



OPERATOR'S MANUAL

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INTRODUCTION

The Aaron Medical® Smoke Shark™ (SE01) System is designed to remove smoke and noxious odors produced by surgical smoke during laser and electrosurgical procedures.

The Smoke Shark (SE01) System has been designed with a high-suction, high-flow rate centrifugal action pump. The ultra-quiet motor is used to draw the surgical smoke from the surgical site through the vacuum tubing and into the SF18 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 Aaron Medical SF18 filter contains four different stages within to decontaminate the smoke plume.

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

The second stage filtration is a VSLI (Very Large Scale Integrated) grade ULPA (Ultra Low Penetration Air) filter whose high-tech patented design captures particulates and micro-organisms down to 0.012 μm at an efficiency of 99.99995%. Each VLSI grade ULPA filter is pre-tested and certified before use.

The third stage filtration uses the highest grade virgin activated carbon, especially designed for Aaron Medical for the removal and absorption 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 (SE01) system preferentially removes toxic organic gases rather than water vapor and provides optimal odor removal.

The fourth stage filtration is an expanded foam and paper media used to trap activated carbon fines from migrating out of the filter. The first, second and fourth stages of the 18-hour filter have been impregnated with a chemical agent. The chemical agent has been applied with a patented process that prevents the agent from being washed or blown off the filter media.

The electronic controls on the face panel of the Smoke Shark (SE01) system have been designed to be user friendly and facilitate unit setup and operation. Please refer to the section "Operating Instructions" for details.

INSPECTION

The Smoke Shark has been thoroughly tested and inspected before shipment from the factory. Please check the unit before using it to ensure that no damage has occurred in transit. If damage is evident, please contact Aaron Medical Customer Service at 1-800-537-2790 (US Only) or (727) 384-2323 (International).

In addition, please compare the accessories you received with the standard accessories listed below. If an item is missing, please notify Aaron Medical Customer Service

Standard Accessories:

- Operator's Manual
- Power Cord

Please contact Aaron Medical Customer Service to purchase the following accessories:

- Replacement Filters
- Electronic or Pneumatic Footswitches
- Remote Switch Activator
- Hoses, Tubing, Laparoscopic Kits, Adapters, Wands & Other Accessories

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 Smoke Shark (SE01) system complies with IEC601.1 electrical specifications in the following systems: 120V/60Hz, 100V/50Hz, 220V/50Hz, 240V/50Hz
2. The Smoke Shark (SE01) system has a classification under the UL260 1-1, Clause 5.1 of: CLASS 1 Equipment
3. The Smoke Shark (SE01) system has an identification under the UL2601-1, Clause 5.2 according to the degree of protection against electric shock: Type CF Equipment
4. The Smoke Shark (SE01) system has an identification under the UL2601-1, Clause 5.3 according to the degree of protection against harmful ingress of water: Ordinary Equipment (enclosed equipment without protection against ingress of water).
5. The Smoke Shark (SE01) system has a classification under the

UL2601-1, Clause 5.4 according to the method of sterilization or disinfection recommended by Aaron Medical: Unplug the unit. Wipe the unit with a damp cloth containing a mild disinfectant solution, or soapy water. Wipe the unit dry with a clean cloth. Do not steam sterilize.

6. The Smoke Shark system has a classification under the UL2601-1, Clause 5.5 according to the degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide: Equipment not suitable for use in the presence of Flammable Anesthetic mixture with air or with oxygen or nitrous oxide.
7. The Smoke Shark (SE01) system has a classification under the UL2601-1, Clause 5.6 according to the mode of operation: Continuous Operation.
8. The fuses on the circuit board are to be serviced by an authorized Aaron Medical technician.

The Smoke Shark (SE01) system and all filters and accessories are not intended for contact with patients.

CAUTIONS AND WARNINGS

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

This smoke evacuation system should only be operated by personnel who have been properly trained in its operation.

WARNING: The Aaron Medical 18-hour filter is completely disposable. Please handle these disposable filters according to your local codes or regulations and hospital policy.

These filters may be disposed of or incinerated, whichever is appropriate for your institution.

WARNING: The 18-hour filter should be changed according to the life of the filter. The 18-hour filter, used with the Smoke Shark (SE01) system, 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.

WARNING: This device is not intended for evacuation of fluid. If fluid is expected to be aspirated to the 18-hour 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.

WARNING: Do not operate this device in the presence of explosive gases.

WARNING: Refer routine servicing to qualified biomedical technical personnel.

WARNING: There are no user serviceable components in the Smoke Shark (SE01) system. Refer service to qualified service personnel.

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

CAUTION: 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.

CAUTION: 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.

OPERATING INSTRUCTIONS

System Controls:

The electronic system controls on the Smoke Shark (SE01) system are easy to understand and simple to use. The membrane control panel contains the power on/off switch, suction power adjustment, remote activation indicator, filter-life reset button, filter-life indicator, and service indicator light. (see figure 1)

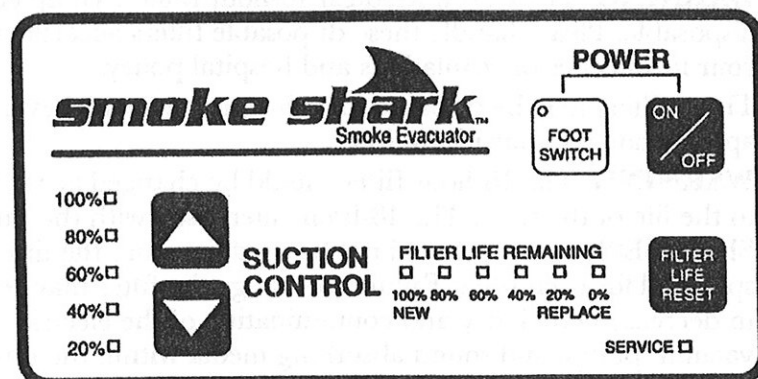


Figure 1

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.

Power ON/OFF & Standby:

There are two ON/OFF switches on the Smoke Shark (SE01) system. The ON/OFF switch that completely disables the electrical power to the unit is normally located on the side of the unit. The ON/OFF switch on the electronic membrane control panel is located in the upper right-hand corner of the membrane panel. To power up the machine, place the power switch on the side of the machine in the ON position and press the ON/OFF switch on the membrane panel until the suction control lights illuminate. Place the unit in "standby" by pressing the ON/OFF membrane switch to the OFF position. Turn the system main power off by placing the power switch on the side of the system in the OFF position.

Suction Control (Membrane Control Panel):

The amount of suction may be adjusted by pressing the UP and DOWN arrow keys. Pressing the UP arrow button increases suction and pressing the DOWN arrow button decreases suction. The suction control should be set at the lowest practical setting to completely remove the surgical smoke from the operative site. Each time either arrow button is pressed the suction will increase or decrease by 10%. When two lights are lit on the flow suction indicator, the actual air flow is the value between the two illuminated percentages.

Footswitch/Remote Switch Activator (Membrane Control Panel):

A footswitch or a remote switch activator may be added to any system by simply plugging in an activation accessory into the appropriate jack on the side of the unit. When the footswitch is plugged in, the unit may be turned on or off by depressing the footswitch pedal once for each operation. For footswitching operation, the power switch on the membrane control panel should be in the ON position. When the footswitch is plugged in, the light on the membrane control panel entitled REMOTE SWITCH will light to indicate that the footswitch is active. For directions on using the Remote Switch Activator, 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 for the Smoke Shark system is 18 hours.

To reset the filter life: after each filter change, press the RESET

button for five seconds to restart the timer for the next filter.

Reading the Filter-life Indicator:

Install a SF18 filter into the system per the installation instructions contained in this operator's manual. When the system is turned on the filter-life indicator will light up all the GREEN, AMBER, and RED LED's. This indicates full filter life. The indicator will progress to red indicators only as the life of the filter is exhausted. After the appropriate time has elapsed, the RED LED indicator will start blinking to indicate that the filter has expended its useful life and requires replacement.

Circuit Breaker (Rear or Side Panel):

Two 15-AMP circuit breakers (8-AMP for international systems) are located on the rear or side 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, the circuit breaker will trip and the system will not operate. To re-start the system, depress the circuit breaker into its original position.

SF18 Filter Instructions:

Before installing or removing any filter, be sure that the system is turned off and the electrical plug has been disconnected.

Filter Installation Instructions:

The installation of the SF18 filter into the Smoke Shark (SE01) system is quick and simple.

1. Remove the SF18 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 SF18 filter into the filter receptacle. Be sure that the filter is seated completely against the bottom of the filter chamber.
3. Press the FILTER LIFE RESET button on the membrane control panel for 5 seconds to rest the filter life clock for the newly installed Aaron Medical SF18 filter.

WARNING: This device is not intended for evacuation of fluid. If fluid is expected to be aspirated using the SF18 filter or the Aaron Medical Smoke Shark 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 SF18 filter has been exhausted and requires changing, turn the smoke evacuation system off and disconnect the unit's electrical cord and any accessory tubing attached to the filter.
2. Pull the SF18 filter from the smoke evacuation system and dispose of in accordance with hospital policy. The SF18 filter may be disposed of or incinerated.
3. Clean the unit with appropriate germicide prior to re-use. Follow the indicated instructions for maintenance and installation of a new SF18 filter.

WARNING: The SF18 filter should be changed when the filter-life indicator shows 0% life remaining. 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.

Setup and Operation:

The operation of the Smoke Shark system is as follows:

1. Install the appropriate 18-hour filter.
2. Attach unit power cord to the receptacle on the side or rear panel into an appropriate grounded power outlet.
3. Optional: attach either Remote Activator Switch or Footswitch plug into appropriate receptacle on side of machine.
4. Ensure that the evacuation tubing is fully seated in the inlet of the filter.
5. Turn on unit main power by placing the power switch on the side panel of the machine in the ON position.
6. Activate the power unit by:
 - a. Pressing the ON/OFF switch on the membrane panel.
 - b. Depressing and releasing the footswitch (if connected), or
 - c. Activating either CUT or COAG on the Smoke Evacuating Pencil (if Remote Activator is connected).
7. Adjust the suction level to the desired setting by pressing the UP and DOWN arrow keys 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. When two indicators are illuminated on the suction control scale,

the suction control setting is the value between the two illuminated percentages.

8. Deactivate the unit by:
 - a. Pressing the 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 Smoke Evacuating Pencil (If Remote Activator is connected).
9. Replace the SF18 filter when the Filter Life Remaining Scale FLASHES RED (0% Life Remaining). Failure to change the filter will affect the performance of the system.

SPECIFICATIONS FOR SMOKE SHARK SYSTEM (SE01)

Configurations	Portable or Tabletop
18-hour filters, single or double ports $\frac{7}{8}$ " (22mm) and/or $1\frac{1}{4}$ " (32mm)	4-Stage filtration in one casing (pre-filter, ULPA, Carbon, post-filter)
Filters	ULPA, VLSI Grade
particle size, μm	0.01 with 99.99995% efficiency
Filter life	18 hours
Max. Flow Setting	Tubing Size
SCFM (Std. cubic ft./min)	$1\frac{3}{8}$ " - NA, $1\frac{1}{4}$ " - 38, $\frac{7}{8}$ " - 28
SLPM (Std. liters/ min)	35mm - NA, 32mm - 1076, 22mm - 793
ACFM (actual cubic feet/minute)	$1\frac{3}{8}$ " - NA, $1\frac{1}{4}$ " - 59, $\frac{7}{8}$ " - 42, $\frac{1}{4}$ " - 4.8
ALPM (actual liters/minute)	35mm - NA, 32m - 1671, 22mm - 1189, 6mm - 136
Variable Flow Control	Yes
Motor hp (kW)	1.25 (0.93)
Static Suction, Inches H ₂ O (mbar)	91.5 (227)
Hoses/tubing	$\frac{1}{4}$ ", $\frac{7}{8}$ ", $1\frac{1}{4}$ " 6mm, 22mm, 32mm
Noise level, dBA - at min power	≤ 50
at max power	≤ 77
Footswitch	Yes (Optional)
Remote control activation	Yes (Optional)

Safety features

Filter housing and handles remain temperate with the outer surface to prevent burns; circuit breaker; CLA, CE and UL classified/listed

Displays
data displayed

LED
Filter Status, Flow Rate,
Footswitch Control

Voltage available
frequency

100/120/220/240 volts
50/60 Hz

H x W x D

10 x 6.5 x 18 inches
25.4 x 16.5 x 45.7 cm

Weight, lbs. (kg)

14.8 (6.7)

MAINTENANCE

General Maintenance Information:

This section contains information for ordinary upkeep of the Aaron Medical Smoke Shark (SE01) 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.

Cleaning:

The exterior of the system may be cleaned by wiping it with a cloth that has been dampened (not dripping) with a mild detergent such as Windex® or Formula 409®. Windex® is a registered trademark of the Drackett Products Company. Formula 409® is a registered trademark of the Clorox Corporation.

Periodic Inspection:

The Smoke Shark (SE01) 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.
- Tightness of the power plug.
- Proper mating, cleanliness and absence of damage to the filter inlet.
- Obvious external or internal damage to the system.

Troubleshooting the System:

PROBLEM	POTENTIAL CAUSE	CORRECTIVE ACTION
1. Smoke Evacuation System is ON but suction is minimal or none	1. Filter not seated completely 2. Filter clogged 3. Vacuum hose clogged 4. Motor/blower obstructed	1. Re-install 18-hour filter, press firmly into place 2. Replace filter use 18-hour Erbium: YAG filter and pre-filters for Erbium: YAG laser procedures 3. Check or replace Smoke Evacuation Tubing.
2. Smoke Evacuation System does not function even though ON button is depressed	1. Not plugged into electrical outlet 2. Circuit breaker(s) tripped 3. Footswitch plugged in 4. Electronic system failure 5. Main power switch in OFF position	1. Check power outlet and connection to rear or side panel of machine 2. Reset circuit breaker(s) on rear or side of system 3. Unplug footswitch 4. Check main power switch on rear or side of system to ensure that it is in the ON (I) position

CUSTOMER SERVICE

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 (SE01) 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" (R.G.A.) number from Customer Service before returning the system.

Step 4: If you have the original packing for your Smoke Shark (SE01) 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.

Ordering Information:

To reorder or obtain replacement parts, contact your local dealer. For more information on a dealer near you call Customer Service at: 800-537-2790, or visit our website at www.aaronmed.com

Aaron accessories:

Contact your local distributor or customer service representative at 1-800-537-2790 for a complete list of available accessories.

Specifications:

Specifications are subject to change without notice.

Shipment of Order:

Aaron Medical will try to accommodate individual customer requests for shipping methods. Aaron Medical reserves the right to decide shipping methods 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 hours after delivery. Aaron Medical'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, Aaron Medical will assist customers in pursuing these claims.

Return of Material:

Return merchandise must have a pre-authorized return number from Aaron Medical 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 Aaron Medical Customer Service before shipping back merchandise.
2. Incorrectly shipped merchandise is exempt from restocking fees. Please contact Aaron Medical Customer Service before shipping back merchandise.

LIMITED WARRANTY

For a period of one (1) year following the date of delivery, Aaron Medical warrants the Smoke Shark (SE01) system against any defects in material or workmanship. This warranty is void if the product is used in a manner or for purposes other than intended.

Warranty:

Aaron Medical warrants that the filter system shall be free from defects in material and workmanship. Products are warranted only to the extent that Aaron Medical will replace without charge any filter systems proved to have defects within one (1) year of the date of delivery. 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 Aaron Medical 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:






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

Entire Agreement:

Purchaser by acceptance of Aaron Medical'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 the State of Florida.

Jurisdiction:

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

SYMBOL	DESCRIPTION / MEANING
	DANGER: Risk of explosion if used in the presence of flammable anesthetics.
	CAUTION: Grounding reliability can only be achieved when the equipment is connected to a receptacle marked "Hospital Grade" or "Hospital Only" CAUTION: Electric shock hazard. Do not remove cover. Refer servicing to qualified service personnel.
	Before connecting, read instructions.
	Type CF equipment.
IPX1	Protect against dripping water.
	Alternating current.



7100 30th Ave. N.
St. Petersburg, FL 33710
Phone: (727) 384-2323
Fax: (727) 347-9144

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