VisiClear™
Surgical Smoke Plume Evacuator

Operator's Manual

BUFFALO Filter
World Leader in Surgical Smoke Evacuation™

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(716) 835-7000 or (716) 835-3414 fax
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Customer Service: 800-343-2324 (U.S. Only)
1-716-835-7000 (International)

For a period of three (3) years following the date of delivery, BUFFALO FILTER® warrants the VisiClear™ 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 902909REVA

Unit Serial Number _____

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

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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1.1 Introduction

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

The VisiClear™ Surgical Smoke Plume Evacuators have been designed with a vacuum motor. The motor is used to draw the surgical smoke from the surgical site through the vacuum tubing and into the VisiClear™ 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® VisiClear™ 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 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 is comprised 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.

The electronic controls on the face panel of the VisiClear™ Surgical Smoke Plume Evacuator 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 VisiClear™ Surgical Smoke Plume 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 (Outside the US).

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
- EZLink™ Automatic Activation Device
- 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® VisiClear™ Surgical Smoke Plume Evacuator(s) complies with IEC60601-1:2005 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: Class I
3. Degree of protection against electric shock: Type CF Applied Part
4. Degree of protection against ingress of water: IPX1
5. Method of sterilization or disinfection recommended by BUFFALO FILTER®:
   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: Not Suitable
7. Mode of operation: Continuous
8. The fuses on the circuit board are (F1, F20 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)
   with Interruption Rating: 1500A@250V
   220/240 VAC, 50/60 Hz use 8 Amp 250 Volt Fuse (Slo-Blo)
   with Interruption Rating: 1500A@250V
9. The fuse on the transformer circuit (F6) to be serviced by an authorized BUFFALO FILTER® technician as follows:
   100/120 VAC, 50/60 Hz use 100 Amp 250 Volt Fuse (Fast-Act)
   with interruption rating: 1500A@250V
   220/240 VAC, 50/60 Hz use 50Amp 250 Volt Fuse (Fast-Act)
   with interruption rating: 1500A@250V
10. The fuses on the motor circuit are to be serviced by an authorized BUFFALO FILTER® technician as follows: 220/240 VAC, 50/60 Hz use 3,15 Amp 250 Volt Fuse (Fast-Acting), (F3)
    with Interruption Rating: 1500A@250V
11. This equipment needs special precautions regarding Electro Magnetic Compatibility and needs to be installed according to EMC information found in this manual.

12. This equipment utilizes mobile RF communications equipment that can affect medical electrical equipment.
13. 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.
14. This equipment operates in the following radio frequency specifications:
    RX modulation: Pulse-width coded, AM 100% modulation
    TX Frequencies: Manchester encoded,
        A = fc =/- 423.75kHz, B = fc +/- 484.29kHz
    Low bit: transition A to B
    High bit: transition B to A
15. 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.
16. Potential Equalization Conductor: Terminal located on back panel for connection of potential equalization. Conductor complies with requirements per IEC 60601-1 (2005).

The VisiClear™ Surgical Smoke Plume Evacuator(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.

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

This device does not have any contradictions for use.

1.4.1 WARNINGS:

- Read this manual thoroughly and be familiar with its contents prior to using this equipment.

- This equipment is intended for use by trained 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 VisiClear™ or shielding the location.
- 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 VisiClear™ system is only intended and suitable for the applications that are mentioned in the operating instructions.
- **The smoke plume 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 plume 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® VisiClear™ 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 EZLink™ Automatic Activation Device 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.

- To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- 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 VisiClear™.
- This equipment should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the VisiClear™ 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 user's authority to operate the equipment.

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.
- The VisiClear™ motor generates heat during operation. To prevent exposure to heat generated by the motor, avoid hand placement on or around the exhaust louvers on the bottom of the unit during or immediately after operation.
- 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.
- Only ViroSafe™ 135 filters were demonstrated to be compatible with the VisiClear™ smoke evacuator. Do not use any other filters with this system.
- 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.
- 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.

- This device is not intended for evacuation of fluid. If fluid is expected to be aspirated to the 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 VisiClear™ Filter should be changed according to the life of the filter. The VisiClear™ Filter, used with the VisiClear™ Surgical Smoke Plume Evacuator(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. The filter life time and RFID Technology is a measure of time only, not a measure of filter performance.
- 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 to140°F (-10°C to 60°C).
- Storage environmental relative humidity 10% to 75%.

There are no user serviceable components in the VisiClear™ Surgical Smoke Plume Evacuator(s). Refer service to qualified service personnel.

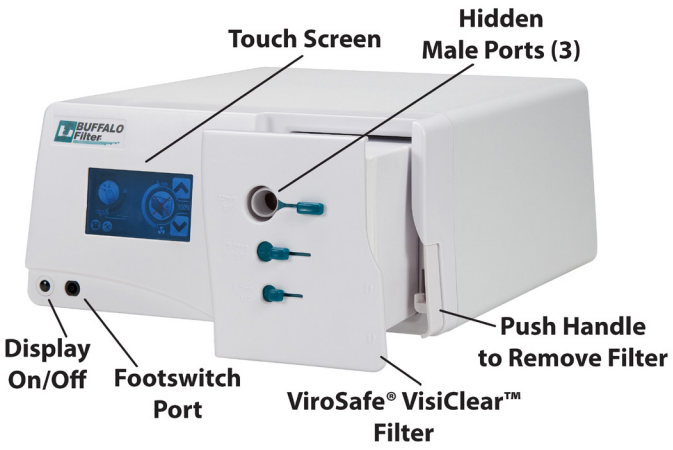
Use only with the power cord provided and always plug into a grounded outlet.

Symbol	Description / Meaning
	CAUTION
	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
	AUTOMATIC ACTIVATION DEVICE
	FOOTSWITCH

2.1 System Controls

The electronic system controls on the VisiClear™ Surgical Smoke Plume Evacuator(s) are easy to understand and simple to use. To power up the machine, connect the supplied power cord to a grounded outlet and the appliance inlet on the back of the smoke evacuation system. Once power has been applied, the unit's touch screen will illuminate and a start up process will begin. This will take about 20 seconds to complete. During this time, Buffalo Filter's logo will appear on the touch screen followed by the name of the system; VisiClear™.

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.



The Display On/Off button located on the front of the panel of the VisiClear™ system will activate or deactivate the touch screen control panel as well as any unit functionality. Power will remain to the system unless the system's power cord is unplugged.

MODE OF OPERATION

After the start-up process is complete, the touch screen control panel will appear and contain buttons to select mode of operation. The choices are Open Tubing, Electrosurgical Pencil Attachment/Integrated Smoke Plume Evacuation Pencil, or Laparoscopic Tubing. See Figure 1.

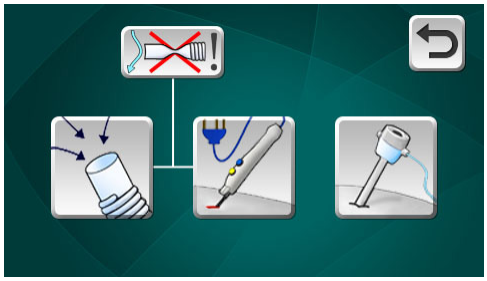


Figure 1.

Please select the mode that is appropriate for your clinical application. The VisiClear™ system will automatically adjust filter life based on the amount of flow needed for these applications.

During an open procedure in which a smoke plume evacuation hose will be utilized, please select the Open Tubing Button. When using either an attachment to your electrosurgical pencil or an integrated smoke plume evacuation pencil such as Buffalo Filter's PlumePen™, please select the Electrosurgical/Diathermy Mode Button. Finally, when attaching to a surgical cannula during laparoscopic procedures, please select the Laparoscopic Button.

At any point, when you would like to return to the previous menu on the VisiClear™ touch screen, use the Back Button to return to the previous screen. See Figure 2.

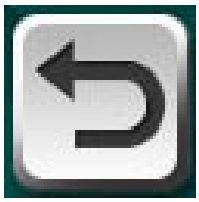


Figure 2.

SUCTION ON & STANDBY

Once the mode is selected on the touch screen interface (See Figure 1), the mode you have selected will appear on the left side of the touch screen. You can activate or deactivate the flow of suction by pressing the button that appears like a fan blade on the unit's touch screen. The fan image will begin to rotate to indicate that the unit's motor is running and the flow of suction has begun. See Figure 3.

Figure 3.

SUCTION CONTROL

The amount of suction may be adjusted by pressing the suction control buttons located to the right of the fan image. Each time the suction control up or down button is depressed, the motor speed is increased or decreased by 10%. The suction speed will not loop. The suction control should be set at the lowest practical setting to completely remove the surgical smoke from the operative site. See Figure 4.

Figure 4.

FOOTSWITCH / EZLINK AUTOMATIC ACTIVATION DEVICE

The VisiClear™ Surgical Smoke Plume Evacuator also comes equipped with a pneumatic footswitch. A footswitch or an EZLink Automatic Activation Device may be added to any system by simply plugging in a BUFFALO FILTER® activation accessory into the appropriate jack on either the front (footswitch) or back (EZLink) panel 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 directions on using the EZLink Automatic Activation Device, please see instructions that accompany that product.

FILTER LIFE INDICATOR

The filter life indicator on the touch screen control panel provides a visual indication of the status of the life of the filter in use. The filter life indicator for the VisiClear™ Surgical Smoke Plume Evacuator will automatically adjust according to the mode setting selected.

CAUTION: Using The filter life time and RFID Technology is a measure of time only, not a measure of filter performance.

Laparoscopic Mode = 35 hours of filter life
Electrosurgical/Diathermy Mode = 21 hours of filter life
Open Tubing Mode = 18 hours of filter life
The VisiClear™ Filter Life Indicator is factory set. All filter life timing is automatic. See Figure 5.

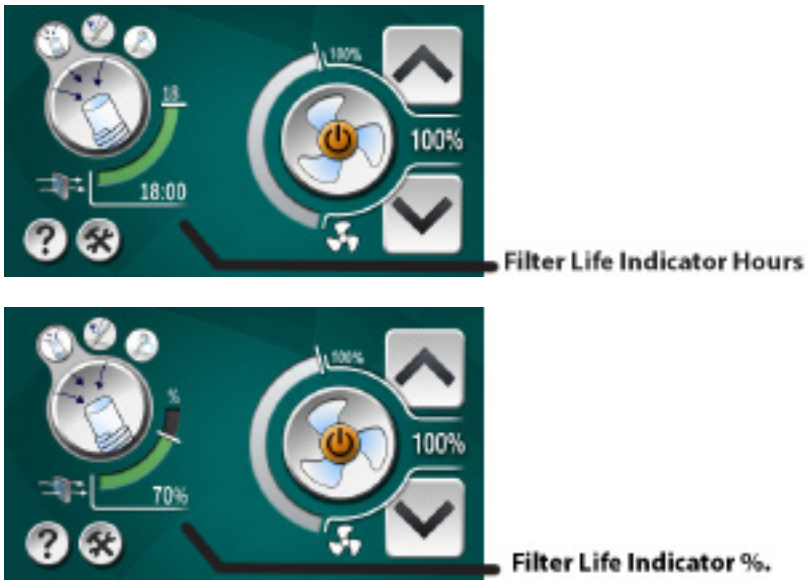


Figure 5.

Filter life can be displayed in both hours and minutes or as a percentage using the Settings button located in the lower left section of the touch screen. See Figures 6 and 7.

Figure 6.

Figure 7.

When the maximum filter life is consumed, the following warning screen will appear indicating that a filter replacement is needed. After inserting a new VisiClear™ Filter, press the green check mark to clear the warning and resume normal operation. During operation, if a filter expires the system will not turn off but will remain running until the system is powered down or 6 hours passes, whichever comes first. At that point, the VisiClear™ will no longer operate until a new filter is inserted into the system. It is always best practice to replace an expired filter immediately; however, a validated contingency life is built into the filter to ensure no interruption to the operative procedure. See Figure 8.

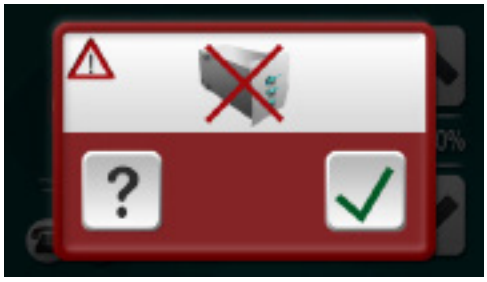


Figure 8.

VISICLEAR™ OCCLUSION ALARM:
The VisiClear™ Surgical Smoke Plume Evacuator is equipped with an occlusion alarm for certain system settings. The default setup for the device has this option disabled. If you wish to utilize the occlusion alarm, during initial start-up please enable by pressing the alarm icon located on the top left of the screen until the red X is not visible. See Figure 9.

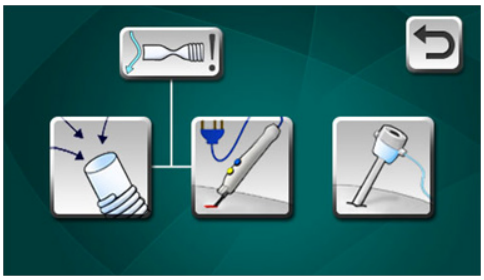


Figure 9.

OPEN TUBING MODE:
When the system is in an open tubing mode, the unit will alarm if suction is obstructed by an object. If an obstruction occurs, the system will alarm, the suction will stop, and the following screen will display. See Figure 10.

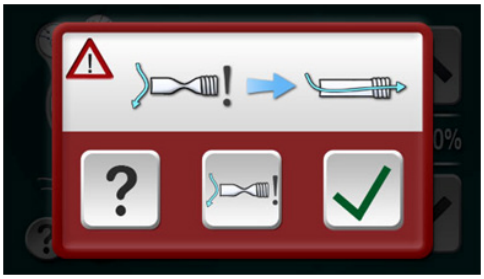


Figure 10.

The unit will continue to cycle the suction, checking to see if the obstruction has been cleared. If the obstruction is cleared, the alarm will automatically turn off and the system will resume normal operation. The user also has the option of disabling the alarm during continued use. If the obstruction is not removed or you wish to disable this feature, you may disable the alarm by pressing the following button on the alarm screen until the red X appears on the occlusion symbol as shown. See Figure 11.

Figure 11.

ESU PENCIL MODE:
When the system is in an ESU Pencil mode and suction setting is 50% or higher, the unit will alarm and the suction will stop if obstructed by an object. If an obstruction occurs, the system will alarm and the following screen will display. See Figure 12.

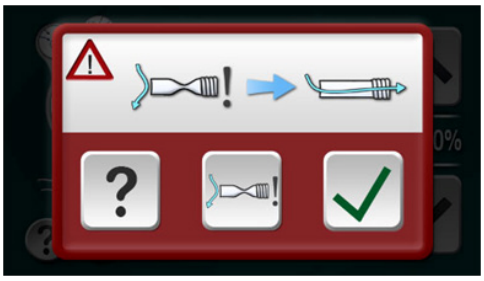


Figure 12.

You have the option of clearing the obstruction (recommended) or disabling the alarm. Please note: If the obstruction is cleared in ESU Pencil mode, the alarm will not automatically turn off. Once the obstruction is removed, to reactivate the unit to normal operation, please press following button on the alarm screen. See Figure 13.

Figure 13.

If the obstruction is not removed or you wish to disable this feature, you may disable the alarm by pressing the following button on the alarm screen until the red X appears on the occlusion symbol as shown. See Figure 14.

Figure 14.
Once the alarm is disabled, please press the green checkmark to remove the warning screen and resume normal operation.

LAPAROSCOPIC MODE:
The occlusion alarm is not functional in the Laparoscopic mode on the VisiClear™ system and will default off in this mode.

In any of the system's modes, if you choose to deactivate the occlusion alarm, you may do so on the home screen by pressing the alarm icon located on the top left of the screen until a red X appears on the occlusion symbol as shown. See Figure 15.

Figure 15.

ADDITIONAL WARNING SCREENS

If the VisiClear™ motor nears the end of its life or if a problem arises with the motor, the following warning screen will appear. See Figure 16.

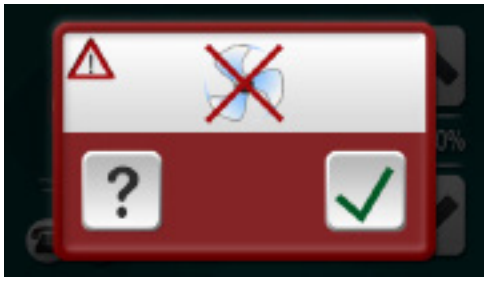


Figure 16

If this message occurs, it is appropriate to notify BioMed or contact BUFFALO FILTER® to arrange service of the VisiClear™ system. The system will continue to operate by pressing the check mark button unless a fatal condition has taken place with the motor. If the system does not respond after the check mark button is pressed, contact BioMed or BUFFALO FILTER® to arrange service of the VisiClear™ system.

Buffalo Filter's contact information can be located by pressing the question mark button located on the lower left section of each of the warning screens as well as the lower left portion of the main screen. See Figure 17.

Figure 17.

SERVICE AND CONTACT

Should you need to contact BUFFALO FILTER® for service or other customer support needs, simply press the button shown in Figure 11 from any of the three warning screens or from the main operating screen and the following information will appear. See Figure 18.

Figure 18.

SETTINGS

The VisiClear™ Surgical Smoke Plume Evacuator is flexible in its user settings and can be customized in a number of fashions. As explained in the Filter Life Indicator section above, filter life can be displayed in both hours and minutes or as a percentage of remaining life. Simply press the Settings Button shown in Figure 5 and press the % 0:00 filter setting button to toggle between time and percentage filter life display. See Figure 19.

Figure 19.

You may also adjust the brightness of your touch screen display by pressing the button that contains a sun illustration. See Figure 20.

Figure 20.

Once you press this button, the screen below will appear and you may use the negative button to decrease brightness or positive button to increase brightness. See Figure 21.

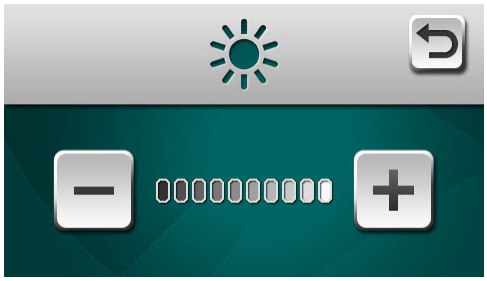


Figure 21.

The VisiClear™ also allows you to increase or decrease the amount of time the VisiClear™ System remains on after release of the electrosurgical button when the system is coupled with our EZLink Automatic Activation Device. This delay is for the purpose of capturing residual smoke plume that may linger after the electrosurgical unit is deactivated. By pressing the button indicated an electrosurgical pencil and hourglass, you can adjust the delay from 0-10 seconds by pressing the negative sign to decrease the delay or the positive sign to increase the delay. If the EZLink is set to 3 seconds and the VisiClear™ is set to +5 the actual delay time will be 8 seconds. See Figures 22 and 23. You may press the Back Button to return to the previous menu.

Figure 22.

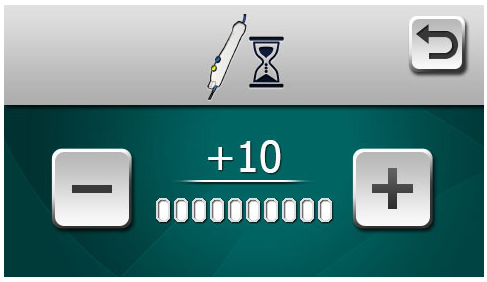


Figure 23.

FUSES (circuit board)

Two 10 AMP fuses (8 AMP for 220/240 VisiClear™ Systems) are located on the circuit board within the housing of the system. It electrically protects both the systems and the operator from damage or injury. If the system is overheated or if there is an electrical surge in the electrical system, fuses will break and the system will not operate.

When the Service light illuminates, please contact BUFFALO FILTER® Customer Service for system service instructions.

2.2 VisiClear™ Filter Instructions

Buffalo Filter VisiClear™ P / N	VSI35 (also available in 2 pack and 4 pack)
VisiClear™ Filter - 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	Time Replacement

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

Filter Installation Instructions:

The installation of the VisiClear™ Filter into the BUFFALO FILTER® VisiClear™ Surgical Smoke Plume Evacuator(s) is quick and simple.

1. Remove the VisiClear™ 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 VisiClear™ Filter into filter receptacle. Be sure that the filter is seated completely against the bottom of the filter chamber and clip is fully engaged.

WARNING: This device is not intended for evacuation of fluid. If fluid is expected to be aspirated using the VisiClear™ Filter or the BUFFALO FILTER® VisiClear™ 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 VisiClear™ Filter has been exhausted and requires changing, turn the smoke evacuation system off and disconnect any accessory tubing attached to the filter.

2. Depress the tab and pull the VisiClear™ Filter from the smoke evacuation system and dispose of in accordance with hospital policy. The VisiClear™ 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 VisiClear™ 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 VisiClear™ Filter should be changed when the Filter Life Indicator touch screen indicates an expired filter. 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.

2.4 Performance References*

Performance		
Model Number		VisiClear™
Maximum Flow Setting (CFM-U.S.)		
Standard Hose I.D.		
	7/8”	30 CFM **
	3/8”	4.6 CFM
	1/4”	1.9 CFM
Standard Hose I.D.		
	22 mm	850 LPM **
	9.5 mm	130 LPM
	6.4 mm	54 LPM
Dimensions (H x W x D)	inches	7 x 14 x 16
Dimensions (H x W x D)	centimeters	17.8 x 35.6 x 40.6
Weight	lbs (kg)	17 lbs (7.7 kg)
Noise Level, dBA	MAXIMUM	55 dBA
Footswitch Pneumatic		Standard
Remote Control Activation		YES (optional)
Safety Features		UL Classified
		CE Marked
		Fuse protection
Display		Touch Screen
		Filter Status
		Flow Rate
		Service Information
Voltage Available		100/120 VAC, 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)	25.69

*For reference purposes only
**Using a new 7/8 in x 6 in (22 mm x 1.8 m) hose

2.5 Electromagnetic Compatibility Information per IEC60601-1-2

Table 1

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The Surgical Smoke Plume Evacuator model VisiClear™ is intended for use in the electromagnetic environment specified below. The customer or user of the VisiClear™ should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	The VisiClear™ 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 VisiClear™ 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 VisiClear™ is intended for use in the electromagnetic environment specified below. The customer or user of the model VisiClear™ should assure that it is used in such an environment.			
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)	<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)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Model VisiClear™ requires continued operation during power mains interruptions, it is recommended that the Model VisiClear™ be powered from an uniterruptible power supply or a battery.
	for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	
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 VisiClear™ is intended for use in the electromagnetic environment specified below. The customer or user of the model VisiClear™ should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Model EVL including cables, than the Recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF	3 V/m		d = 1.7 √P 80 MHz to 800 MHz
IEC 61000-4-3	80 MHz to 2.5 GHz	3 V/m	d = 2.3 √P 800 MHz to 2.5 GHz
		3 Vrms	d = [3.5/V1} √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 strengths 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.			
Field 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 Model EVL is used exceeds the applicable RF compliance level above, the model VisiClear™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model VisiClear™. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 4

Recommended Separation Distance Between Portable and Mobile RF Communications Equipment and the Model @ 3 Vrms			
The model VisiClear™ is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the model VisiClear™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model VisiClear™ 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 80 MHz $d = \left[\frac{3.5}{v_1}\right]\sqrt{P}$	80 kHz to 800 MHz $d = \left[\frac{3.5}{v_1}\right]\sqrt{P}$	800 kHz to 2.5 GHz $d = \left[\frac{3.5}{v_1}\right]\sqrt{P}$
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.			

3.1 General Maintenance Information

This section contains information for ordinary upkeep of the BUFFALO FILTER® VisiClear™. 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 prior to cleaning. Wipe unit with a damp cloth containing mild disinfectant solution. Do not clean smoke evacuator with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the touch panel or damage the smoke evacuator. Wipe dry with a clean cloth. Do not steam sterilize.

3.3 Periodic Inspection

The VisiClear™ Surgical Smoke Plume Evacuator 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. 2. Filter is clogged. 3. Vacuum hose or tube is clogged. 4. Motor/blower is obstructed.	1. Re-install VisiClear™ Filter, press firmly into place and fully engage clip. 2. Replace filter with a genuine Buffalo Filter VisiClear™ Filter. 3. Replace vacuum hose or tube with genuine Buffalo Filter products. 4. Call BioMed or BUFFALO FILTER® Technical Services at 1.800.343.2324 or 716.835.7000.
2. Smoke Evacuation System does not function even though suction ON button is depressed.	1. Not plugged into an electrical outlet. 2. Fuses are blown. 3. Electronic system failure. 4. Filter life has expired or invalid filter inserted.	1. Check power outlet and connection to rear or side panel of the machine. 2./3. Call BioMed or BUFFALO FILTER® Technical Services at 1.800.343.2324 or 716.835.7000. 4. Replace filter with a genuine Buffalo Filter VisiClear™ Filter.

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 VisiClear™ Surgical Smoke Plume Evacuator.

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 VisiClear™ Surgical Smoke Plume Evacuator, 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
1 (716) 835-7000

or contact your authorized BUFFALO FILTER® Distributor/Representative.

BUFFALO FILTER® VisiClear™ Surgical Smoke Plume Evacuator versions available:

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

Available accessories:

- VisiClear™ Filters
- Suction Canister
- EZLink Automatic Activation Device
- Hoses & Tubing
- Reducer Fittings
- Electrosurgical Pencil Adapters
- Electrosurgical Smoke Pencil

5.1 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.

5.2 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 VC120 & VC220 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.

5900 Genesee Street, Lancaster, New York 14086, USA
(716) 835-7000 or (716) 835-3414 fax
www.buffalofilter.com
Customer Service: 800-343-2324 (U.S. Only)
1-716-835-7000 (International)