# **FUMOVAC 700**

Surgical Smoke Evacuator

# **Operator's Manual**

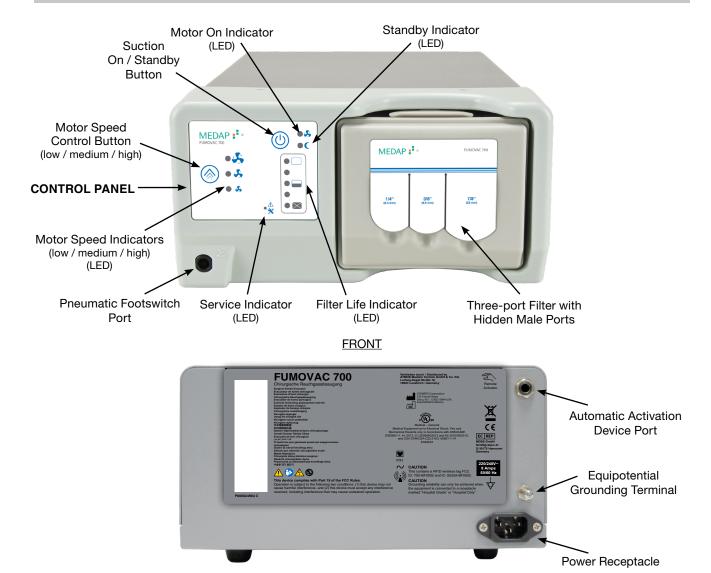




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## **DIAGRAM / CONTENTS**



**REAR** 

Figure 1



Name	Description		
AMP	Ampere, unit of electric current		
Automatic Activation Device	Device used to remotely operate the Surgical Smoke Evacuator to control the suction on/standby modes in conjunction with ESU activation saving filter life. (sold separately)		
CISPR	International Special Committee on Radio Interference		
EMC	Electromagnetic Compactibility		
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 which serves for connection to a grounding conductor. Devices and equipment which are to benefit from this safety feature must have an appropriate three-prong plug which is inserted into this outlet. There are other possible arrangements for such outlets, including the use of lateral grounding contacts which 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 which emits light when activated.		
Pneumatic Footswitch	Device used to remotely operate the Surgical Smoke Evacuator to control suction on/standby modes		
Power Cord	A cable used to connect the Surgical Smoke Evacuator to a grounded electrical outlet.		
RF	A frequency or band of frequencies in the range 10 <sup>4</sup> to 10 <sup>11</sup> or 10 <sup>12</sup> Hz, suitable for use in telecommunications.		
Suction On/Standby Button	Button to shift between two modes of suction control: on and standby.		
Surgical Smoke Evacuator	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		

#### 1.1 Introduction

The 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, and ultrasonic devices).

The Surgical Smoke Evacuator has been designed to provide appropriate suctioning using one of three motor speeds to manage surgical smoke. 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 .1 to .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 Surgical Smoke Evacuator was thoroughly tested and inspected prior to shipment. Please inspect the Surgical Smoke Evacuator before using to ensure all items included have been received and that no damage occurred during transit. If items are missing or damage is evident, please contact Customer Service.

## Items Included:

- Operator's Manual
- Filter
- Power Cord
- Pneumatic Footswitch

## 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 Surgical Smoke Evacuators comply with IEC 60601-1 electrical specifications.
- 2. Type of protection against electrical shock: Class I
- 3. Degree of protection against electric shock: Type CF Applied Part
- 4. Degree of protection against ingress of water: IPX1
- 5. Method of sterilization or disinfection recommended:
  - Unplug Surgical Smoke Evacuator. Wipe 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: Not Suitable
- 7. Mode of operation: Continuous

8. Upon request, the following will be provided:

Service and Repair Instructions, including Circuit Diagrams and Parts List

9. The fuses on the circuit board are to be serviced by an authorized technician. Please call Technical Services.

100/120 VAC, 50/60 Hz use 10 AMP 250 Volt Fuse (Slo-Blo), (F1, F2) 220/240 VAC, 50/60 Hz use 8 AMP 250 Volt Fuse (Slo-Blo), (F1, F2)

- 10. The Surgical Smoke Evacuator requires special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed according to EMC information found in this manual.
- 11. The Surgical Smoke Evacuator utilizes mobile Radio Frequency (RF) communications equipment that can affect medical electrical equipment.
- 12. The Surgical Smoke Evacuator 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 Surgical Smoke Evacuator is operated in a commercial environment. The Surgical Smoke Evacuator 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 the Surgical Smoke Evacuator 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.

The Surgical Smoke Evacuator 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

- 13. To isolate the Surgical Smoke Evacuator from supply mains, unplug the Power Cord from the power receptacle on the Surgical Smoke Evacuator or receptacle in the wall. Position the equipment to allow for ease of unplugging Power Cord.
- 14. Potential Equalization Conductor: Terminal located on back panel for connection of potential equalization. Conductor complies with requirements per IEC 60601-1.
- 15. The Surgical Smoke Evacuator and all Filters are not intended for contact with patients.
- In Europe, the Smoke Evacuator is a Short Range Device, RF Class I, per Commission Decision 2006/177/EC with no restrictions. This product operates at 13.56 MHz with an H-field strength of -4.61dBμA/m at 10m.

## 1.4 Cautions and Warnings

All Cautions and Warnings should be read and understood before using the Surgical Smoke Evacuator.

Attention: Consult Instructions Before Use.

# **1.4.1 WARNINGS:**

The warranty on the 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 Surgical Smoke Evacuator.
- Confirm operational set-up of the Surgical Smoke Evacuator prior to a surgical procedure.
- Disconnect the Surgical Smoke Evacuator from the grounded electrical outlet prior to inspecting Surgical Smoke Evacuator components.
- The Surgical Smoke Evacuator is only intended and suitable for the applications mentioned in the operating instructions.
- The Surgical Smoke Evacuator produces a strong vacuum, therefore, check the Motor Speed Indicator setting before activating. Adjust the motor speed and the position of 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.
- Route Pneumatic Footswitch and any other attached accessories to prevent a tripping hazard or crimping of cords, which could cause unreliable operation.
- Do not operate the Surgical Smoke Evacuator in the presence of flammable or explosive gases.
- The Surgical Smoke Evacuator is intended for use by healthcare professionals only.
- The 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 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 Surgical Smoke Evacuator.
- If adjacent or stacked use is necessary, the Surgical Smoke Evacuator should be observed to verify normal operation.
- Refer routine servicing to qualified facility biomedical technical personnel.
- Changes or modifications not expressly approved by the manufacturer could void the warranty.
- To avoid risk of electric shock, this equipment must only be connected to a supply mains with a grounded electrical outlet.

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- United States Federal Law restricts the 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 Surgical Smoke Evacuator to be inoperable voiding the warranty.
- Care must be exercised in the installation of tubing, adapters, and fluid collection devices. Failure to
  follow the procedures outlined in this manual may result in overheating of the motor and may void the
  warranty.
- The Surgical Smoke Evacuator is not intended for evacuation of fluid. If fluid is expected to be aspirated, a fluid collection device must be installed onto the Filter. Failure to install a fluid collection device could cause Filter blockage and electrical damage.
- 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.
- Do not block either the tubing or the Filter during operation. An occlusion or significant restriction may cause the motor to overheat and the Surgical Smoke Evacuator to stop working.
- Installation of the Surgical Smoke Evacuator 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 Surgical
  Smoke Evacuator may cause reduced performance, damage, and/or cause the 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 must be kept between 700 hPa to 1,060 hPa.
- Storage environmental ambient temperature should be kept between 14°F to140°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 Surgical Smoke Evacuator. Refer routine servicing to qualified facility biomedical technical personnel or technical services.
- Use only with the Power Cord provided and always plug into a grounded electrical outlet.
- European Commission requires that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Symbol	Description / Meaning
A	DANGER HIGH VOLTAGE CAUTION - ELECTRICAL SHOCK HAZARD. DO NOT REMOVE COVER. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL.
	DANGER CAUTION - RISK OF EXPLOSION IF USED IN THE PRESENCE OF FLAMMABLE ANESTHETICS.
<u>^</u>	WARNING
	CAUTION
	TYPE CF APPLIED PART
IPX1	PROTECTION AGAINST INGRESS OF WATER AS DETAILED IN IEC 60529
~	ALTERNATING CURRENT
	PROTECTIVE EARTH, (GROUND)
A	EQUIPOTENTIALITY
	DENOTES THE DATE THE EQUIPMENT WAS MANUFACTURED
	DENOTES THE MANUFACTURER OF THE DEVICE
(( <u>(·)</u> ))	NON-IONIZING RADIATION
	CONSULT INSTRUCTIONS
2	REMOTE ACTIVATOR
X	WEEE SYMBOL

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

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

## **POWER ON/OFF**

To power on the Surgical Smoke Evacuator, connect the supplied Power Cord to a grounded electrical outlet and the power receptacle at the rear of the Surgical Smoke Evacuator. Once power has been applied, the Standby LED illuminates the color yellow. Turn the Surgical Smoke Evacuator main power off, by unplugging the Power Cord from the power receptacle on the 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 and the Standby LED illuminates the color yellow.

## MOTOR SPEED CONTROL

Press the Motor Speed Control Button to adjust between three (3) motor speed settings: low / medium / high. The motor speed should be set at the lowest practical setting to effectively remove the surgical smoke from the operative site.

## 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 and will automatically adjust according to the motor speed setting selected.

Low (motor speed setting) = up to 35 hours of Filter Life Medium (motor speed setting) = up to 24 hours of Filter Life High (motor speed setting) = up to 18 hours of Filter Life

Install an unused Filter into the Surgical Smoke Evacuator as per the installation instructions. 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 green LEDs to a yellow LED as time elapses and begin flashing RED to indicate the Filter has expired and requires replacement.

When the maximum Filter life has expired and the Surgical Smoke Evacuator is not powered off for greater than six (6) hours or if the main power is disconnected, a new Filter is required to activate the Surgical Smoke Evacuator and make operational.

## PNEUMATIC FOOTSWITCH PORT

The Surgical Smoke Evacuator is equipped with a Pneumatic Footswitch as an alternative method to using the Suction On/Standby Button. The Pneumatic Footswitch may be inserted by plugging it into the Pneumatic Footswitch Port located on the front of the Surgical Smoke Evacuator. The Pneumatic Footswitch may be controlled by depressing the footswitch pedal to shift between the Suction On and Standby modes.

#### **AUTOMATIC ACTIVATION DEVICE PORT**

The Automatic Activation Device (sold separately) may also be installed by plugging it into the Automatic Activation Device port located on the rear of the Surgical Smoke Evacuator. For directions on using the Automatic Activation Device, please see instructions that accompany that product.

## 2.2 Set-Up and Operation

- 1. Attach Power Cord to the power receptacle on rear of the Surgical Smoke Evacuator and into a grounded electrical outlet.
- 2. Route Power Cord to prevent a tripping hazard or crimping of cords, which could cause unreliable operation or electric shock.
- 3. Install the Filter (see Filter installation instructions).
- 4. Insert Pneumatic Footswitch plug into Pneumatic Footswitch located on the front of the Surgical Smoke Evacuator.
- 5. Ensure that any smoke evacuation capture accessory is fully installed in the Filter port.
- 6. Route Pneumatic Footswitch and any other attached accessories to prevent a tripping hazard or crimping of cords, which could cause unreliable operation.
- 7. Activate the Surgical Smoke Evacuator by:
  - Pressing the Suction On/Standby Button on the Control Panel Depressing and releasing the Pneumatic Footswitch (if connected)
- 8. Adjust the suction level to the desired setting by pressing the Motor Speed Control Button while the Surgical Smoke Evacuator is activated. Noise created by the Surgical Smoke Evacuator may be minimized by selecting the lowest vacuum setting that effectively clears the operative field of surgical smoke.
- 9. Deactivate the Surgical Smoke Evacuator by:
  - Pressing the Suction On/Standby Button on the Control Panel Depressing and releasing the Pneumatic Footswitch (if connected)
- 10. Replace the Filter when the Filter Life Indicator flashes red (0% life remaining). Failure to change the Filter will affect the performance of the Surgical Smoke Evacuator.

### 2.3 Filter Instructions

### Filter Installation Instructions:

Note: Before installing or removing any Filter, be sure that the 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 Filter for damage which may have occurred during shipping and storage. Do not install any Filter with visible signs of structural damage.
- 3. Insert Filter into Filter chamber and ensure Filter is installed completely against the bottom of the Filter chamber and Filter clip is fully engaged.

#### **Filter Removal Instructions:**

- 1. After the Filter life has expired, turn the Surgical Smoke Evacuator to the Standby mode by pressing the Suction On/Standby Button.
- 2. Remove all accessories attached to the Filter.
- 3. Depress the Filter clip and remove the Filter from the Surgical Smoke Evacuator. Dispose according to your local codes or regulations and facility policy.
- 4. Clean the Surgical Smoke Evacuator with appropriate germicide prior to re-use and follow the indicated instructions for maintenance and installation of a new Filter.

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## 2.4 Performance References\*

Performance			
Model Name / Description			FUMOVAC Surgical Smoke Evacuator
Maximum Flow Setting (CFM-U.S.)***			
Standard Hose I.D.			
		7/8"	25 CFM **
		3/8"	4.5 CFM
		1/4"	2 CFM
Standard Hose I.D.			
		22 mm	708 LPM **
		9.5 mm	130 LPM
		6.4 mm	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		12.0
Weight	kg		5.0
Noise Level, dBA	maximum		55.0 dBA
Voltage Available			100/120 VAC, 220/240 VAC
Frequency, auto sensed			50/60 Hz

<sup>\*</sup>For reference purposes only

<sup>\*\*</sup>Using a new 7/8 in (22 mm) tubing.

<sup>\*\*\*</sup>Model 57525422 provides a minimum of 18.4 CFM (521 LPM) flow with a 22 mm tube at sea level

## 2.5 Electromagnetic Compatibility Information per IEC 60601-1-2

## Table 1

Guidance and Manufacturer's Declaration - Electromagnetic Emissions			
The Surgical Smoke Evacuator is intended for use in the electromagnetic environment specified below. The customer or user of the Surgical Smoke Evacuator should ensure that it is used in such an environment.			
Emissions Test	Compliance	Electromagnetic Environment - Guidance	
RF Emissions CISPR 11	Group 1	The Surgical Smoke Evacuator 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 Surgical Smoke Evacuator 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	Class A	Not applicable.	
IEC 61000-3-3			

## Table 2

# Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The Surgical Smoke Evacuator is intended for use in the electromagnetic environment specified below.

The customer or user of the Surgical Smoke Evacuator should ensure that it is used in such an environment.

	IEC 60601		d ensure that it is used in such an environment.
Immunity Test	Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electromagnetic discharge (ESD)	±8 kV contact ±15 kV air	±8 kV contact ±15 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%.
IEC 61000-4-2	011/6	01116	
Electrical fast transient/burst	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-4	±1 kV for input/ output lines	±1 kV for input/ output lines	
Surge	±1 kV differential mode	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-5	±2 kV common mode	±2 kV common mode	
Voltage dips, short interruptions, and voltage variations	0 % U <sub>T</sub> for 0.5 cycle	0 % U <sub>T</sub> for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment.  If the user of the Surgical Smoke Evacuator
on power supply input lines.	At 0°, 45°, 90°, 135°, 180°, 225°,	At 0°, 45°, 90°, 135°, 180°, 225°,	requires continued operation during power main interruptions, it is recommended the Surgical Smoke Evacuator be powered from
IEC 61000-4-11	270°, and 315°	270°, and 315°	an uniterruptible power supply or a battery.
	0 % U <sub>τ</sub> for 1 cycle	0 % U <sub>⊤</sub> for 1 cycle	
	70 % U <sub>T</sub> for 25/30 cycles	70 % U <sub>T</sub> for 25/30 cycles	
	Single phase: at 0°	Single phase: at 0°	
	0° at U <sub>T</sub> : 250/300 cycles	0° at U <sub>τ</sub> : 250/300 cycles	
Power frequency (50/60 Hz) magnetic field	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
IEC 61000-4-8			

## Table 3

## Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The Surgical Smoke Evacuator is intended for use in the electromagnetic environment specified below.

The customer or user of the Surgical Smoke Evacuator should ensure that it is used in such an environment.

Immunity Toot	IEC 60601	Compliance Level	Electromognetic Environment Cuidenes
Immunity Test	Test Level	Levei	Portable and mobile RF communications equipment should be used no closer to any part of the Surgical Smoke Evacuator including cables, than 30 cm (12 in).
Radiated RF	3 V/m		
IEC 61000-4-3	80 MHz to 2.7 GHz	3 V/m	
	80% AM at 1kHz	3 Vrms	
Conducted RF IEC 61000-4-6	3 Vrms 0.15MHz - 80MHz 6 Vrms in ISM		Field strength from fixed RF transmitters, as
bands between 0.15MHz and 80 MHz			determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.
	80% AM at 1 kHz		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 Surgical Smoke Evacuator is used exceeds the applicable RF compliance level above, the Surgical Smoke Evacuator should be observed to verify normal operation.

If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Surgical Smoke Evacuator.

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**MAINTENANCE: SECTION 3.0** 

## 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 Surgical Smoke Evacuator.
- Wipe Surgical Smoke Evacuator with a damp cloth containing mild disinfectant solution or soapy water.
- Wipe Surgical Smoke Evacuator with a dry clean cloth.
- Do not steam sterilize.

## 3.3 Periodic Inspection

The Surgical Smoke Evacuator should be visually inspected at least every year. The inspection should include checks for:

- Damage to the Power Cord or Power Inlet Module.
- Obvious external or internal damage to the Surgical Smoke Evacuator and Filter.

## **FUSES (Circuit Board)**

Two 10 AMP fuses for 100/120 Surgical Smoke Evacuators or two 8 AMP fuses for 220/240 Surgical Smoke Evacuators are located on the circuit board within the housing of the system. The fuses electrically protect both the Surgical Smoke Evacuator and the operator from damage or injury. If the Surgical Smoke Evacuator is overheated or if there is an electrical surge, fuses will break and the Surgical Smoke Evacuator will not operate. When the Service LED Light Indicator illuminates, please contact Customer/Technical Services.

## 3.4 Troubleshooting

PROBLEM	POTENTIAL CAUSE	CORRECTIVE ACTION
Surgical Smoke     Evacuator is on	Filter is not seated completely.	Re-install Filter, press firmly into place and fully engage clip.
but suction is minimal or none.	2. Filter is clogged.	2. Replace Filter with the manufacturer's Filter.
	Vacuum tubing is clogged.	3. Replace vacuum tubing with manufacturer's products.
	Motor/blower is obstructed.	Call facility BioMed Department or manufacturer's     Technical Services.
2. Surgical Smoke Evacuator does not function even though On/ Standby Button is depressed.	Not plugged into an electrical outlet.	Check the grounded electrical outlet connection and the power receptacle located at the rear of the Surgical Smoke Evacuator.
	2. Fuses are blown.	Call facility BioMed Department or manufacturer's     Technical Services.
	Electronic Surgical     Smoke Evacuator failure.	Call facility BioMed Department or manufacturer's     Technical Services.
	Filter Life has expired or invalid Filter installed.	4. Replace Filter.

Report serious incidents involving this device to CONMED at customerexperience@conmed.com or to your local distributor.

## **CUSTOMER SERVICE: SECTION 4.0**

## 4.1 Product Return

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

- Step 1: Write down Surgical Smoke Evacuator model name and serial number.
- Step 2: Call Customer Service and describe problem.
- **Step 3**: If the problem cannot be resolved over the phone and the Surgical Smoke Evacuator must be returned for repair, a Return Material Authorization (RMA) number must be obtained from Customer Service before returning the Surgical Smoke Evacuator.
- Step 4: Use the original packaging material to return your 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 shipper. A ship to address will be supplied by Customer Service.

## 4.2 Ordering Information

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

Available accessories:

- Replacement Filters
- Fluid Trap
- Automatic Activation Device
- Tubing
- Reducer Fittings
- Electrosurgical Surgical Smoke Pencils & Adapters

## **TERMS & WARRANTY: SECTION 5.0**

## 5.1 Terms & Warranty

## **SPECIFICATIONS**

Specifications are subject to change without notice.

### SHIPMENT OF ORDER

**ATMOS** will try to accommodate individual customer requests for shipping method. **ATMOS** 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.

**ATMOS'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. **ATMOS** will assist customers in pursuing these claims.

## **RETURN OF MATERIAL**

All returned merchandise must have a pre-authorized Return Material Authorization (RMA) from **ATMOS** and be marked with the 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 ATMOS Customer Service before shipping back merchandise.
- Incorrectly shipped merchandise is exempt from restocking fees. Please contact ATMOS Customer Service before shipping back merchandise.

## **WARRANTY**

**ATMOS** warrants that the Surgical Smoke Evacuator manufactured by **ATMOS** shall be free from defects in material and workmanship. Products are warranted only to the extent that **ATMOS** will replace without charge any Surgical Smoke Evacuator proven to have defects within one (1) year of the date of delivery of Surgical Smoke Evacuator and provided **ATMOS** 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 **ATMOS** 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.

#### CONFIDENTIAL INFORMATION

The information, drawings, plans, and specifications being furnished by **ATMOS** have been developed at **ATMOS's** expense and shall not be used or disclosed by purchaser for any purpose other than to install, operate, and maintain the Surgical Smoke Evacuator supplied.

## **TERMS & WARRANTY: SECTION 5.0**

## **CONSEQUENTIAL DAMAGES/LIMITS OF LIABILITY**

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

**ATMOS's** offer does acknowledge and agree to the terms and conditions contained herein. All matters involving the validity, interpretation and application of this agreement shall be controlled by the laws of New York State. Using any Filter not manufactured by **ATMOS** may cause damage to the systems and will be cause for voiding the warranty.

## **ENTIRE AGREEMENT**

Purchaser by acceptance of **ATMOS's** offer does acknowledge and agree to the terms and conditions contained herein. All matters involving the validity, interpretation and application of this agreement shall be controlled by the laws of New York State. Using any Filter not manufactured by **ATMOS** may cause damage to the Surgical Smoke Evacuator and will be cause for voiding the warranty.

#### **JURISDICTION**

Purchaser hereby consents to the jurisdiction of the New York Courts with respect to any controversy or dispute arising out of this agreement or the merchandise sold hereunder.

For a period of one (1) year following the date of delivery, **ATMOS**® warrants the FUMOVAC 700 Surgical Smoke Evacuator against any defects in material or workmanship. **ATMOS** will repair or replace (at **ATMOS**'s option) the same without charge, provided that routine maintenance as specified in this manual has been performed using replacement parts approved by **ATMOS**. This warranty is void if the product is used in a manner or for purposes other than intended.



# ATMOS MedizinTechnik GmbH & Co. KG 79853 Lenzkirch, Germany (www.atmosmed.com)

# Customer/Technical Services: 0049 7653 6890

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 P000038551 A 03/2022

Unit Serial Number \_\_\_\_\_







MEDICAL – GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH

ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012,

and CSA CAN/CSA-C22.2 NO. 60601-1:14

E349034

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.

This product operates at 13.56 MHz with an H-field strength of -4.61 dBµA/m at 10 m.

In Europe, the Smoke Evacuator is a Short Range Device, RF Class I, per Commission Decision 2006/177/EC with no restrictions. This product operates at 13.56 MHz with an H-field strength of -4.61 dB $\mu$ A/m at 10 m.

European Commission requires that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

