



BUFFALO FILTER[®]
Smoke Evacuation Systems

Operator's Manual
DELL PlumeSafe[®]
Smoke Evacuation System



Limited Warranty

For a period of one (1) year following the date of delivery, BUFFALO FILTER warrants the Dell PlumeSafe® Evacuation System against any defects in material or workmanship. For a period of one (1) year following the date of delivery, 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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595 Commerce Drive
Buffalo, New York USA 14228
(716) 835-7000
Division of Medtek Devices, Inc.

Customer Service: 800-343-2324 (U.S. Only)

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 DPSEMAN Rev. A
4/2004**

Unit Serial Number _____

Classified by Underwriters Laboratories, Inc.® with respect to electric shock, fire and mechanical hazards only in accordance with UL/IEC 60601
9D93



Table of Contents

& List of Illustrations

Section	Title	Page
1.0	SYSTEM DESCRIPTION	1.1
1.1	Introduction	1.1
1.2	Inspection	1.1
1.3	Operational Information	1.2
1.4	Cautions and Warnings	1.2
2.0	OPERATING INSTRUCTIONS	2.1
2.1	System Controls	2.1
2.2	ViroSafe [®] Filter Instructions	2.2
2.3	Set-up and Operation	2.3
2.4	Specifications	2.4
3.0	MAINTENANCE	3.1
3.1	General Maintenance Information	3.1
3.2	Cleaning	3.1
3.3	Periodic Inspection	3.1
3.4	Troubleshooting	3.1
4.0	CUSTOMER SERVICE	4.1
4.1	Equipment Return	4.1
4.2	Ordering Information	4.1
5.0	TERMS & WARRANTY	5.1

System Description

Section 1.0

1.1 Introduction

The Dell PlumeSafe® Smoke Evacuation Systems is designed to remove smoke and noxious odors produced by surgical ablation during laser procedures.

The Dell PlumeSafe Smoke Evacuation Systems have been designed with a precision 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 three different filter stages. 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.

The first stage of filtration is a prefilter whose function is to trap and remove gross particulate and casual fluid.

The second stage of 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 Dell PlumeSafe Smoke Evacuation Systems preferentially removes toxic organic gases rather than water vapor and provides optimal odor removal.

The third stage of filtration is a ULPA (Ultra Low Penetration Air) filter whose high-tech patented design captures particulates and micro-organisms down to 0.12 µm at an efficiency of 99.99995%. Each ULPA filter is certified before use.

The electronic controls on the face panel of the Dell PlumeSafe smoke evacuation system is designed to be “user friendly” and facilitate easy unit set up and operation. Please refer to Section 2.0 for Operating Instructions.

1.2 Inspection

The Dell PlumeSafe 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, if you have ordered kit #DPSWKIT01, please compare the accessories you may have received with the standard accessories list below. If an item is missing, please notify BUFFALO FILTER Customer Service.

Standard Accessories:

- Operator’s Manual (1)
- Power Cord (1)
- ViroSafe Dell Filters (2)
- Footswitch (1)
- Asico Fixation Handpiece (2)
- 3/8” x 10’ Tubing (2)

Please contact BUFFALO FILTER Customer Service to purchase any additional accessories for your smoke evacuation system.

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 Dell PlumeSafe Smoke Evacuation System(s) complies with IEC601.1 electrical specifications in the following systems: 100-120V 50/60Hz,
2. The Dell PlumeSafe Smoke Evacuation System(s) has a classification under the UL2601-1, Clause 5.1 of: CLASS 1 Equipment
3. The Dell PlumeSafe Smoke Evacuation System(s) has an identification under the UL Clause 5.2 according to the degree of protection against electric shock: Type CF Equipment
4. The Dell PlumeSafe Smoke Evacuation System(s) has an identification under the UL Clause 5.3 according to the degree of protection against harmful ingress of water: Ordinary Equipment (enclosed equipment without protection against ingress of water).
5. The Dell PlumeSafe Smoke Evacuation System(s) has a classification under the UL Clause 5.4 according to the 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. The Dell PlumeSafe Smoke Evacuation System(s) has a classification under the UL Clause 5.5 according to the degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide: Equipment not suitable for use in the presence of Flammable Anesthetic mixture with air or with oxygen or nitrous oxide.
7. The Dell PlumeSafe Smoke Evacuation System(s) has a classification under the UL Clause 5.6 according to the mode of operation: Continuous Operation.
8. The Dell PlumeSafe is “CE marked”, indicating compliance to the EU Medical Device Directives.
9. Upon request, BUFFALO FILTER will provide the following: Service and Repair Instructions, including Circuit Diagrams and Parts List.
10. The fuses on the circuit board are to be serviced by an authorized BUFFALO FILTER technician as follows: 0.0625 Amp 250 Volt fuse

1.4 Cautions and Warnings

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

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

WARNINGS:

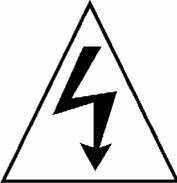
The **BUFFALO FILTER ViroSafe Filters** are completely disposable. Please handle these disposable filters according to your local codes or regulations and hospital policy.

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

- The ViroSafe Filter should be changed according to the prescribed life of the filter. The ViroSafe Filter, used with the Dell PlumeSafe Smoke Evacuation System(s), should not be used for more than 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.
- 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.

WARNING: DO NOT OPERATE THIS DEVICE IN THE PRESENCE OF EXPLOSIVE GASES.

WARNING: REFER ROUTINE SERVICING TO QUALIFIED BIOMEDICAL TECHNICAL PERSONNEL.

SYMBOL	DESCRIPTION/MEANING
	DANGER - RISK OF EXPLOSION IF USED IN THE PRESENCE OF FLAMMABLE ANESTHETICS
	CAUTION - GROUNDING RELIABILITY CAN ONLY BE ACHIEVED WHEN THE EQUIPMENT IS CONNECTED TO A RECEPTACLE MARKED "HOSPITAL GRADE" OR "HOSPITAL ONLY" CAUTION - ELECTRICAL SHOCK HAZARD. DO NOT REMOVE COVER. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL.
	CAUTION - BEFORE CONNECTING READ INSTRUCTION
	TYPE CF EQUIPMENT CLASS 1
IPX1	PROTECT AGAINST DRIPPING WATER
	ALTERNATING CURRENT

There are no user serviceable components in the Dell PlumeSafe Smoke Evacuation System(s). Refer service to qualified service personnel.

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

CAUTIONS:

- **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 to the system and will void the warranty.**
- **Care must be exercised in the installation of hoses, and adapters. Failure to follow the procedures outlined in this manual may result in overheating of the motor and may void the unit warranty.**

Operating Instructions

Section 2.0

2.1 System Controls

The electronic system controls on the Dell PlumeSafe Smoke Evacuation System(s) are designed to be easy to understand and simple to use. The membrane control panel contains the motor on/off switch, suction power adjustment, footswitch enabled, filter life reset button, filter life indicator, TURBO and normal modes (refer to page 2.5).

Note: Please be sure to read all instructions before installing accessories or operating this equipment. Failure to do so may result in damage to the unit and/or personal injury.

- **POWER ON/OFF & Standby**

There are two ON/OFF switches on the Dell PlumeSafe Smoke Evacuation System(s). The ON/OFF (main) switch that completely disables the electrical power to the unit is located on the back of the unit. The motor ON/OFF switch on the electronic membrane control panel is located in the lower left hand corner of the membrane panel. To power up the machine, place the power switch on the rear of the machine in the ON position and press the ON/OFF switch on the membrane panel. To place the unit in “standby” press the ON/OFF membrane switch to the OFF position.

Turn the system main power off by placing the power switch on the back of the system in the OFF position.

- **MICRO FLOW ADJUSTMENT (Membrane Control Panel)**

Every movement of the Micro Flow adjustment, the suction will increase or decrease as indicated by the illuminated LCD liters per minute display. The amount of suction in liters per minute as indicated on the LCD readout is the actual flow volume measured through the integral mass flow meter and may be adjusted by turning the Micro Flow adjustment. Turning counter clockwise increases suction and turning clockwise decreases suction. The suction control should be set at the lowest practical setting to completely remove the surgical smoke from the operative site.

- **MODE BUTTON**

The “TURBO” button located on the upper left corner of the membrane keypad on the front of the Dell PlumeSafe . During *normal* operation, the amount of suction may be adjusted by the Micro Flow adjustment. When additional air flow is immediately necessary, the TURBO button may be pressed at anytime. The TURBO button will illuminate once pressed to indicate system is in TURBO mode. TURBO mode significantly increases the airflow to quickly remove smoke plume from the surgical site or assist in drying the corneal bed without having to adjust the Micro Flow adjustment.

- **FOOTSWITCH ACTIVATOR (Membrane Control Panel)**

A footswitch activator may be added to the system by plugging in a BUFFALO FILTER electronic footswitch into the footswitch jack on the front 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 footswitch operation, the power switch on the membrane control panel should be in the ON position. When the footswitch is plugged in, the light on the membrane control panel entitled FOOTSWITCH ENABLED will light to indicate that the footswitch is active. When the footswitch is enabled, it overrides the motor on/off button on the keypad.

- ***FILTER LIFE INDICATOR (Membrane Control Panel)***

The filter life indicator on the membrane control panel provides a visual indication of the status of the life of the filter in use. The filter life indicator for the Dell PlumeSafe Smoke Evacuation System(s) ViroSafe filter is one hour.

To reset the filter life: After each filter change, press and hold the RESET button for five seconds to reset the timer for the next filter.

Reading the Filter Life Indicator

Install a ViroSafe Filter into the system per the installation instructions contained in this operator's manual. When the system is initially turned on, the filter life indicator will light up all the GREEN, AMBER, and RED LED's. This indicates full filter life. The amber LED indicates that 10-20 minutes of filter life remains. The indicator LED's will turn off one at a time until the red indicator light blinks indicating the life of the filter is exhausted. After the appropriate time has elapsed, the RED LED indicator will blink to indicate that the filter has expended its useful life and requires replacement. Each filter life led represents 10 minutes of filter life (60 minutes total).

- ***CIRCUIT BREAKER (Rear Panel)***

Two 15 AMP circuit breakers are located on the rear of the system. They electrically protect both the system and the operator from damage or injury. If the system is overheated or if there is an electrical surge in the facility, the circuit breaker will "trip" and the system will not operate. To re-start the system, depress the circuit breaker back into its original position.

2.2 ViroSafe Filter Instructions

Filter Installation Instructions:

The installation of the ViroSafe Filter into the Dell PlumeSafe 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 back of the filter chamber.
3. Press and hold the FILTER LIFE RESET button on the membrane control panel for 5 seconds to reset the filter life clock for the newly installed ViroSafe Filter.

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 facility biohazard practice and 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 filter or accessory not supplied by BUFFALO FILTER may cause damage to the system and may void the warranty.

WARNING: The ViroSafe Filter should be changed when the red blinking Filter Life Indicator shows 0% life remaining. Failure to change this filter may result in decreased efficiency and contamination of the electric motor, vacuum pump, and sound absorbing media within the system.

2.3 Set-Up and Operation

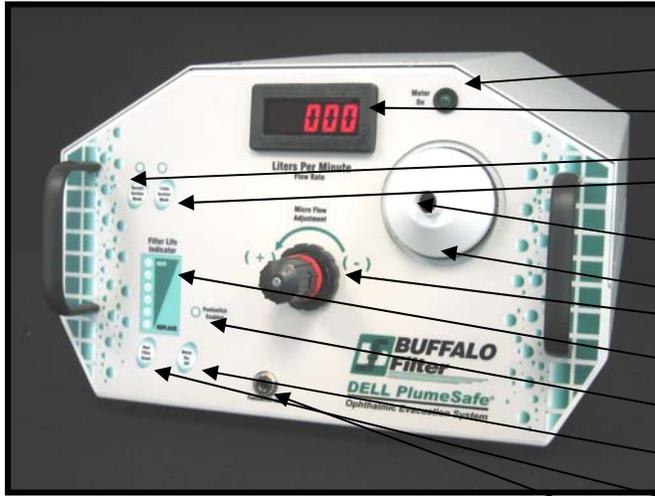
The operation of the Dell PlumeSafe Smoke Evacuation System(s) are as follows:

1. Install the appropriate ViroSafe Filter.
2. Attach unit power cord to the receptacle on the rear panel of the system. Plug the pronged power cord into an appropriate grounded power outlet.
3. Optional: Insert Footswitch plug into appropriate receptacle on the front of system.
4. Ensure that the evacuation tubing and accessories are fully seated in the inlet of the filter.
5. An evacuation tubing mast is provided with each Dell PlumeSafe Smoke Evacuation System. This mast is located on the right side with an adjustable locking positioner. The evacuation tubing fits within the loop of mast to provide an “Extension Hanger” for convenient location during use.
6. Turn on unit main power by placing the power switch on the rear panel of the machine in the “ON” position.
7. Activate the suction by pressing the motor ON/OFF switch on the membrane panel, OR depressing and releasing the footswitch (if connected).
8. Adjust the suction level to the desired setting by turning the Micro Flow adjustment while the unit is activated. The actual flow rate in liters per minute is indicated in the illuminated LCD display.
9. Deactivate the suction by pressing the ON/OFF switch on the membrane panel, OR depressing and releasing the footswitch (if connected).
10. Replace the ViroSafe Filter when the Filter Life indicator BLINKS RED (0% Life Remaining). Failure to change the filter will significantly diminish performance of the system and may cause a health hazard.

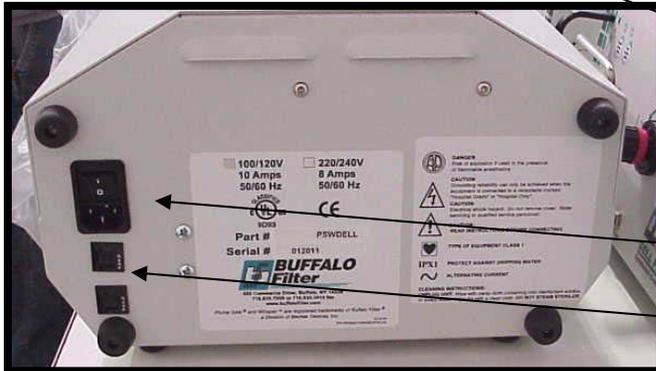
2.4 Specifications

Dell PlumeSafe® Whisper	
<i>BUFFALO FILTER P/N</i>	PSWDELL
CONFIGURATION	Portable with handles
Dell ViroSafe® Filters 3/8" port	3-Stage filtration in one casing (pre-filter, Carbon, ULPA)
Filter(s)	ULPA Grade
Particle size, µm	0.12 with \geq 99.9995% efficiency
Filter life	1 hour
Filter life indicator	Timed replacement
ViroSafe Filter P/N	Dell Filter (2Pk)
MAX. FLOW SETTING	70 Lpm
Variable flow control	Yes
Motor, hp (kW)	0.33 (0.25)
HOSES/TUBING	3/8"
NOISE LEVEL, dBA	\leq 62
FOOTSWITCH	Yes (Optional)
SAFETY FEATURES	Filter housing and handles remain temperate with the outer surface to prevent burns; circuit breaker; CE and UL classified in U.S. and Canada
DISPLAYS	LCD-Digit liters per minute
Data displayed	Filter Status, flow rate per minute, footswitch control, Turbo mode
VOLTAGE AVAILABLE	100-120 volts - 50/60 Hz
FREQUENCY	<i>For International 220/240V – 50/60Hz Operation, a Buffalo Filter BTD600 Isolation Transformer is required.</i>
H x W x D	13" x 13" x 8" 50.8 x 35.6 x 35.6 cm
Weight, lbs. (kg)	17.5 (13.0)

Dell PlumeSafe Smoke Evacuation System



1. Motor Suction ON Indicator
2. Liter Per Minute Flow Rate Indicator
3. TURBO Suction Mode
4. Normal Suction Mode
5. Proximal evacuation hose connection to filter
6. Filter Receptacle with filter
7. Micro Flow Adjustment
8. Filter Life Indicator
9. Footswitch Enabled LED
10. Motor Suction On/Off
11. Filter Life Reset
12. Footswitch Jack



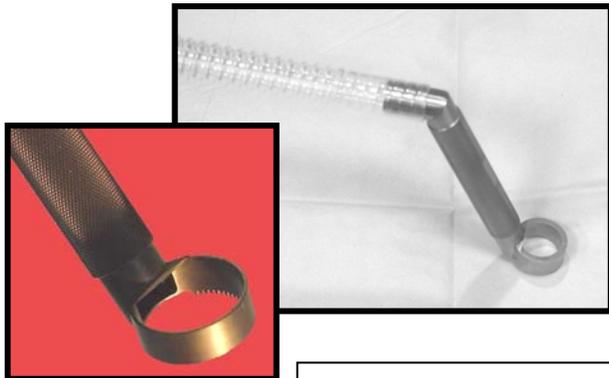
- Main Power Switch – I/O
- Circuit Breakers



- Dell60UF ULPA One-hour filters (2)
- 3/8" x 10' non-sterile tubing (2)



Electronic Footswitch
FS10003



ASICO AE-9060 or
AE-9061 Fixation
Handpiece (2 Per Kit)

Maintenance

Section 3.0

3.1 General Maintenance Information

This section contains information for ordinary upkeep of the Dell PlumeSafe Smoke Evacuation System(s). 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

The exterior of the system may be cleaned by wiping it with a cloth that has been dampened (not dripping) with a mild detergent and / or surface disinfectant .

3.3 Periodic Inspection

The Dell PlumeSafe Smoke Evacuation System(s) should be visually inspected at least every year. This inspection should include checks for:

- Damage to the power cord.
- Damage to the power plug.
- Tightness of the power plug.
- Proper mating, cleanliness and absence of damage to the filter inlet.
- Obvious external or internal damage to the system.

3.4 Troubleshooting the System – see below.

PROBLEM	POTENTIAL CAUSE	CORRECTIVE ACTION
1. Smoke Evacuation System is ON but suction is minimal or none	<ol style="list-style-type: none"> 1. Filter not seated completely 2. Filter clogged 3. Vacuum hose clogged 4. Motor/blower obstructed 5. Micro flow adjustment set at 0 (zero) lpm 	<ol style="list-style-type: none"> 1. Re-install ViroSafe Filter, press firmly into place 2. Replace filter 3. Check or replace Smoke Evacuation Tubing. 4. Adjust Micro flow adjustment. Call BioMed or BUFFALO FILTER. 5. Buffalo Filter Technical Services at: 1-800-343-2324 or (716) 835-7000
2. Smoke Evacuation System does not function even though ON button is depressed	<ol style="list-style-type: none"> 1. Not plugged into electrical outlet 2. Circuit breaker(s) tripped 3. Footswitch plugged in 4. Electronic system failure 5. Main power switch in OFF position 	<ol style="list-style-type: none"> 1. Check power outlet and connection to rear or side panel of machine 2. Reset circuit breaker(s) on rear of system 3. Unplug footswitch 4. Check main power switch on rear or side of system to ensure that it is in on the ON (I) position 5. Call BioMed or BUFFALO FILTER Technical Services at: 1-800-343-2324 or (716) 835-7000

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 Dell PlumeSafe 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 Goods Authorization" (R.G.A.) number from Customer Service before returning the system.

Step 4: If you have the original packing for your Dell PlumeSafe 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.

Return to:

BUFFALO FILTER
595 Commerce Drive
Buffalo, New York 14228
Attn: Technical Services

R.G.A. Number _____

4.2 Ordering Information

To reorder filters and tubing, 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 Dell PlumeSafe Smoke Evacuation System versions available:

- 100-120 VAC 50/60 Hz

Available accessories:

- ViroSafe Dell Filters
- Footswitch
- Asico Fixation Handpiece
- 3/8" x 10' Tubing
- BTD600 Isolation Transformer for 220/240V 50/60Hz Operation and specific connector cord

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 or repair without charge any filter systems proved to have defects within one (1) year of the date of delivery 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.



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