OPERATOR'S MANUAL

SURGIFRESH® PureVac™ TURBO

SAFETY PRECAUTIONS
This manual contains information that is important to your safety and preventing damage to your smoke evacuator

CAREFULLY READ THIS INSTRUCTION MANUAL
BEFORE ATTEMPTING TO OPERATE THIS SMOKE EVACUATOR

Model #	
Serial #	
Purchase Date	/ /

SMOKE EVACUATION SYSTEM

SAFETY PRECAUTIONS

This symbol is intended to alert the user to the presence of uninsulated "dangerous voltage" within the product's enclosure that may be of sufficient magnitude to constitute a risk of electric shock to persons.

This symbol is intended to alert the user to the presence of important operating and maintenance instructions in the literature accompanying the product.

Warning -- indicates that a condition may exist which could adversely affect the operator or patient.

Caution -- indicates that a condition may exist which could damage the smoke evacuation system.

This Owner's Manual and the equipment discussed herein are to be used only by qualified and properly trained medical personnel who are skilled in the particular technique and surgical procedure to be performed.

Notice: Federal (USA) law restricts this device to sale by or on the order of a physician.

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http://www.surgimedics.com

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WARNINGS

Warning: **To prevent electric shock**

- Do not connect a wet power cord to the wall receptacle.
- Do not expose to moisture.
- Do not use extension cords, adapter plugs, or a non-approved hospital grade grounded polarized receptacle. Be sure blades are fully inserted.
- Do not remove covers from the unit. The unit is non-serviceable. Refer to qualified service personnel.
- Unplug the unit from the wall receptacle before cleaning.
- Unplug the unit from the wall receptacle if it is not to be used for several days or more.
- To disconnect the power cord, pull it out by firmly grasping the plug, never pull the cord itself.

WARNINGS

Warning: The smoke evacuator produces a strong vacuum. Properly adjust the suction control and the position of the inlet end of the suction tubing or wand to prevent injury to the patient or inadvertent damage to surgical materials prior to turning power on.

Warning: Laser and electrosurgical plume are potentially hazardous. Used filters, tubing, and accessories should be handled according to your institution's procedures for biohazardous materials.

Warning: To prevent a fire and explosion hazard, do not use the unit in the presence of flammable or potentially flammable materials.

Warning: Some cannulas, valves, or other instruments combined with suction may cause rapid reduction of pneumoperitoneum in laparoscopic procedures.

CAUTION

Caution: Use the unit in a well-ventilated area.

Caution: Introduction of fluids greater than incidental (up to 50cc) into smoke filters may damage the filters and the smoke evacuation system.

Caution: An occlusion of the smoke evacuation system can overheat the unit.

INTRODUCTION

1.0 INTENDED USE

The SurgiFresh® PureVac™ Turbo Smoke Evacuation System is intended to be used to evacuate smoke created by electrosurgery, laser surgery, laparoscopic or power tool surgical procedures.

Do not use the SurgiFresh® PureVac™ Turbo for applications other than its intended use of this device.

Use only Surgimedics accessories with the SurgiFresh® PureVac™ Turbo. Use of non-Surgimedics disposables may void warranty.

Contact Surgimedics with questions concerning features, performance, intended use of this device, and to order Surgimedics accessories.

Distributed by: Surgimedics, a division of Coastal Life Systems, Inc.
7027 Fairgrounds Pkwy.
San Antonio, TX 78238 USA

800-645-7418

www.surgimedics.com

2.0 DESCRIPTION OF SYMBOLS

The following is a description of the symbols located on the SurgiFresh® PureVac™ Turbo

Caution, consult accompanying documents.

Consult instructions for use.

Not category AP equipment.
Danger, explosion risk if used in presence of flammable anesthetics.

Medical Electrical Equipment Classified with respect to electrical shock, fire and mechanical hazards only in accordance with UL 60601-1 and CAN/CSA-22.2 No. 601.1 61CB

OPERATING INSTRUCTIONS

1.0 FEATURES AND CONTROLS

Figure 1

a) Suction Control -- changes motor speed for increasing/decreasing normal suction.
b) Power On Light --indicates power switch is on and unit is powered or in footswitch standby mode.
c) Power Switch -- activates main unit electrical power.
d) Footswitch Connection -- tubing port for remote footswitch.
e) Filter Cartridge Brackets -- supports slide on disposable ULPA Clear™ (P/N 901301) filter cartridge.

Figure 2

a) Circuit Beakers – Double pole fused breakers for 120VAC input power.
b) Plug Connection -- female receptacle for 120V AC hospital grade power cord. (included)

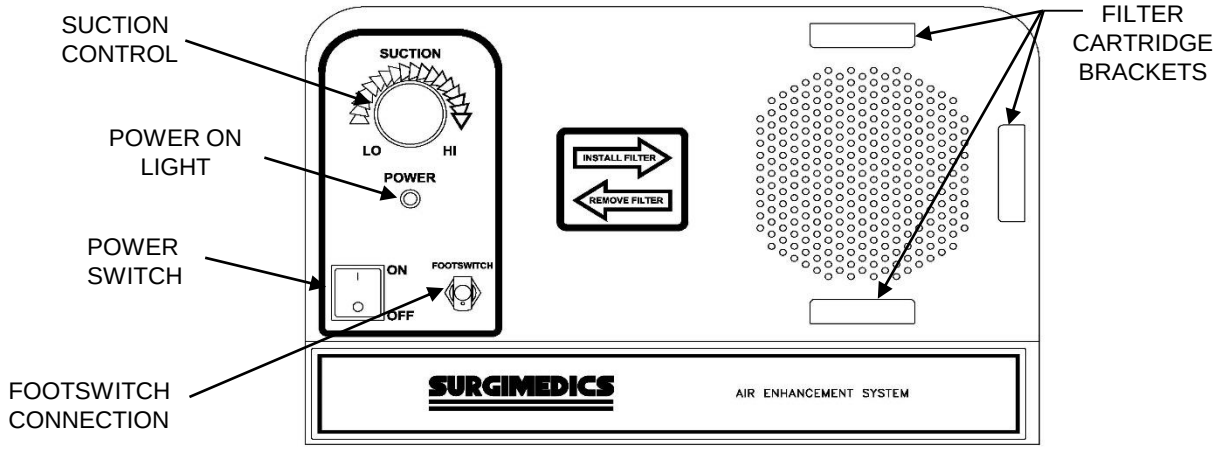

FIGURE 1

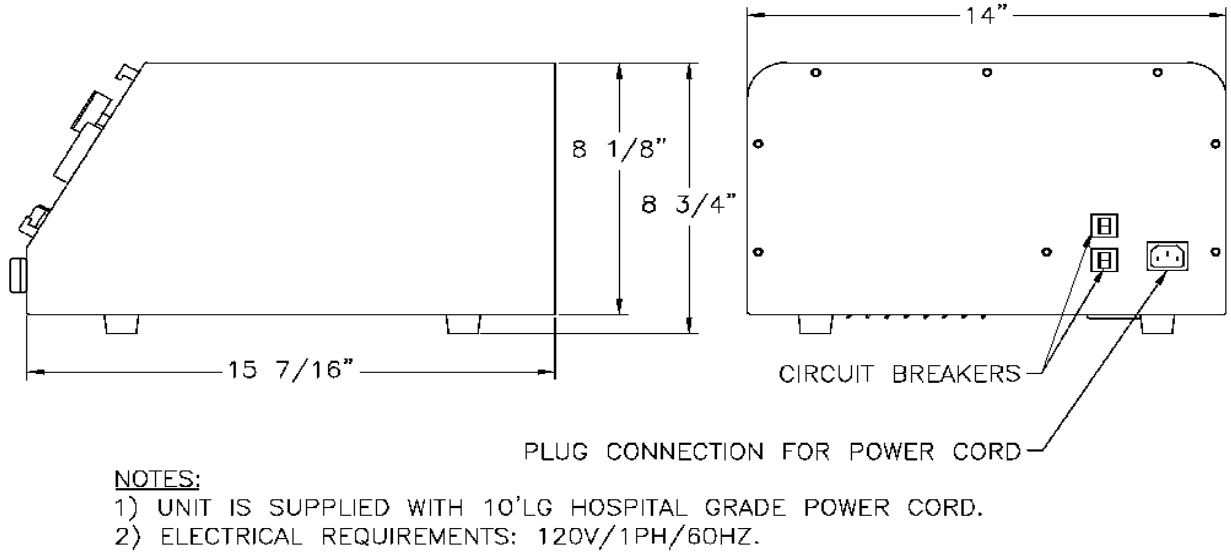

FIGURE 2

OPERATING INSTRUCTIONS

2.0 SYSTEM SET-UP

2.1 Installation

The SurgiFresh® PureVac™ Turbo with manual, pneumatic footswitch and hospital grade power cord will arrive in a single carton. Inspect the carton and the product for any scratches, dents or damage which may have occurred during shipment. If any damage is noted, follow the instructions per the Warranty section.
All smoke evacuation disposables and accessories will be shipped separately. The same shipping damage instructions apply to these items.

After removal from the carton, the SurgiFresh® PureVac™ Turbo is set up as follows:

Note: Save carton and packing for future use.

1. Place the unit on a cart or counter near the procedure site. Do not obstruct vents located on the bottom and rear of the unit.

2. Connect the footswitch tube to the front tubing port on the smoke evacuator. If the footswitch is not desired for use, make sure the unit is running when the footswitch is disconnected.

3. Install an ULPA-Clear™ cartridge filter (P/N 901301) onto the front of the unit by sliding from left to right into the filter brackets. Remove the cartridge tubing connection plug and retain for cartridge disposal.

   Caution: Make sure the filter is firmly in place under all three brackets.

   Note: Mark time used sticker on cartridge after each 10 minutes of use up to 1 hour.

4. Connect the power cord to the back of the unit and connect to an appropriate electrical receptacle.

5. Select the appropriate tubing and accessories, and prepare the unit for use as described in Section 2.2

   Warning: Sterile tubing should be handled using your institution's sterile procedures.

2.2 Typical Setup Instructions

1. **<u>FOR ALL PROCEDURES</u>**

   a. Ensure an ULPA-Clear™ cartridge filter is installed per 2.1.
   b. Connect the 7/8” tubing appropriate for the procedure to the ULPA-Clear™ cartridge filter by pushing tubing with a twisting motion securely over filter connection port.
   c. Install accessories that are applicable for the procedure.

OPERATING INSTRUCTIONS

2.3 Operative Use

Warning: The smoke evacuator produces a strong vacuum. Properly adjust the suction control and the position of the inlet end of the suction tubing or wand to prevent injury to patient or inadvertent damage to surgical materials.

Warning: Some cannulas, valves, or other instruments combined with suction may cause rapid reduction of pneumoperitoneum in laparoscopic procedures.

Caution: Ensure a sponge guard is attached to prevent surgical materials or tissue from being aspirated / pulled into the tubing.

1. Move the SurgiFresh® PureVac™ Turbo into position near the procedure area.
2. Attach tubing per the instructions in Section 2.2.
3. Push the Power switch on the front panel to the 'ON' position. **Note:** If the unit was turned off with the footswitch, it will be in standby mode with the Power turned on and the indicator light lit, use the footswitch to turn the unit on.
4. Adjust the Suction Control Knob to full flow (Turbo) to seat the filter and then back to the desired level for the procedure. Verify adequate air flow is set by inquiring with the surgeon. Adjust as necessary with the motor speed control knob. Turning the knob clockwise increases the air flow; turning counter-clockwise decreases the air flow. Turn the unit off until ready to use.
5. The footswitch may be pressed by personnel in the operative area to start and stop the suction as needed during the procedure.
6. Recover the footswitch and electrical cord when the procedure is finished.
7. The following procedure reduces odor from escaping the ULPA filter. After completing each procedure, set the unit speed to the lowest level, and remove the suction tubing, and wand (if applicable). These items should be handled/discarded according to hospital procedures for bio-hazardous materials.
8. Turn the unit on with the footswitch.
9. Replace the cartridge tubing connection plug, turn the unit off with the power switch and remove the ULPA-Clear™ filter cartridge by sliding to the left. This item should be retained for same day procedures up to one hour of use or handled/discarded according to hospital procedures for bio-hazardous materials.

Warning: Follow instructions and procedures for biohazardous materials recommended by your institution.
Follow cleanup instructions per Section 2.5.

2.4 Maximizing Use Suggestions

1. Air flow
   a. The distance of the tubing from the plume source affects capture and removal of the plume. The tubing end should be within several inches of the procedure site.
   b. The larger the tubing, the better the air flow and removal of plume. Do not occlude tubing.

2. Noise
   a. Lower speed equals less noise.
   b. Larger tubing equals less noise. Do not occlude tubing.
   c. Use the footswitch to turn the suction on and off as it is needed during the procedure.

3. Fluids
   a. The ULPA-Clear™ cartridge filter has a built in 50 cc fluid trap. It is designed to protect the filter from small incidental fluid suction. Do not use as a primary fluid suction device.

OPERATING INSTRUCTIONS

b. Do not reuse the ULPA-Clear™ Turbo cartridge filter if it has been contaminated by fluids.
c. The SurgiFresh® PureVac™ Turbo should not be used as a primary fluid suction system.

4. Tubing
   a. Check throughout the procedure to be sure tubing is not occluded.

2.5 Clean-Up

After each procedure, the SurgiFresh® PureVac™ Turbo smoke evacuation system should be cleaned and prepared for subsequent activity.

1. Disconnect and discard all disposable accessories and tubing sets.
2. Turn off the power switch and unplug the unit from the wall receptacle.
3. Wipe the footswitch and footswitch cord with an appropriate hospital disinfectant. Coil the footswitch cord and store with the unit.
4. Wipe the power cord with an appropriate hospital disinfectant. Coil the power cord and store with the unit.
5. Thoroughly wipe all external surfaces of the SurgiFresh® PureVac™ Turbo with an appropriate hospital disinfectant. Follow the procedures approved by your institution.

Warning: Ensure the unit is completely dry before restoring power.

MAINTENANCE

3.0 ROUTINE MAINTENANCE

3.1 Power Cord

1. Prior to each use, check the power cord along its entire length and at both plugs to ensure no damage has occurred.
2. Do not use a power cord with exposed wires, cracks, or frayed areas.
3. Check the footswitch tubing for damage prior to each use.

CUSTOMER SERVICE

4.0 Customer Service:

4.1 Parts and Accessories: Surgimedics
7027 Fairgrounds Pkwy.
San Antonio, TX 78238 USA
Phone: 800-645-7418

Customer Service Department:

1. If a problem is experienced, first review the troubleshooting section of this manual. For troubleshooting support, please contact Surgimedics Customer Service (800) 645-7418.
2. In the event your unit needs service or repair, do not attempt to repair, please contact Surgimedics Customer Service for assistance.

TROUBLESHOOTING

5.0 TROUBLESHOOTING

5.1 General

If the SurgiFresh® PureVac™ Turbo smoke evacuation system is not functioning properly, review the items in this section for assistance.

1. Inspect the unit for visible signs of physical damage.
2. Verify all tubing and cords are connected properly.
3. Verify that the power cord has no exposed wires.
4. Ensure a filter cartridge is securely seated.
5. Check to see if the power cord is plugged into the an appropriate electrical receptacle at the wall.
6. Check to see if the power switch is turned on.
7. Check to see if footswitch is functioning properly.

5.2 Specific Conditions

If the solution is not readily apparent, these items may be of assistance:

Condition	Causes	Correction
Smoke evacuator does not operate when you turn on the power switch.	1. Disconnected or faulty power cord.	1. Check and correct power cord connections. Check cord for damage and replace as needed.
	2. No power from electrical receptacle.	2. Connect power cord to functional electrical receptacle.
	3. Unit is in footswitch standby mode, unit was turned off with footswitch and no footswitch is installed.	3. Install footswitch and use footswitch to turn unit on.
	4. Circuit breaker needs to be reset.	4. Press the circuit breaker switch on the rear panel to reset the circuit breaker.
No suction when footswitch is depressed.	1. Improperly connected footswitch.	1. Check and correct footswitch cord connection.
	2. Damaged footswitch.	2. Check footswitch cord for damage and replace as needed.
	3. Kink in footswitch cord.	3. Straighten kinked section of cord
Smoke evacuator is operating but there is inadequate or no vacuum.	1. Improperly installed filter.	1. Turn the smoke evacuator off (O). Ensure filter cartridge is seated properly.
	2. Clogged or kinked tubing.	2. Unclog or replace tubing.
	3. Clogged filter cartridge.	3. Replace filter.
	4. Obstructed or malfunctioning motor and/or blower.	5. Refer to your Bio-Engineering Dept. or Surgimedics Service.
System does not adsorb Smoke.		
Odors.	1. The charcoal component of the ULPA filter has expired.	1. Replace the filter cartridge.
Noise/Whining.	1. Poorly seated filter cartridge.	1. Check bottom of filter cartridge for condition of seal. Seat filter cartridge by sliding completely to the right and turning unit to full and back to desired flow..
	2. Variation in line voltage.	2. Position motor speed control knob slightly lower than maximum to ensure controlled constant speed even with slight line voltage fluctuations.
	3. Motor brushes worn.	3. Return to Surgimedics for service.

SPECIFICATIONS

6.0 TECHNICAL SPECIFICATIONS

All specifications are nominal and subject to change without notice.

ULPA-Clear™ cartridge filter (P/N 901301)

50 cc fluid trap
0.1 micron particulate size at 99.9995% efficiency
activated charcoal for gas and odor adsorption.

Tubing Diameter vs. Flow Rate

Tubing Inside Diameter	Flow Rate*
7/8”	30 cfm
3/8”	6 cfm
1/4"	4 cfm

* Nominal Values. Air flow tested at 120 VAC in a controlled environment with a digital anemometer.

Maximum Static Suction

92 inches H_20 (172mm Hg) suction pressure motor fan rating (sealed)

Safety

Circuit breakers: 8 amps / ea

Power cord: 10 ft x 3 - prong hospital grade plug

Leakage Current: 300µA max.

Power

Input mains voltage : 120VAC

Mains frequency (nominal): 60 Hz

Mains current: 6.5 amps maximum during normal operation

Physical Characteristics

Height: 8 3/4 inches (22.2 cm)
Depth: 15 1/2 inches (39.4 cm)
Width: 14 inches (35.6 cm)
Weight: 15.75 pounds (7.14 kg) without filter

7.0 TRANSPORT AND STORAGE

Ambient temperature range –40°F to 158°F (-40°C to 70°C)
Relative Humidity: <75%, noncondensing
Use original packaging materials when shiping or transporting via carrier

WARRANTY

Warranty Limitations

Surgimedics makes no express guarantees, warranties, or other representations as to its products, other than those appearing in its written form in its own trade literature or written proposals. **Surgimedics expressly disclaims the implied warranties of merchantability, fitness for a particular purpose, and noninfringement in relation to any of its products. In no event shall Surgimedics be liable to the purchaser of any product for consequential, incidental, or special damages irrespective of whether such damages are alleged to arise in tort, contract, law, equity, or by statute.** The above provisions relating to the exclusion of consequential, incidental, and special damages shall survive and remain in force notwithstanding a finding by a court of competent jurisdiction that the exclusive remedy provided below to a product purchaser has failed of its essential purpose.

For a period of one year, Surgimedics will repair or replace, at its option, any product, or part thereof, that fails because of a material or manufacturing defect; provided that (1) the defect is not caused by the purchaser or its customer, (2) the product was not custom manufactured to the specifications of the purchaser, and (3) the product has not been damaged, altered, or defaced. This limited warranty shall be the sole and exclusive remedy of the purchaser, irrespective of whether the claims of purchaser are made in contract, tort, warranty, law, equity, or by statute. In the event that a court of competent jurisdiction determines that the exclusive remedy set forth above has failed of its essential purpose, such a failure shall entitle the purchaser to a return of the purchase price of the product involved.

Shipping Damage

Title and risk of loss will pass to purchaser upon delivery at the (Ex-Works) point. Delivery shall be (Ex-Works San Antonio, Texas). Surgimedics will, as an accommodation to purchaser unless otherwise directed in writing, ship product to purchaser at its address, freight prepaid and insured at purchasers risk and expense. Purchaser should (1) inspect all packaging for external damage, (2) report the same to the carrier, (3) obtain an inspection report from the carrier within 15 days, and (4) file a claim with the carrier.

Returned Goods Policy

A request for return authorization must be submitted to Surgimedics Customer Service Department prior to the return of any product. The request for return authorization must include the product catalog number, product lot number, quantity, and specific reason for the return. No product may be returned after 90 days from the original date of purchase, unless defective.

Where a return of any product is authorized, Surgimedics will provide a return authorization number and a Certificate of Cleanliness to be completed by customer. Each shipping container must be marked with the return authorization number on the outside of shipping box, as well as a completed Certificate of Cleanliness, or it will not be accepted. All product must be returned freight prepaid except returns due to our shipping error, material or manufacturing defects, or damage during shipment that renders the product unsalvageable upon receipt. Unsalvageable product must be returned via the original carrier.

Credit may be issued to the original purchaser for authorized returns of salable, unused product in unopened boxes in Surgimedics current catalog, subject to a 35% restocking fee. Surgimedics Quality Assurance Department will inspect returned product to determine whether it is in salable condition. Credit, including transportation costs, will be issued to the original purchaser for authorized returns within 90 days for product discovered upon inspection to be unsalvageable or shipped in error. Except for defective products, no credit will be issued for unauthorized returns, returns after 90 days from original date of purchase, custom manufactured product, or unsalable product.