE IS DAMAGED. |
| Rx ONLY | CAUTION:<br>FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN. |

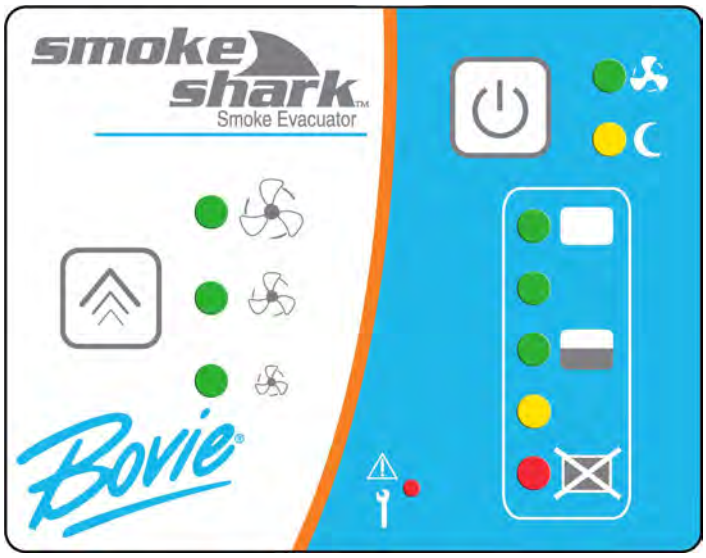
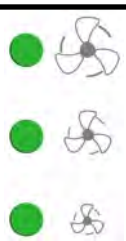
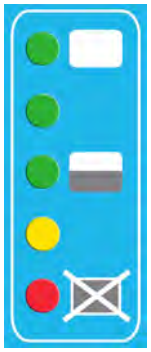



*Figure 1*
*Unit Control Panel*

| | |
|---|---|
|  | **SYSTEM MOTOR POWER BUTTON** |
|  | **SUCTION SPEED BUTTON: PRESS TO CYCLE THROUGH HIGH, MEDIUM AND LOW SPEEDS** |
|  | **MOTOR ON LED INDICATOR** |
|  | **STANDBY MODE LED INDICATOR** |
|  | **SERVICE/TROUBLESHOOTING REQUIRED LED INDICATOR** |
|  | **MOTOR SPEED LED INDICATORS: Upper Light: HIGH SPEED Center Light: MEDIUM SPEED Lower Light: LOW SPEED** |
|  | **CURRENT FILTER LIFE INDICATOR: AS LIGHTS MOVE FROM GREEN TO RED, FILTER LIFE DEPLEATS. REPLACE FILTER WHEN RED.** |

## 2.1 System Controls

The electronic system controls on the Smoke Shark II Smoke Evacuation System(s) are easy to understand and simple to use. The membrane control panel contains the suction on/off switch, suction power adjustment, filter life indicator, and service indicator light. See Figure 1.

Note: Please be sure to read all instructions before installing accessories or operating this equipment. Failure to do so may result in damage to the unit and/or personal injury.

- **SUCTION ON & Standby**

There is one ON/OFF button on the Smoke Shark II Smoke Evacuation System(s). The suction ON switch on the electronic membrane control panel is located in the upper right hand corner of the membrane panel. To power up the machine, connect the supplied power cord to a grounded outlet and the appliance inlet on the back of the smoke evacuation system. Once power has been applied, the yellow standby LED will illuminate on the keypad. Press the ON/OFF button on the membrane panel to illuminate the "fan running" green LED indicating active suction. Place the unit in "standby" by pressing the suction ON membrane switch to illuminate yellow STANDBY LED. Turn the system main power off**,** by unplugging the power cord from the appliance inlet on the unit or the receptacle in the wall.

- **SUCTION CONTROL**
  **(Membrane Control Panel)**

The amount of suction may be adjusted by pressing the suction control button. Each time the suction control button is depressed, the motor speed in increased. Once the suction has reached the maximum level, depressing the button again will return suction level to lowest setting. The suction control should be set at the lowest practical setting to completely remove the surgical smoke from the operative site. Each time the arrow button is pressed, the suction will change to a different flow setting (low / medium / high).

- **FOOTSWITCH / REMOTE ACTIVATION DEVICE**
  **(Membrane Control Panel)**

The Bovie® Smoke Shark II Smoke Evacuation System also comes equipped with a pneumatic footswitch.

A footswitch or a Remote Activation Device may be added to any system by simply plugging in a Bovie® activation accessory into the appropriate jack on the front of the unit. When the footswitch is plugged in, the unit suction may be turned on or off by depressing the footswitch pedal once for each operation. For directions on using the Remote Activation Device, please see instructions that accompany that product.

- **FILTER LIFE INDICATOR**
  **(Membrane Control Panel)**

The filter life indicator on the membrane control panel provides a visual indication of the status of the life of the filter in use. The filter life indicator for the Bovie® Smoke Shark II Smoke Evacuation System will automatically adjust according to the flow setting selected.

| |
|---|
| Low Flow Setting = 35 hours of filter life<br>Medium Flow Setting = 24 hours of filter life<br>High Flow Setting = 18 hours of filter life |

The Filter Life Indicator is factory set. All filter life timing is automatic.

**Reading the Filter Life Indicator:**

Install an unused Bovie® SF35 Filter into the system per the installation instructions contained in this operator's manual. When the system is turned on, the filter life indicator with light up the leftmost GREEN LED, indicating 100% filter life. The indicator will progress thru subsequent GREEN LEDs, to an AMBER LED as time elapses and begin flashing RED to indicate that the filter has expended its useful life and requires replacement.

**When the maximum filter life is expended:**
**The unit will cease operation in six (6) hours or when the unit is manually powered off, (whichever occurs first). The smoke evacuator will not resume functionality until a new filter is installed.**

- **FUSES**
  **(circuit board)**

Two T10AH250V [10 AMP] fuses (T8.0AH250V [8 AMP] for 220/240 Bovie® Smoke Shark II Smoke Evacuation Systems) are located on the circuit board within the housing of the system. It electrically protects both the system and the operator from damage or injury. If the system is overheated or if there is an electrical surge in the electrical system, fuses will break and the system will not operate.

**When the Service light illuminates, please contact Bovie Medical Corporation Customer Service for system service instructions. (See Section 4.0)**

## 2.2 Bovie® SF35 Filter Instructions

| | |
|---|---|
| **Bovie® P/N:** | **SF35** |
| **Configuration:** | **Portable or tabletop** |
| **Bovie® SF35 Filter - Multi Port 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:** | **Automatic Factory Set Filter Sensor** |
| **Filter Life Indicator:** | **Timed Replacement** |

**Note: Before installing or removing any filter, be sure that the system is turned off.**

**Filter Installation Instructions:**

The installation of the Bovie® SF35 Filter into the Bovie® Smoke Shark II Smoke Evacuation System(s) is quick and simple.

1. Remove the Bovie® SF35 Filter from the shipping box and discard any protective wrapping. Examine all filters for damage during shipping and storage. Do not install any filter with visible signs of structural damage.
2. Insert the Bovie® SF35 Filter into the filter receptacle. Be sure that the filter is seated completely against the bottom of the filter chamber and clip is fully engaged.

**WARNING: This device is not intended for evacuation of fluid. If fluid is expected to be aspirated using the Bovie® SF35 Filter or the Bovie® Smoke Shark II system, fluid collection devices must be installed with the vacuum hose assembly. Failure to install a fluid collection device may cause filter blockage and/or electrical damage.**

**Filter Removal Instructions:**

1. After the Bovie® SF35 Filter has been exhausted and requires changing, turn the smoke evacuation system off and disconnect any accessory tubing attached to the filter.
2. Depress the filter tab and pull the filter from the smoke evacuation system and dispose of in accordance with hospital policy. The Bovie® SF35 Filter may be disposed of or incinerated.
3. Wipe unit with a damp cloth containing mild disinfectant solution or soapy water. Wipe dry with a clean cloth. Do not steam sterilize. Follow the indicated instructions for maintenance and installation of a new Bovie® SF35 Filter.

**CAUTION: Using any other filter or accessory not supplied by Bovie Medical Corporation may cause damage to the system and/or cause the system to be inoperable and may void the warranty.**
**WARNING: The Bovie® SF35 Filter should be changed when the Filter Life Indicator shows red flashing LED (replace). Failure to change this filter may result in decreased efficiency and contamination of the electric motor, vacuum pump, and sound absorbing media within the system, or non-operation of smoke evacuator.**

## 2.3 Set-Up and Operation

The operation of the Smoke Shark II Smoke Evacuation System is as follows:

1. Install the Bovie® SF35 Filter.

2. Attach unit power cord to the receptacle on the rear of the system. Plug the pronged power cord into an appropriate grounded power outlet. Route power cord in such a way as to minimize potential trip hazard by users or patients or pinch hazard that could cause electric shock.

3. Optional: Attach either Remote Activation Device or Footswitch plug into appropriate jack on rear or front of machine. Route footswitch or Remote Activation Device cord in such a way as to minimize potential trip hazard by users or patients or pinch hazard that could result in unreliable operation.

4. Ensure that the evacuation tubing is fully seated in the inlet of the filter. Route tubing in such a way as to minimize potential trip hazard by users or patients.

5. Activate the power unit by:
   a. Pressing the suction ON/OFF switch on the membrane panel,
   b. Depressing and releasing the footswitch (if connected), or
   c. Activating either CUT or COAG on the Electrosurgical Pencil (if Remote Activation Device is connected).

6. Adjust the suction level to the desired setting by pressing the UP arrow button while the unit is activated. Noise created by the smoke excavation power unit may be minimized by selecting the lowest vacuum setting that effectively clears the operative field of surgical smoke.

7. Deactivate the unit by:
   a. Pressing the suction ON/OFF switch on the membrane panel,
   b. Depressing and releasing the footswitch (if connected), or
   c. Releasing either the CUT or COAG button on the Electrosurgical Pencil (If Remote Activation Device is connected).

8. Replace the Bovie® SF35 Filter when the Filter Life Remaining Scale FLASHES RED (0% Life Remaining). Failure to change the filter will affect the performance of the system.

## 2.4 Performance References*

| PERFORMANCE | | |
|---|---|---|
| Model Number | | Smoke Shark II |
| Maximum Flow Setting | | |
| Standard Hose I. D. (CFM) | | |
| | 7/8” | 25 CFM |
| | 3/8” | 4.5 CFM |
| | 1/4” | 2 CFM |
| | | |
| Standard Hose I. D. (LPM) | | |
| | 22mm | 708 LPM |
| | 9.5mm | 130 LPM |
| | 6.4mm | 57 LPM |
| Dimensions (H x W x D) | inches | 6 x 11 x 15.5 |
| Dimensions (H x W x D) | centimeters | 15.2 x 27.9 x 39.4 |
| Weight | lbs (kg.) | 10 lbs / (4.3 kgs) |
| Noise Level, dBA | MAXIMUM | 55.0 dBa |
| Footswitch Pneumatic | | Standard |
| Remote Control Activation | | YES (optional) |
| Safety Features | | UL Classified |
| | | CE Marked |
| | | Fuse Protection |
| Display | | LED |
| | | Filter Status |
| | | Flow Rate |
| | | Service Required |
| Voltage Available | | 100/120 VAC, 220/240 VAC |
| Frequency, auto sensed | | 50-60 Hz |
| Variable Flow Control | | Yes |
| Motor | Watts | 1000 ±10% |
| Motor Static Suction | kPa (6.5 mm orifice) | 25.69 |

*For reference purposes only

## 2.5 Electromagnetic Compatibility Information per IEC60601-1-2

**Table 1**

| Guidance and manufacturer's declaration - electromagnetic emissions | | |
|---|---|---|
| The Smoke Evacuation System model Smoke Shark II is intended for use in the electromagnetic environment specified below. The customer or user of the Smoke Shark II should assure that it is used in such an environment. | | |
| **Emissions Test** | **Compliance** | **Electromagnetic environment - guidance** |
| RF Emissions<br><br>CISPR 11 | Group 1 | The Smoke Shark II 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<br><br>CISPR 11 | Class A | The model Smoke Shark II 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<br><br>IEC 61000-3-2 | Class A | Not applicable. |
| Voltage Fluctuations/ Flicker Emissions<br><br>IEC 61000-3-3 | Class A | Not applicable. |

**Table 2**

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The model Smoke Shark II is intended for use in the electromagnet environment specified below. | | | |
| Immunity test | IEC 60601<br>Test level | Compliance level | Electromagnetic environment - guidance |
| Electromagnetic discharge (ESD)<br><br>IEC 61000-4-2 | ±6 kV contact<br><br>±8 kV air | ±6 kV contact<br><br>±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<br><br>IEC 61000-4-4 | ±2 kV for power supply lines<br><br>±1 kV for input/output lines | ±2 kV for power supply lines<br><br>±1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br><br>IEC 61000-4-5 | ±1 kV differential mode<br><br>±2 kV common mode | ±1 kV differential mode<br><br>±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<br><br>IEC 61000-4-11 | <5 % $U_T$<br>(>95 % dip in $U_T$)<br>for 0.5 cycle<br><br>40 % $U_T$<br>(60 % dip in $U_T$)<br>for 5 cycles<br><br>70 % $U_T$<br>(30 % dip in $U_T$) | <5 % $U_T$<br>(>95 % dip in $U_T$)<br>for 0.5 cycle<br><br>40 % $U_T$<br>(60 % dip in $U_T$)<br>for 5 cycles<br><br>70 % $U_T$<br>(30 % dip in $U_T$) | Mains power quality should be that of a typical commercial or hospital environment. If the user of the Smoke Shark II requires continued operation during power mains interruptions, it is recommended that the Smoke Shark II be powered by an uninterruptible power supply or battery. |

| | | | |
|---|---|---|---|
| | for 25 cycles<br><br><5 % $U_T$<br>(>95 % dip in $U_T$)<br>for 5 sec | for 25 cycles<br><br><5 % $U_T$<br>(>95 % dip in $U_T$)<br>for 5 sec | |
| 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. |

**Table 6**

| Guidance and manufacturer's declaration - electromagnetic emissions | | | |
|---|---|---|---|
| The model Smoke Shark II is intended for use in the electromagnet environment specified below. The customer or end user of the Smoke Shark II should assure that it us 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 Model EVL including cables, than the Recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
| Radiated RF | 3 V/m | | d = 1.7 √P 80 MHz to 800 MHz |
| IEC 61000-4-3 | 80MHz to 2.5 GHz | 3 V/m | d = 2.3 √P 800 MHz to 2.5 GHz |
| Conducted RF | | 3 Vrms | d = [3.5/V1] √P |
| 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 strengths 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 structures, objects and people. | | | |
| [a] 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 Model EVL is used exceeds the applicable RF compliance level above, the Smoke Shark II should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Smoke Shark II. | | | |
| [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. | | | |

**Table 4**

| Recommended separation distance between<br>Portable and mobile RF communications equipment and the model @ 3Vrms | | | |
|---|---|---|---|
| The Smoke Shark II is intended for use in an electromagnetic environment in which radiated RF distubances are controlled. The customer or the user of the Smoke Shark II can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Smoke Shark II as reccomended 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 $d = \left[\frac{3.5}{v_1}\right]\sqrt{P}$ | 80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ | 800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ |
| 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 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |

# Maintenance
# Section 3.0

## 3.1 General Maintenance Information

This section contains information for ordinary upkeep of the Bovie® Smoke Shark II Smoke Evacuation System. While the system has been designed and manufactured to high industry standards, it is recommended that periodic inspection and performance testing be performed by a qualified Biomedical Technician to ensure continued safe and effective operation.

## 3.2 Cleaning

Unplug Unit. Wipe unit with a damp cloth containing mild disinfectant solution or soapy water. Wipe dry with a clean cloth. Do not steam sterilize.

## 3.3 Periodic Inspection

The Smoke Shark II Smoke Evacuation System should be visually inspected at least every year. This inspection should include checks for:

- Damage to the power cord.
- Damage to the power plug or power inlet module.
- Proper mating, cleanliness and absence of damage to the filter inlet.
- Obvious external or internal damage to the system.

## 3.4 Troubleshooting the System – see below.

| PROBLEM | POTENTIAL CAUSE | CORRECTIVE ACTION |
|---|---|---|
| 1. Smoke Evacuation System is ON but suction is minimal or none. | 1. Filter is not seated completely.<br><br>2. Filter is clogged.<br><br>3. Vacuum hose or tube is clogged.<br><br>4. Motor/blower is obstructed. | 1. Re-install Bovie® SF35 Filter, press firmly into place and fully engage clip.<br><br>2. Replace filter with a genuine Bovie® SF35filter.<br><br>3. Replace vacuum hose or tube with genuine Bovie® products.<br><br>4. Call BioMed or Bovie® Medical Corporation Technical Services at 1.800.537.2790 or +1.727.384.2323. |
| 2. Smoke Evacuation System does not function even though suction ON button is depressed. | 1. Not plugged into an electrical outlet.<br><br>2. Fuses are blown.<br><br>3. Electronic system failure.<br><br>4. Filter life has expired or invalid filter inserted. | 1. Check power outlet and connection to rear or side panel of the machine.<br><br>2./3. Call BioMed or Bovie® Medical Corporation Technical Services at 1.800.537.2790 or +1.727.384.2323.<br><br>4. Replace filter with a genuine Bovie® SF35 filter. |

# Customer Service
# Section 4.0

## 4.1 Equipment Return

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

Step 1: Write down model and the serial number of the Smoke Shark II Smoke Evacuation System.

Step 2: Call Customer Service at the toll free or local number listed and describe the problem.

Step 3: If the problem cannot be resolved over the phone and the equipment must be returned for repair, you must obtain a "Return Goods Authorization" (RGA) number from Customer Service before returning the system.

Step 4: If you have the original packing for your Smoke Shark II Smoke Evacuation System, use it to properly return your unit. If you do not have the original packing material, ask Customer Service for advice on how to pack the unit for return shipment.

Step 5: Freight for all returned goods should be prepaid by the shipper. Address will be supplied by Customer Service.

## 4.2 Ordering Information

To reorder, obtain replacement parts or to return a unit for service, call Customer Service at:

**Call Us At:**
**800.537.2790**
**Or**
**+1.727.384.2323**
**Or Visit:**
**www.boviemed.com**
or contact your authorized Bovie® Distributor/Representative

Bovie® Smoke Shark II Smoke Evacuation System versions available:
- 100/120 VAC 50-60 Hz
- 220/240 VAC 50-60 Hz

Available accessories:
- Bovie® SF35 Filters
- Suction Canister
- Remote Activation Device
- Hoses & Tubing
- Reducer Fittings
- Electrosurgical Pencil Adapters
- Electrosurgical Smoke Pencil

# Terms & Warranty
# Section 5.0

**SPECIFICATIONS:**

Specifications are subject to change without notice.

**SHIPMENT OF ORDER:**

Bovie Medical Corporation will try to accommodate individual customer requests for shipping method. Bovie® 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. Bovie®'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. Bovie® will assist customers in pursuing these claims.

**RETURN OF MATERIAL:**

Return merchandise must have a pre-authorized return number from Bovie® and be marked with this number prior to returning. Transportation costs must be prepaid by the shipper and all risks 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 on new, unused, unopened equipment or disposables.

**EXCEPTIONS:**

1. Defective merchandise may be returned for replacement only. Please contact Bovie® Customer Service before shipping back merchandise.
2. Incorrectly shipped merchandise is exempt from restocking fees. Please contact Bovie® customer service before shipping back merchandise.

**WARRANTY*:**

Bovie® warrants that the filter system manufactured by Bovie® shall be free from defects in material and workmanship. Products are warranted only to the extent that Bovie® will replace without charge any filter systems proved to have defects within two (2) years of the date of delivery for the system and provided Bovie® has been given the opportunity to inspect the system 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 Bovie® 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.

**CONSEQUENTIAL DAMAGES/LIMITS OF LIABILITY:**

Bovie® shall not in any case whatsoever be liable for special, incidental, indirect or consequential damages of any kind. In no case shall Bovie®'s liability exceed the amount paid Bovie® by purchaser for the specific system giving rise to the liability. Purchaser agrees to indemnify and hold Bovie® harmless from and against all liabilities, claims, and demands of third parties of any kind relating to the system and its use.



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