Service Manual

RapidVac™

Smoke Evacuator

Part Number: 1075303

Preface

This manual and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed. It is intended as a guide for servicing the RapidVac Smoke Evacuator only. Additional users information is available in the *RapidVac Smoke Evacuator User's Guide*.

Equipment covered in this manual:

RapidVac Smoke Evacuator—110 V and 220 V

Device is compliant with the European Communities Council Directive 93/42/EEC, Medical Device Directive.

Conventions Used in this Guide

Warning

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

Caution

Indicates a hazardous situation which, if not avoided, may result in minor or moderate injury.

Notice

Indicates a hazard which may result in product damage.

Important

Indicates *an operating tip or maintenance suggestion.*

Limited Warranty

Covidien warrants each covered product listed below to be free from defects in material and workmanship for normal use and service for the period(s) set forth below. Covidien's obligation under this warranty is limited to the repair or replacement, at its sole option, of any product, or part thereof, which has been returned to it (or its authorized distributor) within the applicable time period shown below after delivery of the product to the original purchaser, and which examination discloses, to Covidien's satisfaction, that the product is defective. This limited warranty does not apply to any product, or part thereof, which has been repaired or altered in a way so as, in Covidien's judgment, to affect its stability or reliability, or which has been subjected to misuse, neglect, or accident.

The warranty periods for Covidien products are as follows:

RapidVac™ Smoke Evacuator	One year from date of shipment

Notwithstanding any other provision herein or in any other document or communication, Covidien's liability with respect to this limited warranty and the products sold hereunder shall be limited to the aggregate purchase price for the products sold to the customer. This limited warranty is non-transferable and runs only to the original purchaser of the covered product(s). There are no warranties which extend beyond the terms hereof. Covidien disclaims any liability hereunder or elsewhere in connection with the sale of products and for any form of indirect, tort, or consequential damages.

This limited warranty and the rights and obligations hereunder shall be construed under and governed by the laws of the State of Colorado, USA. The sole forum for resolving disputes arising under or relating in any way to this limited warranty is the District Court of the County of Boulder, State of Colorado, USA.

Covidien reserves the right to make changes in covered products built or sold by it at any time without incurring any obligation to make the same or similar changes to equipment previously built or sold by it.

THE OBLIGATION TO REPAIR OR REPLACE A DEFECTIVE OR NONPERFORMING PRODUCT IS THE SOLE REMEDY OF THE CUSTOMER UNDER THIS LIMITED WARRANTY. **EXCEPT AS EXPRESSLY PROVIDED HEREIN, COVIDIEN DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, ORAL OR WRITTEN, WITH RESPECT TO PRODUCTS, INCLUDING WITHOUT LIMITATION ALL IMPLIED WARRANTIES, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.**

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Chapter 1

Introduction

This chapter provides an overview of the features and functions of the RapidVac Smoke Evacuator.

Caution
Read all warnings, cautions, and instructions provided with this system before use.
Read the instructions, warnings, and cautions provided with smoke evacuator accessories before use. Specific instructions are not included in this manual.

Parts Shipped with the Smoke Evacuator

When unpacking the smoke evacuator, verify that the following parts are included:

- Power cord
- User's guide and service manual

Upon initial receipt, inspect the smoke evacuator for dents, cracks, or damage that may have occurred during shipment. If damage is present, notify the freight carrier for assessment.

Additional items available from Covidien:

- Replacement RapidVac Filters
- RapidVac Footswitch
- RapidVac Remote Switch Activator
- RapidVac Interlink Cable
- Laparoscopic Smoke Evacuator Tubing Kit
- Hoses, tubing, adapters, wands and other accessories
- Smoke pencil

About the RapidVac Smoke Evacuator

Indications for use for the RapidVac Smoke Evacuator include:
To remove and filter smoke and aerosols from a surgical site produced during electrosurgical and laser procedures.

The RapidVac Smoke Evacuator is designed with a vacuum motor. The motor is used to draw surgical smoke from the surgical site through the vacuum tubing and into the 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 RapidVac SEA3700 filter contains four different stages within to capture the smoke plume:

- The first stage filtration is a prefilter whose function is to trap and remove gross particulate.
- The second stage filtration is ULPA (Ultra Low Penetration Air) grade filter whose high-tech design captures particulates and micro-organisms from .1 to .2 microns at an efficiency of 99.999%.
- The third stage filtration is comprise of virgin activated carbon.
- The fourth stage filtration is a woven fiberglass filtration media used to reduce the amount of activated carbon fines from migrating out of the filter.

Features

RapidVac Smoke Evacuator features include:

- Filter-life monitoring for its four-stage, 25-hour filter
- Standby, RapidVac+, footswitch, or continuous operation modes
- Adjustable flow
- Compatibility with all Covidien electrosurgery pencils and generators

RapidVac+ System

The RapidVac Smoke Evacuator incorporates the RapidVac+ mode, which controls the flow of the smoke evacuator when using a Covidien electrosurgical pencil. When the electrosurgical pencil is activated, the smoke evacuator operates in the preselected flow setting. When the pencil is deactivated, the airflow reduces to a low-flow purge setting.

Two Covidien accessories link the electrosurgical generator and smoke evacuator to enable the RapidVac+ mode:

- RapidVac Remote Switch Activator
- RapidVac Interlink Cable

Operating Modes

Four operating modes are available: standby, footswitch, RapidVac+, and continuous.

- **Standby** mode powers up the unit without activating the motor or vacuum flow.
- **Footswitch** mode is used to turn the smoke evacuator on or off with the optional footswitch pedal.
- **RapidVac+** mode is used to control the vacuum flow simultaneously with activation of an electrosurgical pencil. This mode is controlled with the optional interlink cable or electrosurgery sensor.
- **Continuous** mode is used to operate the smoke evacuator using continuous airflow.

Service Personnel Safety

General

Warning

During initial set up, inspect the smoke evacuator for any damage that may have been caused during shipping. If damaged, do not use or attempt to repair. Call Covidien for service assistance.

The RapidVac Smoke Evacuator filter is a disposable component that captures potentially hazardous particles. Handle used filters as you would any biohazardous material. Dispose of used filters according to your local codes and regulations, and follow your institution's procedures for disposal.

The smoke evacuation filter has a life of approximately 25 hours of use and should not be used beyond the specified time. If the replace-filter indicator illuminates during operation, the smoke evacuator will continue to run until it is turned off. Turning power off to the smoke evacuator will require replacement of the filter before subsequent use.

Failure to change the filter accordingly may result in decreased efficiency in smoke evacuation and contamination of the motor, and sound absorbing media within the smoke evacuator.

The RapidVac Smoke Evacuator filter is disposable. Dispose of used filters according to your local codes and regulations, and follow your institution's procedures for disposal.

Do not operate this device in potentially explosive environments, such as in the presence of flammable anesthetics.

Refer routine servicing to qualified biomedical technical personnel.

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

Do not use two- or three-prong adapters with the smoke evacuator power cords.

The power-cord assembly should be checked periodically for damaged insulation or connectors. Do not use damaged cords.

Use of extension cords may result in fire hazards.

This device is not intended for the evacuation of fluid. If fluid is expected to be aspirated to the smoke evacuation filter, a fluid-collection device must be installed with the vacuum hose assembly. Failure to install a fluid-collection device could cause filter blockage and electrical damage. Contact Covidien Service for additional information.

Do not connect a wet power cord to the wall receptacle.

Connect the smoke evacuator power cord to a properly grounded receptacle. Plug the power cord directly into the power receptacle without any adapter plugs. Use of power plug adapters may result in electric shock.

If the smoke evacuator becomes wet, either from a leaking tube or from being sprayed, unplug the smoke evacuator from the Mains outlet. Wipe dry or allow to air dry before proceeding.

Warning

Do not remove any covers or panels exposing the internal components of the smoke evacuator. Refer to a Covidien representative for service.

The smoke evacuator produces a strong vacuum. Adjust the airflow and the position of the inlet end of the wand or tubing to prevent patient injury and to prevent suction of surgical materials and surgical specimens.

If the smoke evacuator is activated while the airflow is set to a high speed, it may produce a sudden, strong suction action. Check the airflow setting before activating the smoke evacuator to prevent patient injury and to prevent suction of surgical materials and surgical specimens.

Caution

Do not stack equipment on top of the smoke evacuator or place the smoke evacuator on top of electrical equipment. These configurations are unstable and/or do not allow for adequate cooling.

Use only RapidVac SEA3700 ULPA Filters in the RapidVac Smoke Evacuator. Filters from other manufacturers may cause damage to the system, thereby voiding the warranty.

Provide as much distance as possible between the smoke evacuator and other electronic equipment (such as monitors). An activated smoke evacuator may cause interference with them.

Read all warnings, cautions, and instructions provided with the RapidVac Smoke Evacuator before using.

To maximize patient safety, the tubing or wand should not come in direct contact with tissue. Otherwise, patient injury may result.

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 shut down.

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.

Notice

Using any unapproved filter or accessory with the smoke evacuator may cause damage and will void the warranty.

The RapidVac Smoke Evacuator functions properly only when the ULPA filter is installed properly. If the filter is installed incorrectly, the amber replace-filter indicator flashes and the Service indicator is illuminated.

Fluids may damage the filters. When evacuating smoke and incidental fluids, always use the appropriate tubing,

Connect the power cord to a wall receptacle having the correct voltage. Otherwise, product damage will result.

Notice

Power line voltage below 100 VAC (110 V SEA3690) and 200 VAC (220 V SEA3695) will significantly reduce airflow.

Connecting multiple lengths of tubing together may cause the smoke evacuator to overheat.

The RapidVac Smoke Evacuator has been specially designed to fit on Covidien mounting carts only. Do not install the smoke evacuator on a cart other than a Covidien cart. Installing the smoke evacuator inside a cart with improper ventilation may result in overheating or may adversely affect the stability of the cart.

Periodically check the cart brackets that hold the smoke evacuator in place to ensure that the screws are securely fastened.

Stacking the smoke evacuator on top of a generator may cause an unstable condition and/or cause the smoke evacuator to overheat.

Do not use sterile accessory products if sterile packaging has been compromised.

Maintenance

Warning

Always turn off and unplug the smoke evacuator before cleaning.

The ULPA filter captures potentially hazardous particles. Handle used filters as you would any biohazard material. Dispose of filters with other operative waste materials according to the procedures for your institution.

Do not reuse or re-sterilize smoke evacuator accessories labeled "disposable," "single use only," or "sterile."

Notice

Do not rub, touch, or clean the smoke evacuator with alcohol or caustic, corrosive, or abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the control panel or damage the smoke evacuator.

Do not autoclave, pressure sterilize, or gas sterilize the smoke evacuator.

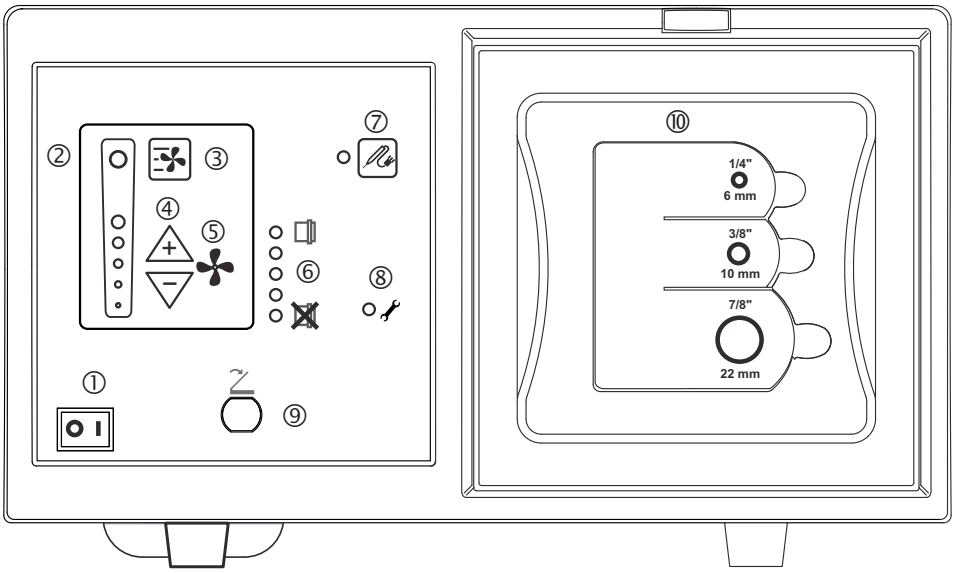
Keep the smoke evacuator away from liquids. Liquids that enter the smoke evacuator will damage internal components.

Chapter 2

Controls, Indicators, and Receptacles

This chapter describes the front and rear panels of the RapidVac Smoke Evacuator Service Manual smoke evacuator, including all controls, indicators, receptacles, and ports.

Front Panel



① Power on/off switch
② Airflow indicators (LED)
③ Turbo button
④ Airflow controls
⑤ Power-on indicator (LED centered in fan symbol)
⑥ Filter-life indicators (LED)
⑦ RapidVac+ button
⑧ Service-required indicator
⑨ Footswitch jack
⑩ Air filter with tubing connectors

Caution

Connect accessories to the proper receptacle type. Otherwise, the smoke evacuator may not function properly.

The electronic system controls on the RapidVac Smoke Evacuator are easy to understand and simple to use. The control panel contains the suction on/off switch, suction power adjustment, filter-life indicator, and service indicator light.

Notice

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 Switch

The power switch that controls power to the RapidVac Smoke Evacuator is in the lower-left corner of the front panel. To power up the smoke evacuator, place the power switch in the on position (**I**). The smoke evacuator starts in standby (system power is on with no suction). When the smoke evacuator is on in standby, the LED in the center of the fan symbol on the front panel will blink continually until a fan speed is selected.

Turn the system power off by placing the power switch in the off position (**O**).

Airflow Controls

The level of suction is controlled by the airflow controls: up-arrow (+) and down-arrow (−) buttons. To start the fan from standby mode, press the up-arrow button. It starts in the lowest suction setting indicated by a single illuminated airflow indicator.

The suction control should be set at the lowest practical setting to completely remove the surgical smoke from the operative site. Pressing either the up- or down-arrow buttons changes the current suction. The selected level of suction is displayed by the airflow-indicator LEDs.

Turbo Button

When increased smoke removal is necessary, the Turbo button may be pressed at anytime to increase suction. Turbo mode effectively increases the airflow to 100% suction flow to quickly remove the smoke plume from the surgical site.

Filter-Life Indicator

The filter-life indicator provides a visual indication of the status of the life of the filter in use. Each illuminated LED represents five hours of remaining time on the 25-hour filter. The RapidVac Smoke Evacuator tracks the time each filter has been used allowing for an accurate display of remaining use for new or previously used filters.

Reading the Filter-Life Indicator

Install an unused RapidVac filter into the system. When the smoke evacuator is on, all five of the filter-life indicator LEDs illuminate indicating the new filter has 100% filter life. The indicator will regress through subsequent LEDs until the final LED is illuminated indicating less than 5 hours of filter life remaining. At one hour remaining, the LED changes to amber. When the time remaining reaches 30 minutes, the amber LED flashes slowly.

RapidVac+ Button

When the smoke evacuator is connected to a generator using the RapidVac Interlink Cable, pressing the RapidVac+ button synchronizes the smoke evacuator with the use of an electrosurgical pencil. When a pencil is activated, the smoke evacuator activates to a preselected airflow level.

Footswitch Jack

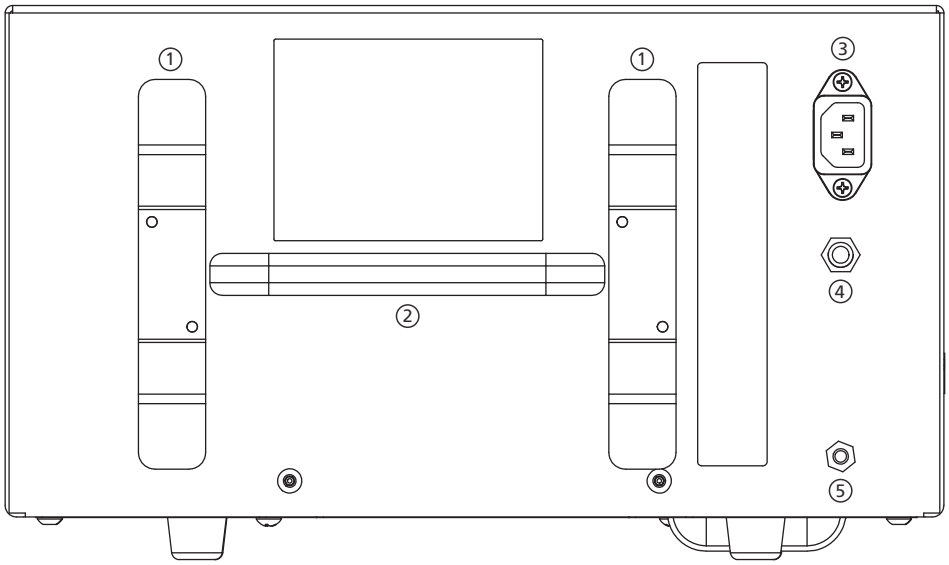
A RapidVac Footswitch (SEA3745) is available for use with the RapidVac Smoke Evacuator II.

A footswitch may be added to any system by simply plugging it into the footswitch jack on the front panel. The unit may be turned on or off by depressing the footswitch pedal once for each operation. For footswitching operation, the smoke evacuator should be on and the suction level to be activated from the footswitch should be selected on the control panel.

Service-Required Indicator

The motor powering the RapidVac Smoke Evacuator requires regular maintenance every 500 hours. When the smoke evacuator has been in use for 500 hours, the service-required Indicator illuminates. Contact the Covidien Customer Service Department and return the smoke evacuator for service.

Rear Panel



① Cord brackets
② Carrying handle
③ Power-cord receptacle
④ Remote Activator jack
⑤ Equipotential grounding lug

Power-Cord Receptacle

The cord receptacle provides power to the smoke evacuator using a removable cord appropriate for regional power supplies. Cord can be wound on the cord brackets to store with the smoke evacuator.

Remote Activator Jack

A RapidVac Interlink Cable (SEA3730) and Remote Switch Activator (SEA3741) are available for the automatic remote activation of the RapidVac Smoke Evacuator.

The RapidVac Interlink Cable is compatible with the Covidien Force FX™, Force EZ™ and ForceTriad™ generators. The cable attaches to a generator's RF activation port and to the smoke evacuator's Remote Activator jack. When the generator is activated, the smoke evacuator automatically initiates the pre-set suction.

The Remote Switch Activator (RSA) is programmed to recognize cut and coag activation currents emitted from the generator. The recognized current initiates activation of the smoke evacuator.

Equipotential Grounding Lug

The equipotential grounding lug provides an alternate route for electrical energy back to ground when attached to an earth-ground cable.

Chapter 3

Technical Specifications

All specifications are nominal and subject to change without notice.

Performance Characteristics

Dimensions and Weight

Width	14″ (36 cm)
Depth	18.75″ (48 cm) with cord wrap and handle
Height	8″ (20.5 cm)
Weight	20.5 lb (9.9 kg) without filter

Filter

ULPA filter	0.1-0.2 micron particulate size at 99.999% efficiency; activated charcoal

Airflow

0 - 1.25 m^3/min. (0 - 44 cfm) with 7/8″ x 10′ (2.2 cm x 3 m) tubing with sponge guard.

Airflow measured at sea level.

Safety

110 Volt	**220 Volt**
Fuse: 10 AMPS, 250 V (Slo-Blo™*)	Fuse: 8 AMP, 250 V (Slo-Blo)
Power cord: 3-prong hospital grade plug	Power cord: 3-prong locally approved connector
Leakage current: (50/60 Hz)	Leakage current: (50/60 Hz)
Normal polarity, smoke evacuator in standby mode < 300 µA	Normal polarity, smoke evacuator in standby mode < 300 µA
Reverse polarity, smoke evacuator in standby mode < 300 µA	Reverse polarity, smoke evacuator in standby mode < 300 µA

Power

This unit is equipped from the factory with either a 110 VAC hospital grade NEMA 5-15 power cord or a 220 VAC CEE7/7 power cord. Should the AC power cord need replacing to match another plug configuration, the replacement plug/cable/receptacle configuration must meet or exceed the following specifications.

100 - 120 VAC

Power Cord - SJT, No. 16AWG, 3 Conductor, IEC Female, 125VAC-13A, UL/IEC Approvals

220 - 240 VAC

Power Cord - HOVV-F3G1.00, IEC Female, 250VAC-10A, EU Approvals

Operating Parameters

Ambient temperature range	50 °F to 104 °F (10 °C to 40 °C)
Relative humidity	30% to 75%, noncondensing

Transport and Storage

Ambient temperature range	-29 °F to 149 °F (-34 °C to 65 °C)
Relative humidity	25% to 85%, noncondensing

EMC for the RapidVac Smoke Evacuator

Electromagnetic Compatibility (IEC 60601-1-2)

The RapidVac Smoke Evacuator complies with the appropriate IEC 60601-1-2 specifications regarding electromagnetic compatibility.

The RapidVac Smoke Evacuator meets the following requirements:

- ESD Immunity (IEC 60601-1-2 sub-clause 36.202 and IEC 61000-4-2)
- Radiated Immunity (IEC 60601-1-2 sub-clause 36.202.2 and IEC 61000-4-3)
- Electrical Fast Transient/Burst (IEC 60601-1-2 sub-clause 36.202.3.1 and IEC 61000-4-4)
- Surge Immunity (IEC 60601-1-2 sub-clause 36.202.3.2 and IEC 61000-4-5)
- Emissions (IEC 60601-1-2 sub-clause 36.201.1)
- Harmonic distortion (IEC 60601-1-2 sub-clause 36.201.3.1 and IEC 61000-3-2)
- Conducted disturbances (IEC 60601-1-2 sub clause 36.202.6 and IEC 61000-4-6)
- Power frequency magnetic fields (IEC 60601-1-2 sub-clause 36.202.8.1 and IEC 610004-8)
- Voltage dips, short interruptions and variations (IEC 60601-1-2 sub-clause 36.202.7 and IEC 61000-4-11)

Summary of EMC Immunity Test Results

Standard	Description	Severity Required	Performance Criteria Met	(1) Performance Criteria Allowed
IEC 61000-4-2 EN 6100-4-2	Electrostatic Discharge	• ±2kV; ±6kV Discharge (Directed and Indirect) • ±2kV; ±4kV; ±8kV	A A	A A
IEC 61000-4-3 EN 6100-4-3 ENV 50204	Radiated RF Immunity	3 V/m, 80–2700 MHz, 2 Hz, 80% AM modulation (Dwell Time is 1 second for 1kHz modulation)	A	A
IEC 61000-4-4 EN 6100-4-4	Electrical Fast Transient	• ±2kV on Power Supply Lines • ±0.5kV on I/O Lines	A A	A A
IEC 61000-4-5 EN 6100-4-5	Surge Withstand	• ±2kV on Power Supply Lines • ±1kV on I/O Lines	A A	A A

Standard	Description	Severity Required	Performance Criteria Met	(1) Performance Criteria Allowed
IEC 61000-4-6 EN 6100-4-6	Conducted RF Immunity	3V, 150 MHz–80 MHz, 1k Hz or 2 Hz, 80% AM modulation (Calibration required level set to 0–25% of target voltage.) Patient coupled leads are tested with current clamp.	A	A
IEC 61000-4-8 EN 6100-4-8	Magnetic Field Immunity	50 and 60 Hz, 3 A/m	A	A
IEC 61000-4-11 EN 6100-4-11	Dips Dips Dropout Interrupts	• <60% UT (>95%dip in UT) for 0.5 cycles for 3 times • 30% 25 cycles for 3 times • Drop-outs >0.5 cycles for 3 times • Interrupts <95% UT (>95% cycles for 5 times)	A A A C	A A A C
IEC 61000-3-2 EN 6100-3-2	Harmonic Current Emissions	Class A	Pass	Pass
IEC 61000-3-3 EN 6100-3-3	Voltage Fluctuation and Flicker in Low-Voltage Supplies	Voltage Fluctuation and Flicker	Pass	Pass
EN 60601-1-2 Clause 6.2.14	Variations of power frequencies	• Variation of power frequency at ±49 Hz, Dell Time 3 min. • 61 Hz 3 min. & 61 Hz for min.	Pass	Pass
*Note: Applicable to all life support equipment and any equipment with less than 1kVA input power, equipment with input power above 1kVA and below 16A per phase need only meet criteria B. (1) Allowed performance criteria is specified in the individual basic standard.				

FCC Compatibility

The RapidVac Smoke Evacuator:

- Complies with Part 15 of the FCC rules. Operation is subject to the following two conditions:
  - (1) This device may not cause harmful interference.
  - (2) This device must accept any interference received, including interference that may cause undesired operation.
- Has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at their expense.
- Utilizes mobile RF communications equipment that can affect medical electrical equipment.
- Operates in the following radio frequency specifications:
  - RX modulation: Pulse-width coded, AM 100% modulation
  - TX frequencies: Manchester encoded, A = fc =/-423.75 kHz, B = fc+/-484.29 kHz
    Low bit: transition A to B
    High bit: transition B to A.

Description of Symbols

Front Panel

Power Off/On

Turbo Button. Press to jump to maximum suction at 100% motor speed.

Airflow Control. Press up-arrow button (+) to increase flow 20%, or down-arrow button (-) to decrease flow by 20%.

Power-on Indicator. LED at the center of the fan illuminates when power to the smoke evacuator is on. A flashing LED indicates the smoke evacuator is in standby mode.

New Filter. With its position next to the top filter-life indicator, it signifies the filter has 100% of its filter life remaining.

Replace Filter. With its position next to the bottom filter-life indicator, it signifies the filter has no filter life remaining and needs to be replaced.

RapidVac+ Button. Remote Switch Activator cord is attached to a generator. Electrosurgery sensor will activate the smoke evacuator.

Footswitch Jack. Attach pneumatic footswitch.

Service-required Indicator. After 500 hours of use, the LED illuminates **indicating the motor needs to be serviced.**

Rear Panel

Remote Activator Connector

Manufacturer

Authorized European Representative

Do not dispose of in unsorted, municipal trash

Date of Product Manufacture, Year - Month

Standards and IEC Classifications

Type CF applied part. Complies with IEC 60601-1

IPX1

Protect against dripping water

Non-ionizing electromagnetic radiation

Alternating current

Danger, explosion risk if used with flammable anesthetics

To reduce the risk of electric shock, do not remove the cover. Refer servicing to qualified service personnel. (Symbol is black with yellow background)

Consult instructions for use (Symbol is white with blue background)

Caution, consult accompanying documents

Product complies with European Product Directives

Indicates the presence of an RFID tag or RFID interrogator

MEDICAL - GENERAL MEDICAL EQUIPMENT
AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH UL 60601-1, ANSI/AAMI ES60601-1 (2005, 3rd ed.),
CAN/CSA C22.2 NO. 601.1, AND CAN/CSA-C22.2 No. 60601-1 (2008)
9D93
E351320

Chapter 4

Setup and Tests

After unpacking the RapidVac Smoke Evacuator, set it up and verify that it functions correctly by performing the tests described in this chapter.

Cleaning the Smoke Evacuator

Clean the smoke evacuator before servicing or testing to minimize the risk of coming in contact with contaminants present from previous use.

Warning

Always turn off and unplug the smoke evacuator before cleaning.

The tubing and filter capture potentially hazardous particles. When removed, handle as you would any biohazardous material. Dispose of these items with other operative waste materials according to the procedures for your institution.

Wear appropriate protective gear when cleaning the filter ports and covering flap to avoid coming in contact with incidental contaminants on these surfaces.

Notice

Do not rub, touch, or clean the smoke evacuator with alcohol or caustic, corrosive or abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the control panel or damage the smoke evacuator.

Do not autoclave, pressure sterilize, or gas sterilize the smoke evacuator.

Keep the smoke evacuator away from liquids. Liquids that enter the smoke evacuator will damage internal components. Do not spray liquid cleaner into the filter ports.

1. Ensure the power switch on the front panel is off (**O**).
2. Disconnect the power cord from the wall receptacle.
3. Thoroughly wipe all external surfaces with a mild detergent or disinfectant.
4. Thoroughly clean both sides of the flap covering the filter ports. Do not spray liquid cleaner into the filter ports.
5. Clean the surface around the filter ports. Do not spray liquid cleaner into the filter ports. Follow procedures approved by your institution, or use a validated infection-control procedure.

Warning

Wear protective gloves when cleaning around filter ports. Do not place fingers into ports or touch the internal surface of the ULPA filter. Contaminants may be present.

6. Ensure the smoke evacuator is completely dry before use.

Testing the Smoke Evacuator

This section provides instructions for setting up and testing the following smoke evacuator components:

- RapidVac ULPA Filter
- Airflow controls
- RapidVac footswitch (as applicable)
- RapidVac Remote Switch Activator (as applicable)
- RapidVac Interlink Cable (as applicable)

Checking the Remaining Filter Life

RapidVac Smoke Evacuator filters have a use duration of 25 hours. As a filter is used, information about the amount of time the individual filter has been used is stored in the filter's RFID tag. Whenever a new or previously used filter is inserted, the smoke evacuator reads the stored information from the tag. The remaining filter life is visually displayed by the corresponding number of filter-life indicators on the smoke evacuator front panel.

1. Turn on the smoke evacuator and insert a filter.
2. Check the filter-life indicators on the front panel to verify the filter has ample remaining time to complete a procedure.

Illuminated Filter-Life Indicators	Remaining Use
All	25 to 20 hours
4	20 to 15 hours
3	15 to 10 hours
2	10 to 5 hours
1 (green)	5 hours to 1 hour
1 (amber)	less than 1 hour
1 (flashing amber)	less than 30 minutes

Important

Replace the filter when indicated. Failure to replace the filter may reduce airflow and compromise the efficiency of the filter.

Changing the Filter

Warning

The ULPA filter captures potentially hazardous particles. Handle used filters as you would any biohazardous material. Dispose of filters with other operative waste materials according to the procedures for your institution.

1. Remove the filter by depressing the locking tab on the top edge of the filter while pulling the filter straight out of the opening.
2. Dispose of this filter with other operative waste materials according to the procedures for your institution.
3. Install a new filter in the smoke evacuator as described earlier in this chapter.

Testing the Airflow Controls

Warning

The smoke evacuator produces a strong vacuum. Properly adjust the airflow and the position of the inlet end of the wand or tubing to prevent patient injury and to prevent suction of surgical materials and surgical specimens.

You can start, stop, and change the vacuum airflow rate when the smoke evacuator is on. Illuminated LEDs display the airflow setting. Each pressing of the up-arrow (+) or down-arrow (−) increases or decreases suction.

There are five suction flow indicator LEDs that light in succession. Turbo Mode illuminates the sixth LED next to the Turbo button.

1. Verify that the filter is installed properly.
2. Ensure the power cord is plugged into a hospital-grade power receptacle.
3. Turn on the smoke evacuator by pressing the power-on switch (|) on the lower left of the front panel. The smoke evacuator powers up with the fan motor off (standby mode). The LED in the center of the fan symbol blinks indicating power is on.
4. Press the up-arrow (+) button once to start suction at the lowest airflow setting.
5. Press the up-arrow (+) button and pause briefly to progress to the next level of suction. Verify that the level of suction noticeably increases with each progression.
6. When all suction flow LEDs are lit steadily (100% motor speed), press the down-arrow (−) button repeatedly to regress through the settings to the lowest setting.

Installing and Testing the Footswitch (optional)

Use only the RapidVac Footswitch with the smoke evacuator. Other footswitches are not compatible.

1. Turn on the smoke evacuator.
2. Connect the footswitch cord to the footswitch jack on the front panel.
3. Turn on the airflow to any setting.
4. Press the footswitch once to turn off the airflow.
5. Press the footswitch again to activate the airflow.

Installing and Testing the Remote Switch Activator (optional)

Use the RapidVac Remote Switch Activator (RSA) with any of Covidien's electrosurgical pencils and generators.

1. Select a space on the front of the generator or generator cart near the 3 prong ESU pencil cable input where the Remote Switch Activator is to be mounted.
2. Clean the surface of the selected area with alcohol. Allow the alcohol to evaporate.
3. Remove the backing from the gasket on the RSA.
4. Affix the RSA to the generator or generator cart.
5. Plug the RSA connector into the Remote Activator jack on the back panel of the smoke evacuator.
6. Turn on the smoke evacuator and press the up-arrow (⚠+) button twice to illuminate the first two airflow indicators.
7. Press the RapidVac+ button.
8. Set up the surgical pencil and generator as instructed in their user documentation.
9. Drape the ESU wire into the RSA cradle. More than one ESU wire may be placed in this cradle. Test the connectivity of the RSA by depressing the cut or coag button on the electrosurgical pencil. The smoke evacuator should start. Deactivate the pencil.
10. An optional delayed stop can be set for the smoke evacuator once deactivation of the pencil occurs. Press and hold the button located on the front of the RSA for the desired amount of delay. This delay can be set from 0-10 seconds. To return to delay of 0 seconds, tap the button once.

Installing and Testing the RapidVac Interlink Cable (optional)

The RapidVac Interlink Cable attaches to a RapidVac Smoke Evacuator and a compatible Covidien generator to synchronize smoke evacuation with the activation of the generator. The cable is compatible with the Covidien Force FX, Force EZ, and ForceTriad generators.

1. Turn power off and unplug the smoke evacuator and generator from the power source.

2. Remove the metal cover plate in the center of the generator back panel to access optional ports.

3. Plug the interlink cable into the generator RF Activation port.

4. Plug the interlink cable into the Remote Activator jack on the back panel of the smoke evacuator.

5. Plug the generator and smoke evacuator into outlets of proper voltage.

6. Turn power on to both devices.

7. When the generator and smoke evacuator have completed their self tests, set the level of suction to be used when the smoke evacuator is activated.

8. Press press the up-arrow (⚠+) button until reaching the desired pre-setting.

9. Press the RapidVac+ button.

The pre-set suction level is now selected. The smoke evacuator continues to run and suction reduces to a minimal level. Use of the surgical pencil will automatically activate the RapidVac to the pre-set suction level. When the pencil is deactivated, the smoke evacuator will return to minimal suction.

Chapter 5

Troubleshooting

This chapter describes solutions to problems that may occur when operating the smoke evacuator.

If the smoke evacuator is not functioning properly, use the information in this chapter to assist in identifying and correcting the malfunction.

Inspecting the RapidVac Smoke Evacuator

If there is a problem with the operation of the smoke evacuator, inspect the unit for obvious conditions that can cause a malfunction:

- Check for visible signs of damage.
- Verify the connections of all cables and tubing.
- Verify proper filter installation.
- Verify that the power switch is on and the power-on indicator LED in the center of the fan symbol is blinking.
- Check the filter-life indicators to ensure the filter has available filter time remaining.

Correcting Specific Malfunctions

If a solution to the problem is not readily apparent, use the following table to identify and correct specific malfunctions. After correcting the malfunction, verify that the smoke evacuator is working properly.

Situation	Possible Cause	Recommended Action
Smoke evacuator is on but there is minimal or no vacuum or airflow at the wand or tubing	Improperly installed ULPA filter	Ensure the ULPA filter is properly installed. Reposition it if necessary.
	Clogged tubing	Unclog/replace the tubing.
	Clogged ULPA filter	Replace the filter.
	Obstructed or malfunctioning motor and/or blower	Contact Covidien service for assistance.
Smoke evacuator does not operate	Disconnected or faulty power cord	Check and correct the power cord connections. Check the cord for damage. Replace cord if needed.
	No power from wall receptacle (power cord is connected to wall receptacle, but mode indicator is not illuminated)	Check the power at the wall receptacle. Connect power cord to a functional wall receptacle.
	Power switch on the front panel is off (**O**)	Turn the power switch on (**|**).
	Fuses damaged	Contact Covidien service.

Situation	Possible Cause	Recommended Action
Footswitch does not activate smoke evacuator when footswitch mode is selected	Improperly connected footswitch	Check that the footswitch is securely connected at the front of the smoke evacuator.
	Malfunctioning footswitch	Replace the footswitch.
	Incorrect footswitch connected to the smoke evacuator	Connect the RapidVac Footswitch (SEA3745) to the smoke evacuator.
	Filter incorrectly installed	Reinstall the filter. Ensure that the filter is fully seated in the smoke evacuator and the securing tab locks into place.
	Malfunction in the smoke evacuator	Contact Covidien service.
Indicator LEDs do not illuminate	No electrical power	Refer to electrical utility maintenance.
	Fuses damaged	Contact Covidien service.
	Malfunction in the smoke evacuator	Contact Covidien service.
Motor does not run, but power-on LED illuminates	Filter incorrectly installed	Reinstall the filter. Ensure the filter is fully seated in the smoke evacuator and the securing tab locks into place.
	Malfunction in smoke evacuator	Contact Covidien service.
ESU remote does not activate when RapidVac mode is selected	RapidVac Interlink cable incorrectly installed	Ensure the RapidVac Interlink is properly connected to the rear panel of the smoke evacuator and the Covidien generator.
	Remote Switch Activator incorrectly installed	Ensure the Remote Switch Activator is connected to the rear of the smoke evacuator. **or** Check the ESU pencil lead installation on the electrosurgery sensor bobbin.
	ULPA filter incorrectly installed	Reinstall the filter. Ensure the filter is fully seated in the smoke evacuator and the securing tab locks into place.

Chapter 6

Return Policy and Procedure

Refer to this chapter for information about:

- The manufacturer's responsibility
- Returning the smoke evacuator for service
- Technical service

Responsibility of the Manufacturer

Covidien is responsible for the safety, reliability, and performance of the smoke evacuator only under the following circumstances:

- Installation and setup procedures in this manual are followed.
- Readjustments, modifications, or repairs to the unit are carried out by persons authorized by Covidien.
- The electrical installation of the relevant room complies with local codes and regulatory requirements, such as UL.
- The accessories are used in accordance with the Covidien instructions for use.

For warranty information, refer to the *Limited Warranty* at the beginning of this guide.

Obtaining a Return Authorization Number

Notice
For repairs, return the smoke evacuator to Covidien.

Before you return the smoke evacuator, call the Covidien Customer Service Department (1-800-255-8522) for a Return Authorization Number or call your Covidien Representative for assistance.

Have the following information ready when you call:

- Hospital/clinic name/customer number
- Telephone number
- Department/address, city, state, and zip code
- Model number
- Serial number
- Description of the problem

Returning the Smoke Evacuator for Service

Follow this procedure when returning the smoke evacuator for service. Service center information is provided below.

1. Remove the filter and any attached tubing and fluid container.

Warning

The ULPA filter captures potentially hazardous particles. Handle used filters as you would any biohazardous material. Dispose of filters with other operative waste materials according to the procedures for your institution.

2. Clean the smoke evacuator thoroughly. Follow the procedures approved by your institution or use a validated infection-control procedure.
3. Attach a tag to the smoke evacuator that includes the Return Authorization Number and the information listed above (i.e., hospital, phone number, etc.).
4. Be sure the smoke evacuator is completely dry. Then, package the smoke evacuator in its original shipping container, if available.
5. When you receive the Return Authorization Number, ship the smoke evacuator prepaid according to Covidien's instructions.

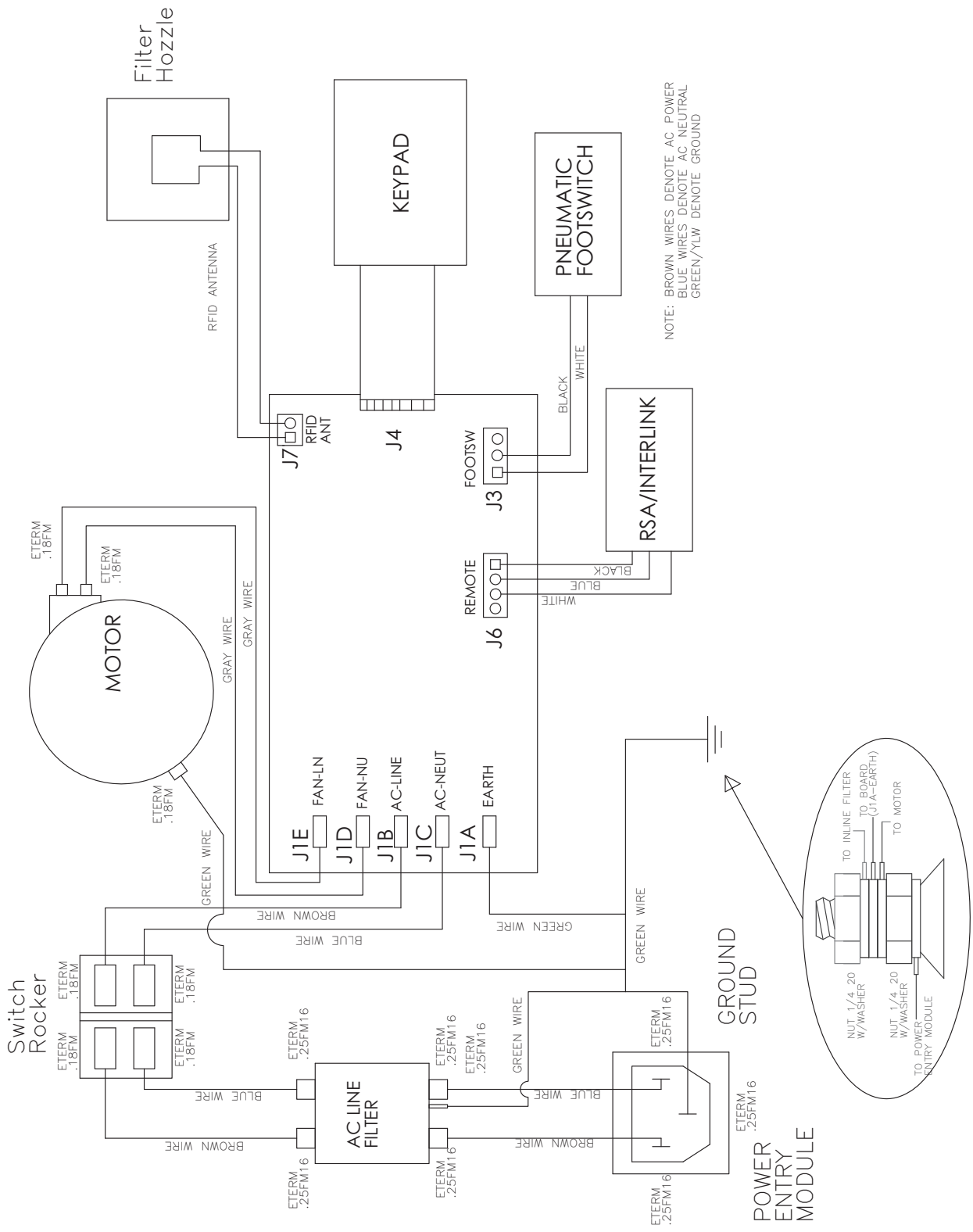
Technical Service

For service information, please refer to the Covidien web site: http://surgical.covidien.com/service-centers

Chapter 7

RapidVac Schematic

This chapter contains a schematic drawing for the RapidVac Smoke Evacuator.


Filter Hozzle
RFID ANTENNA
KEYPAD
PNEUMATIC FOOTSWITCH
NOTE: BROWN WIRES DENOTE AC POWER
BLUE WIRES DENOTE AC NEUTRAL
GREEN/YLW DENOTE GROUND
J7
RFID ANT
J4
BLACK
WHITE
FOOTSW
J3
RSA/INTERLINK
REMOTE
J6
BLACK
BLUE
WHITE
ETERM .18FM
MOTOR
GRAY WIRE
GRAY WIRE
GREEN WIRE
J1E
FAN-LN
J1D
FAN-NU
J1B
AC-LINE
J1C
AC-NEUT
J1A
EARTH
BROWN WIRE
BLUE WIRE
GREEN WIRE
GREEN WIRE
Switch Rocker
ETERM .25FM16
AC LINE FILTER
BLUE WIRE
BROWN WIRE
GREEN WIRE
BLUE WIRE
BROWN WIRE
GROUND STUD
POWER ENTRY MODULE
TO INLINE FILTER
TO BOARD (J1A-EARTH)
TO MOTOR
NUT 1/4 20 W/WASHER
NUT 1/4 20 W/WASHER
TO POWER ENTRY MODULE