

PlumeSafe® Turbo™

Surgical Smoke Plume Evacuator

Operator's Manual



For a period of three (3) years following the date of delivery, BUFFALO FILTER warrants the Turbo Auto-Sense™ against any defects in material or workmanship. BUFFALO FILTER will repair or replace (at BUFFALO FILTER'S option) the same without charge, provided that routine maintenance as specified in this manual has been performed using replacement parts approved by BUFFALO FILTER. This warranty is void if the product is used in a manner or for purposes other than intended.

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The revision level of this manual is specified by the highest revision letter found on either the inside front cover or enclosed errata pages (if any).

Manual Number 900989 Rev J
PlumeSafe® TURBO Auto-Sense™



EC REP
EMERGO EUROPE
Prinsessegracht 20
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The Netherlands

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

ANSI/AAMI ES60601-1: A1:2012, 1:2009/(R)2012 and A2:2019/(R)2012,
and CSA CAN/CSA-C22.2 NO. 60601-1:14

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) this device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.

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System Description

Section 1.0

1.1 Introduction

BUFFALO FILTER® Turbo Auto-Sense™ Smoke Evacuation Systems are intended to evacuate and filter surgical smoke plume and aerosols created by the interface surgical tools with tissue, examples being lasers, electrosurgery systems, and ultrasonic devices.

The Turbo Auto-Sense™ Smoke Evacuation Systems have 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 ViroSafe® 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 Buffalo Filter ViroSafe® 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 and casual fluid.

The second stage filtration is ULPA grade (Ultra Low Penetration Air) filter whose high-tech patented (U.S. Patent #5874052) design captures particulates and micro-organisms from .1 to .2 microns at an efficiency of 99.999%.

The third stage filtration uses the highest grade virgin activated carbon, especially designed for Buffalo Filter for the removal and adsorption 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 Turbo Auto-Sense™ Smoke Evacuation Systems preferentially removes toxic organic gases rather than water vapor and provides optimal odor removal.

The fourth stage filtration is an expanded foam used to trap activated carbon fines from migrating out of the filter.

The electronic controls on the face panel of the Turbo Auto-Sense™ Smoke Evacuation System has been designed “user friendly” and facilitate unit set up and operation. Please refer to Section 2.0 for Operating Instructions.

1.2 Inspection

The Turbo Auto-Sense™ Smoke Evacuator has been thoroughly tested and inspected before shipment from the factory. Please check the unit before using it to insure that no damage has occurred in transit. If damage is evident, please contact BUFFALO FILTER Customer Service at 1-800-343-2324 (US Only) or (716) 835-7000 (International)

In addition, please compare the accessories you receive with the standard accessories list below. If an item is missing, please notify BUFFALO FILTER Customer Service.

Standard Accessories:

- Operator's Manual
- Power Cord
- Pneumatic Footswitch

Please contact BUFFALO FILTER Customer Service to purchase the following accessories:

- Replacement Filters
- EZ Link® Remote Activator
- Hoses, Tubing, Laparoscopic Kits, Adapters, Wands & Other Accessories

1.3 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 BUFFALO FILTER Turbo Auto-Sense™ Smoke Evacuation System(s) complies with IEC60601.1 electrical specifications in the following systems:
100/120 VAC 50/60 Hz, 220/240 VAC 50/60 Hz
2. Type of protection against electrical shock (UL 60601-1, Clause 5.1): Class I
3. Degree of protection against electric shock (UL 60601-1, Clause 5.2); Type CF Applied Part
4. Degree of protection against ingress of water (UL 60601-1, Clause 5.3): IPX1
5. Method of sterilization or disinfection recommended by BUFFALO FILTER (UL 60601-1, Clause 5.4):
Unplug Unit. Wipe unit with a damp cloth containing mild disinfectant solution or soapy water. Wipe dry with a clean cloth. Do not steam sterilize.
6. Degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide (UL 60601-1, Clause 5.5): Not Suitable
7. Mode of operation (UL 60601-1, Clause 5.6): Continuous
8. Upon request, BUFFALO FILTER will provide the following:
Service and Repair Instructions, including Circuit Diagrams and Parts List
9. The fuses in the power entry module are to be serviced by an authorized BUFFALO FILTER technician as follows:
100/120 VAC, 50/60 Hz use 10 Amp 250 Volt Fuse (Slo-Blo)
220/240 VAC, 50/60 Hz use 8 Amp 250 Volt Fuse (Slo-blo)

10. This equipment needs special precautions regarding Electromagnetic Compatibility and needs to be installed according to EMC information found in this manual.
11. This equipment utilizes mobile RF communications equipment that can affect medical electrical equipment.
12. This equipment 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.
13. This equipment operates in the following radio frequency specifications:
 - RX modulation: Pulse-width coded, AM 100% modulation
 - TX Frequencies: Manchester encoded,
 $A = fc \pm 423.75\text{kHz}$, $B = fc \pm 484.29\text{kHz}$
 - Low bit: transition A to B
 - High bit: transition B to A
14. To isolate equipment from supply mains, unplug the power cord from the appliance inlet on the unit or receptacle in the wall. Position the equipment to allow for ease of unplugging power cord.
15. Potential Equalization Conductor: Terminal located on back panel for connection of potential equalization. Conductor complies with requirements per IEC 60601-1 (2005).

The Turbo Auto-Sense™ Smoke Evacuation System(s) and all filters are not intended for contact with patients.

1.4 Cautions and Warnings



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

1.4.1 WARNINGS:


- Read this manual thoroughly, and be familiar with its contents prior to using this equipment.
- Test this equipment prior to a surgical procedure. This product was thoroughly tested at the factory before shipment.
- Disconnect the unit from the electrical outlet prior to inspecting system components.
- The Turbo Auto-Sense™ system is only intended and suitable for the applications that are mentioned in the operating instructions.
- **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.**
- **To maximize patient safety, the tubing or wand should not come into direct contact with tissue. Otherwise, patient injury may result.**
- The BUFFALO FILTER ViroSafe® filters and single-use accessories are completely disposable. Please dispose of according to your local codes or regulations and hospital policy. These filters may be disposed of or incinerated, whichever is appropriate for your institution.
- Care should be taken to route the power cord, foot pedal, smoke evacuation tubing, and EZ Link cable as to not cause a tripping hazard or crimping of cords.
- Do not operate this device in the presence of flammable or explosive gases.
- This equipment is intended for use by healthcare professionals only. This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Turbo Auto-Sense™ or shielding the location.
- The use of ACCESSORIES other than those specified by BUFFALO FILTER, or sold by BUFFALO FILTER as replacement parts for internal components, may result in increased emissions or decreased immunity of the Turbo Auto-Sense™.
- This equipment should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Turbo Auto-Sense™ should be observed to verify normal operation in the configuration in which it will be used.

- Refer routine servicing to qualified biomedical technical personnel.
- Changes or modifications not expressly approved by Buffalo Filter could void the manufacturer's warranty.
- To avoid risk of Electric Shock, this equipment must only be connected to a supply mains with protective earth.

The warranty on this product is void if any of these warnings are disregarded.











1.4.2 CAUTIONS:

- Federal law (United States of America) restricts this device to be used by, or on the order of a physician.
- 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.
- Using any other filter or accessory not supplied by BUFFALO FILTER may cause damage and/or cause the system to be inoperable and may void the warranty.
- 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.
- When using an accessory that will be connected to a surgical cannula, ensure that a mechanical means of closing the flow to the evacuator is available, such as a stopcock to prevent unwanted loss of pneumo gasses during the procedure or in case of system failure.
- This device is not intended for evacuation of fluid. If fluid is expected to be aspirated to the ViroSafe® 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.
- The ViroSafe® Filter should be changed according to the life of the filter. The ViroSafe® Filter, used with the Turbo Auto-Sense™ Smoke Evacuation System(s), 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.
- Do not block either the tubing or the filter during operation. An occlusion or significant restriction may cause the motor to overheat and the unit to stop working.

- 
- The installation of this equipment must be performed such that the intake and exhaust vents located on the bottom of the system are not obstructed. Failure to properly install the unit may cause reduced performance, damage and/or cause the system to be inoperable and may void the warranty.
 - The ambient temperature during operation must be kept between 50°F to 104°F (10°C to 40°C)
 - The relative humidity during operation must be kept between 10% to 75%.
 - An atmospheric pressure range of 700 hPA to 1,060 hPa.
 - Storage environmental ambient temperature 14°F to 140°F (-10°C to 60°C).
 - Storage environmental relative humidity 10% to 75%.

There are no user serviceable components in the Turbo Auto-Sense™ Smoke Evacuation System(s). Refer service to qualified service personnel.

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

Symbol	Description / Meaning
	DANGER HIGH VOLTAGE CAUTION - ELECTRICAL SHOCK HAZARD. DO NOT REMOVE COVER. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL.
	WARNING
	TYPE CF APPLIED PART
IPX1	PROTECTION AGAINST INGRESS OF WATER AS DETAILED IN IEC 60529
	ALTERNATING CURRENT
	PROTECTIVE EARTH, (GROUND)
	EQUIPOTENTIALITY
	DENOTES THE DATE THE EQUIPMENT WAS MANUFACTURED
	DENOTES THE MANUFACTURER OF THE DEVICE
	NON-IONIZING RADIATION
	CONSULT INSTRUCTIONS

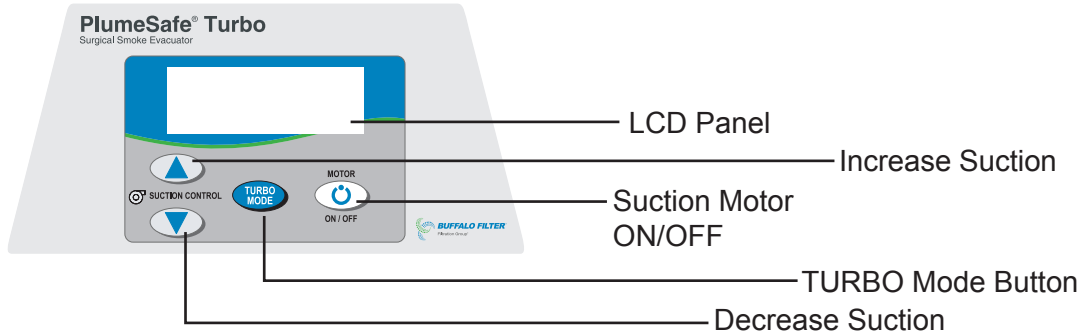
Operating Instructions

Section 2.0

2.1 System Controls

The Turbo Auto-Sense™ LCD control display is user-friendly and completely interactive, allowing for easy to understand use (as displayed on the LCD screen).

Key Pad Diagram:



The following items are important for the operation of your system

POWER ON/OFF

The main power switch is located on the rear panel of your smoke evacuator. This switch completely enables and disables the main power.

When the unit is powered on the following LCD screen will appear.

After inserting a filter a screen will flash for a few seconds to indicate filter type and original life.

Next, the standard screen will appear which displays information regarding the unit's current activity.

```
BUFFALO FILTER
INSERT VIROSAFE
FILTER
```

```
BUFFALO FILTER
VIROSAFE-XLL
18 HOUR FILTER
```

```
Virosafe-XLL   HR-MN
Time Remaining 17-31
Suction Setting 0%
Mode-NORML Motor-OFF
```

MOTOR ON/OFF

The Motor ON/OFF button is located on the LCD key pad (Figure 1). This button turns the motor (for suction) on and off.

SUCTION CONTROL

The amount of suction may be adjusted using the UP or DOWN arrow buttons located on the key pad (Figure 1). It is recommended that you select the lowest suction setting that effectively clears the operative field of surgical smoke.

TURBO MODE

The TURBO button is located on the key pad (Figure 1). The amount of suction is significantly increased when this button is pressed. To return to NORMAL mode, press the TURBO button again.

FILTER LIFE REMAINING

The exact number of hours and minutes remaining on the ViroSafe® filter (in use) are displayed on the LCD screen. When the filter's life is consumed, time remaining will indicate that there are 0 hours and 0 minutes remaining. This line will continually flash. When the filter life reaches this point, a new filter with time remaining should be inserted; however, the suction will still work. When the unit's main power is turned off or the system is left idle for more than 6 hours, a new filter or a filter with remaining filter life MUST be inserted into the filter basket to allow the unit's suction to turn back on.

When the filter's life is exhausted the LCD screen will flash "REPLACE FILTER."



FOOTSWITCH

A pneumatic footswitch is provided. To activate the footswitch, simply plug the footswitch tubing into the jack (↗) on the rear panel. The suction can now be switched ON/OFF by depressing the footswitch.

EZ LINK® REMOTE ACTIVATION DEVICE (EZLINK01)

For directions on using the EZ Link®, see instructions accompanying the EZLINK01.

CIRCUIT FUSES

Two 10 amp circuit fuses (8 amp for International systems) are located on the rear panel within the power entry module. These circuit fuses protect both the system and the operator from damage or injury.

SERVICE

When a service message appears, please contact Buffalo Filter Customer Service for instructions. Below are some examples of service screens that may appear.

If this screen appears the system may be in need of service for the motor.
Call Buffalo Filter.

**Brush Hours=500
IF OVER 500HRS CALL:
1-800-343-2324
1-716-835-7000**

If this screen appears there may be a problem with your system or filter.
Call Buffalo Filter.

**FILTER I.D. ERROR!
CALL FOR SERVICE
1-800-343-2324
1-716-835-7000**

SETTING THE DEFAULT LANGUAGE

1. Turn the main power on without filter inserted.
2. Scroll through languages using suction control arrow buttons and select a language by pressing motor button.
3. Smoke Evacuator will use this language as the default language.
4. To change the default language, remove filter and press motor on and turbo button simultaneously.
5. Repeat step 2.

2.2 ViroSafe® Filter Instructions

Buffalo Filter P/N:	PSWTURBO AS & PSWTURBO AS/220
Configuration:	Portable or tabletop
ViroSafe® Filters - Multi Port Filter:	4-Stage Filtration In One Casing, (Pre-Filter, ULPA, Carbon, Post-Filter)
Filter(s):	ULPA
Particle Size, µm:	0.1 to 0.2 Microns At 99.999% Efficiency
Filter Life:	Automatic Factory Set Filter Sensor
Filter Life Indicator:	Timed Replacement
ViroSafe® Filter P/N:	(Call for selection)

Note: Before installing or removing any filter, be sure that the system is turned off.

Filter Installation Instructions:

The installation of the ViroSafe® Filter into the BUFFALO FILTER Turbo Auto-Sense™ Smoke Evacuation System(s) is quick and simple.

1. Remove the ViroSafe® 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 ViroSafe® Filter into the filter receptacle. Be sure that the filter is seated completely against the bottom of the filter chamber.

WARNING: This device is not intended for evacuation of fluid. If fluid is expected to be aspirated using the ViroSafe® Filter or the BUFFALO FILTER Turbo Auto-Sense™ 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 ViroSafe® Filter has been exhausted and requires changing, turn the smoke evacuation system off and disconnect any accessory tubing attached to the filter.
2. Pull the ViroSafe® Filter from the smoke evacuation system and dispose of in accordance with hospital policy. The ViroSafe® 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 ViroSafe® Filter.

CAUTION: Using any other filter or accessory not supplied by BUFFALO FILTER may cause damage to the system and/or cause the system to be inoperable and may void the warranty.

WARNING: The ViroSafe® Filter should be changed when the Filter Life Indicator on the LCD displays “REPLACE”. 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, or non-operation of smoke evacuator.

2.3 Set-Up and Operation

The operation of the Turbo Auto-Sense™ Smoke Evacuation System is as follows:

1. Install the ViroSafe® Filter.
2. Attach unit power cord to the receptacle on the rear of the system. Plug the pronged power cord into an appropriate grounded power outlet. Route power cord in such a way as to minimize potential trip hazard by users or patients or pinch hazard that could cause electric shock.
3. Optional: Attach either EZ Link® or Footswitch plug into appropriate jack on rear or side of machine. Route footswitch or cord in such a way as to minimize potential trip hazard by users or patients or pinch hazard that could result in unreliable operation.
4. Ensure that the evacuation tubing is fully seated in the inlet of the filter. Route tubing in such a way as to minimize potential trip hazard by users or patients.
5. Activate the power unit by:
 - a. Toggle the rocker switch on the rear of the unit to the ON position, or
 - b. Depressing and releasing the footswitch (if connected), or
 - c. Activating either CUT or COAG on the Electrosurgical Pencil (if EZ Link is connected).
6. Adjust the suction level to the desired setting by pressing the UP/DOWN arrow button 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.
7. Deactivate the unit by:
 - a. Toggle the rocker switch on the rear of the unit to the OFF position, or
 - b. Depressing and releasing the footswitch (if connected), or
 - c. Releasing either the CUT or COAG button on the Electrosurgical Pencil (If EZ Link is connected).
8. Replace the ViroSafe® Filter when the Filter Life Remaining indicator on the LCD Display flashes REPLACE FILTER. Failure to change the filter will affect the performance of the system.

2.4 Performance References*

PERFORMANCE*		
Model Number		Turbo Auto-Sense™ 110v
Maximum Flow Setting (CFM-U.S.)		
Standard Hose I. D.		
	1 3/8"	79 CFM
	1 1/4"	67.9 CFM
	7/8"	44 CFM
	1/4"	5.2 CFM
Standard Hose I. D.		
	35mm	2237 LPM
	32mm	1923 LPM
	22mm	1257 LPM
	6.4mm	147 LPM
Dimensions (H x W x D)	inches	13.75 x 8 x 17.23
Dimensions (H x W x D)	centimeters	34.93 x 20.32 x 43.76
Weight	lbs (kg.)	13.75 (6.24)
Noise Level, dBA	MAXIMUM**	58 dB
Footswitch Pneumatic		Standard
Remote Control Activation		YES (optional)
Safety Features		UL Classified
		CE Marked
		Fuse Protection
Display		LCD
		Filter Status
		Flow Rate
		Service Required
Voltage Available		100/120 VAC
Frequency, auto sensed		50/60 Hz
Variable Flow Control		Yes
Motor	Watts	1000 ±10%
Motor Static Suction		85 inches H O
	(6.5 mm orifice)	(211 mbar)

*For reference purposes only

**using a new 7/8" x 6' hose

PERFORMANCE*		
Model Number		Turbo Auto-Sense™ 220v
Maximum Flow Setting (CFM-U.S.)		
Standard Hose I. D.		
	1 1/4"	43 CFM
	7/8"	35 CFM
	1/4"	2 CFM
Standard Hose I. D.		
	35mm	1218 LPM
	22mm	991 LPM
	6.4mm	56 LPM
Dimensions (H x W x D)	inches	6 x 11 x 15.5
Dimensions (H x W x D)	centimeters	15.2 x 27.9 x 39.4
Weight	lbs (kg.)	4.3
Noise Level, dBA	MAXIMUM**	60 dB
Footswitch Pneumatic		Standard
Remote Control Activation		YES (optional)
Safety Features		UL Classified
		CE Marked
		Fuse Protection
Display		LCD
		Filter Status
		Flow Rate
		Service Required
Voltage Available		220/240 VAC
Frequency, auto sensed		50/60 Hz
Variable Flow Control		Yes
Motor	Watts	1000 ±10%
Motor Static Suction	kPa	
	(6.5 mm orifice)	(21.1)

*For reference purposes only

**using a new 7/8" x 6' hose

Table 1

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The Smoke Evacuation System Model Turbo Auto-Sense™ is intended for use in the electromagnetic environment specified below. The customer or user of the Turbo Auto-Sense™ should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The Turbo Auto-Sense™ uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The Model Turbo Auto-Sense™ is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	Not applicable.
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Class A	Not applicable.

Table 2

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Model Turbo Auto-Sense™ is intended for use in the electromagnet environment specified below.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electromagnetic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines. IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Model Turbo Auto-Sense™ requires continued operation during power mains interruptions, it is recommended that the Model Turbo Auto-Sense™ be powered by an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 3


Guidance and Manufacturer's Declaration - Electromagnetic Emissions			
The model Turbo Auto-Sense™ is intended for use in the electromagnetic environment specified below. The customer or end user of the Turbo Auto-Sense™ should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the <i>Surgical Smoke Evacuator</i> including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. $d = 1.7 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz $d = [3.5/V1] \sqrt{P}$
Conducted RF IEC 61000-4-6	150 kHz to 80 MHz		Where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and D is the recommended separation distance in meters (M). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structure, objects and people.			
<p>^aField strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the <i>Surgical Smoke Evacuator</i> is used exceeds the applicable RF compliance level above, the <i>Surgical Smoke Evacuator</i> should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the <i>Surgical Smoke Evacuator</i>.</p> <p>^bOver the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Table 4

Recommended Separation Distance Between Portable and Mobile RF Communications Equipment and the model @ 3 Vrms

The Turbo Auto-Sense™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Turbo Auto-Sense™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Smoke Shark II as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80MHz	80 kHz to 800 MHz	800 kHz to 2.5 GHz
	$d = \left[\frac{3.5}{v_1} \right] \sqrt{P}$	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.34	0.34	0.74
1	1.7	1.7	2.3
10	3.7	3.7	7.4
100	11.7	11.7	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation Distance (D) in Meters (M) can be estimated using the equation applicable to the frequency of the transmitter, where (P) is the maximum output rating of the transmitter in Watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structure, objects, and people.

Maintenance

Section 3.0

3.1 General Maintenance Information

This section contains information for ordinary upkeep of the BUFFALO FILTER Turbo Auto-Sense™ Smoke Evacuation 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.

3.2 Cleaning

Unplug Unit. Wipe unit with a damp cloth containing mild disinfectant solution or soapy water. Wipe dry with a clean cloth. Do not steam sterilize.

3.3 Periodic Inspection

The Turbo Auto-Sense™ Smoke Evacuation 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 or power inlet module.
- Proper mating, cleanliness and absence of damage to the filter inlet.
- Obvious external or internal damage to the system.

3.4 Troubleshooting the System – see below.

PROBLEM	POTENTIAL CAUSE	CORRECTIVE ACTION
1. Smoke Evacuation System is ON but suction is minimal or none.	1. Filter is not seated completely.	1. Re-install ViroSafe® Filter, press firmly into place and fully engage clip.
	2. Filter is clogged.	2. Replace filter with a genuine ViroSafe® Filter.
	3. Vacuum tubing is clogged.	3. Replace vacuum hose or tube with genuine Buffalo Filter® products.
	4. Motor/blower is obstructed.	4. Call BioMed or Buffalo Filter Technical Services at 1.800.343.2324 or +1.716.835.7000.
2. Smoke Evacuation System does not function even though suction ON button is depressed.	1. Not plugged into an electrical outlet.	1. Check power outlet and connection to rear or side panel of the machine.
	2. Fuses are blown.	2. Call BioMed or Buffalo Filter Technical Services at 1.800.343.2324 or +1.716.835.7000
	3. Electronic system failure.	3. Call BioMed or Buffalo Filter Technical Services at 1.800.343.2324 or +1.716.835.7000
	4. Filter life has expired or invalid filter installed.	4. Replace filter with a genuine Bovie® SF35 filter.

Customer Service

Section 4.0

4.1 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 Turbo Auto-Sense™ Smoke Evacuation 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 Material Authorization” (RMA) number from Customer Service before returning the system.

Step 4: If you have the original packing for your Turbo Auto-Sense™ Smoke Evacuation 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. Address will be supplied by Customer Service.

4.2 Ordering Information

To reorder, obtain replacement parts or to return a unit for service, call Customer Service at:

800-343-2324
OR
(716) 835-7000

or contact your authorized BUFFALO FILTER Distributor/Representative.

BUFFALO FILTER Turbo Auto-Sense™ Smoke Evacuation System versions available:

- 100/120 VAC 50/60 Hz
- 220/240 VAC 50/60 Hz

Available accessories:

- ViroSafe® Filters
- Suction Canister
- EZ Link® Remote Activation Device
- Hoses & Tubing
- Reducer Fittings
- Electrosurgical Pencil Adapters
- Electrosurgical Smoke Pencil

Terms & Warranty

Section 5.0

SPECIFICATIONS:

Specifications are subject to change without notice.

SHIPMENT OF ORDER:

Buffalo Filter will try to accommodate individual customer requests for shipping method. Buffalo Filter reserves the right to decide shipping method on prepaid orders. Care is exercised in the checking and packaging of all merchandise to avoid error, but should discrepancies arise, claims should be made within 24 hours after delivery. Buffalo Filter'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. Buffalo Filter will assist customers in pursuing these claims.

RETURN OF MATERIAL:

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

WARRANTY*:

Buffalo Filter warrants that the filter system manufactured by Buffalo Filter shall be free from defects in material and workmanship. Products are warranted only to the extent that Buffalo Filter will replace without charge any filter systems proved to have defects within three (3) years of the date of delivery for P/N PSWTURBO AS & PSWTURBO AS/220 and provided Buffalo Filter has been given the opportunity to inspect the system alleged to be defective and the installation or use thereof. No warranty is included for incidental or consequential damages of any nature arising from any defect. The warranty above is the only warranty made by Buffalo Filter and is expressly in lieu of all other warranties, expressed or implied, including, without limitation, the warranties of merchantability and fitness for a particular purpose. All warranties implied by any course of dealing or usage between parties are expressly excluded.

CONFIDENTIAL INFORMATION:

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

CONSEQUENTIAL DAMAGES/LIMITS OF LIABILITY:

Buffalo Filter shall not in any case whatsoever be liable for special, incidental, indirect or consequential damages of any kind. In no case shall Buffalo Filter's liability exceed the amount paid Buffalo Filter by purchaser for the specific system giving rise to the liability. Purchaser agrees to indemnify and hold Buffalo Filter 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 Buffalo Filter's offer does acknowledge and agree to the terms and conditions contained herein. All matters involving the validity, interpretation and application of this agreement shall be controlled by the laws of New York State. Using any filter not manufactured by Buffalo Filter may cause damage to the systems and will be cause for voiding the warranty.

JURISDICTION:

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

*** An Extended Warranty Plan is available for purchase for the Turbo Auto-Sense™ Smoke Evacuation System. Please contact Buffalo Filter Customer Service for more information.**



Buffalo Filter LLC

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