

240V SURGIFRESH[®] PureVac[™]

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.

CONTENTS

WARNINGS.....	Page 2	TROUBLESHOOTING.....	Page 8
INTRODUCTION	Page 3	SPECIFICATIONS.....	Page 9
OPERATING INSTRUCTIONS ...	Page 4	TRANSPORT & STORAGE	Page 9
MAINTENANCE	Page 7	ACCESSORIES.....	Page 10
CUSTOMER SERVICE	Page 7	WARRANTY	Page 11



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 from wall receptacle before cleaning.
- Unplug the unit from 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 force. 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: 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 into smoke filters may damage the filters and the smoke evacuation system. Use a disposable suction canister to protect the filters and the unit when fluids are present.

Caution: Occlusion of the smoke evacuation system air can overheat the unit and should be avoided.

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Made in U.S.A.

INTRODUCTION

1.0 INTENDED USE

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

Do not use the SurgiFresh® PureVac™ for applications other than its intended use.

Use only Surgimedics accessories with the SurgiFresh® PureVac™

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

Surgimedics
2950 Mechanic Street
Lake City, PA 16423

800-645-7418

www.surgimedics.com

2.0 DESCRIPTION OF SYMBOLS

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



Danger, explosion risk if used in presence of flammable anesthetics.



Footswitch; identifies the Pneumatic Footswitch tubing connector.
IPX7: The Pneumatic Footswitch is protected against all effects of immersion.

OPERATING INSTRUCTIONS

1.0 FEATURES AND CONTROLS

Figure 1

- a) Suction Control -- changes motor speed for increasing/decreasing 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 filter cartridge.

Figure 2

- a) Circuit Breakers – Double pole fused breakers for 240VAC input power.
- b) Plug Connection -- female receptacle for 240V AC power cord. (included)

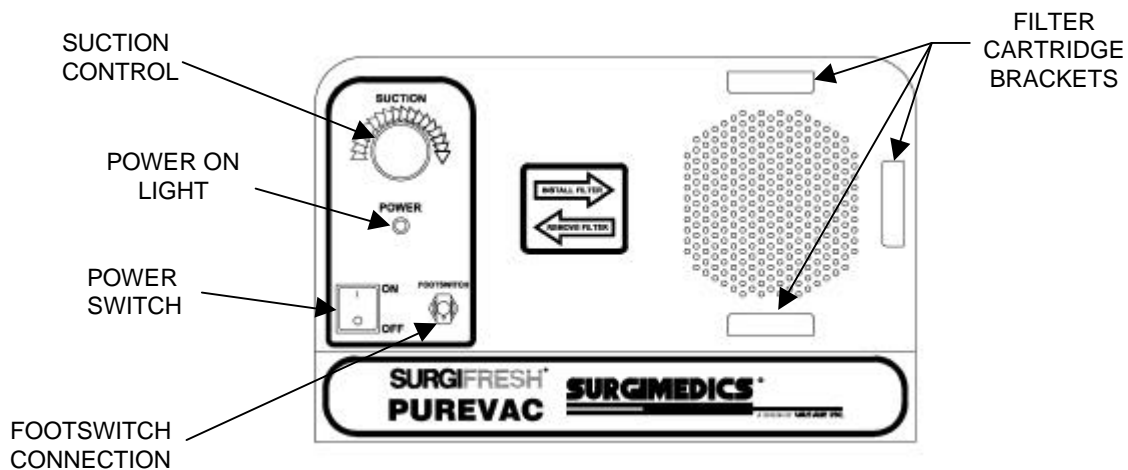
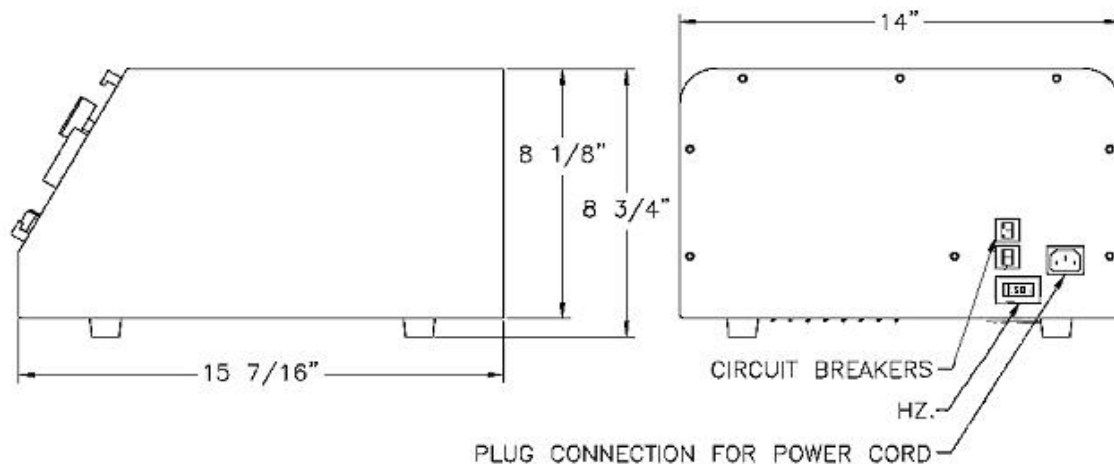


FIGURE 1



ELECTRICAL REQUIREMENTS: 240V/1PH/50-60HZ.

FIGURE 2

OPERATING INSTRUCTIONS

2.0 SYSTEM SET-UP

2.1 Installation

The SurgiFresh® PureVac™ with manual, IPX7 footswitch and 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 on Warranty Attachment. All smoke evacuation disposables will be shipped separately. The same shipping damage instructions apply to these items as well.

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

Note: Save carton and packing for future use.

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

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

4. Connect the power cord into the receptacle on the back of the unit and connect to an appropriate electrical receptacle. Confirm frequency (Hz.) selector switch is set properly.
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. **FOR ALL PROCEDURES**

- a. Ensure an ULPAClear™ cartridge filter is installed per 2.1.
- b. Connect the 7/8" tubing appropriate for the procedure to the ULPAClear™ 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 sponge guard is attached to prevent surgical materials or tissue from being aspirated into the tubing.

1. Move the SurgiFresh® PureVac™ into position near the operative 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 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.
 - b. The larger the tubing, the better the air flow and removal of plume. Do not occlude tubing.
2. Noise
 - a. Lower speed equals lower noise.
 - b. Larger tubing equals lower 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 fluid suction device.

OPERATING INSTRUCTIONS

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

4. Tubing

- a. Check throughout the surgical procedure to be sure tubing is not occluded.

2.5 Clean-Up

After each surgical procedure, the SurgiFresh® PureVac™ 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™ 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
2950 Mechanic Street
Lake city, PA 16423
Phone: 800-645-7418

Service Department and Loaner Program:

1. **If a problem is experienced, first review the troubleshooting section of this manual. For troubleshooting support, please contact Surgimedics Service 814-774-3482**
2. **In the event your unit needs service or repair, do not attempt to repair, please contact Surgimedics Service and request a Loaner Program Fax Back form.**

TROUBLESHOOTING

5.0 TROUBLESHOOTING

5.1 General

If the SurgiFresh® PureVac™ 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 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

50 cc fluid trap
0.01 micron particulate size at 99.99995% efficiency
activated charcoal for gas and odor adsorption.

Air Flow

Motor Speed Setting	With Filter and 7/8" x 6' tubing
Low (0%)	10 cfm
Medium (50%)	15 cfm
High (100%)	25 cfm

Maximum Static Suction

92 inches H₂O (172mm Hg) suction pressure motor fan rating (sealed)

Safety

Circuit breakers: 2 ea. 5 amps

Power cord: 3 - prong plug

Leakage Current (60 HZ): 300µA max.

Power

Input mains voltage : 240VAC

Mains frequency (nominal): 50/60 Hz

Mains current: 3.25 amps maximum during normal operation

Physical Characteristics

Height: 15 1/2 inches (39.4 cm)

Depth: 8 3/4 inches (22.2 cm)

Width: 14 inches (35.6 cm)

Weight: 16 pounds (7.4 kg) without filters

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 shipping or transporting via carrier

ACCESSORIES

8.0 Parts and Accessories:

<u>Part Number</u>	<u>Item Description</u>	<u>Box Quantity</u>
Smoke Evacuator		
906100	SURGIFRESH® PureVac™	1
Filters		
901301	ULPA-Clear™ Filter Cartridge	8
Tubing		
905021	7/8" x 6' tubing (non-sterile)	24
901005	7/8" x 6' tubing (sterile)	24
901015	7/8" x 10' tubing (sterile)	24
905011	3/8" x 10' tubing (sterile)	10
905018	1/4" x 12" tubing with 1 1/3" adapter (sterile)	10
905019	1/4" x 12" tubing with 7/8" adapter (sterile)	10

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 Lake City, Pennsylvania). 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. Each shipping container must be marked with the return authorization number 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 25% 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.