



Operator's Manual

RFID Limited Modular Components

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595 Commerce Drive
Buffalo, New York USA 14228
(716) 835-7000 or (716) 835-3414 fax
Division of Medtek Devices, Inc.

Customer Service: 800-343-2324 (U.S. Only) – www.buffalofilter.com
1-716-835-7000 (International)

Limited Warranty

For a period of one (1) year following the date of delivery, BUFFALO FILTER warrants the **BF0001** 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 BF0001



MEDICAL EQUIPMENT WITH RESPECT TO
ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH UL 60601-1 AND CAN/CSA C22.2 NO. 601.1

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.

System Description

Section 1.0

1.1 Introduction

This manual gives information on the proper installation of the RFID modules into a Smoke Evacuation system by BUFFALO FILTER® or an OEM integrator (per agreement with BUFFALO FILTER®). This installation should only be performed by qualified technical personal, after understanding the information contained in this manual.

1.2 Inspection

The RFID modules and required control and power circuits have been thoroughly tested and inspected before shipment from the factory. Please check the components 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
- Low and High Voltage control printed circuit boards
- Power Cord
- All required interconnecting wiring harnesses

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 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. Mode of operation (UL 60601-1, Clause 5.6): Continuous
3. Upon request, BUFFALO FILTER will provide the following:
Service and Repair Instructions, including Circuit Diagrams and Parts List
4. The fuses on the circuit board 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)*
5. This equipment utilizes mobile RF communications equipment that can affect medical electrical equipment.
6. **FCC Compliance Statements:**
 - 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.
 - NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
 - Reorient or relocate the receiving antenna.
 - Increase the separation between the equipment and receiver.
 - Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
 - Consult the dealer or an experienced radio/ TV technician for help.

7. Industry Canada Notices:

- Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.
- This radio transmitter (IC: 9532A-BF0001) has been approved by Industry Canada to operate with the 49" wire loop antenna included with this module with the maximum permissible gain and required antenna impedance for each antenna type indicated. Other antennas, or antenna types not included, having a gain greater than the maximum gain indicated for that type, are strictly prohibited for use with this device.
- This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

8. OEM Labeling Requirements:

- The Original Equipment Manufacturer (OEM) must ensure that FCC and Industry Canada labeling requirements are met. This includes a clearly visible label on the outside of the final product enclosure that displays the contents shown below.
 - Contains FCC ID: Y92-BF0001
 - Contains IC: 9532A-BF0001

IMPORTANT: The integrator is responsible for its product to comply with IC ICES-003 & FCC Part 15, Sub. B – Unintentional Radiators. ICES-003 is the same as FCC Part 15 Sub. B and Industry Canada accepts FCC test report or CISPR 22 test report for compliance with ICES-003.

9. This equipment operates in the following radio frequency specifications:

RX modulation: Pulse-width coded, AM 100% modulation

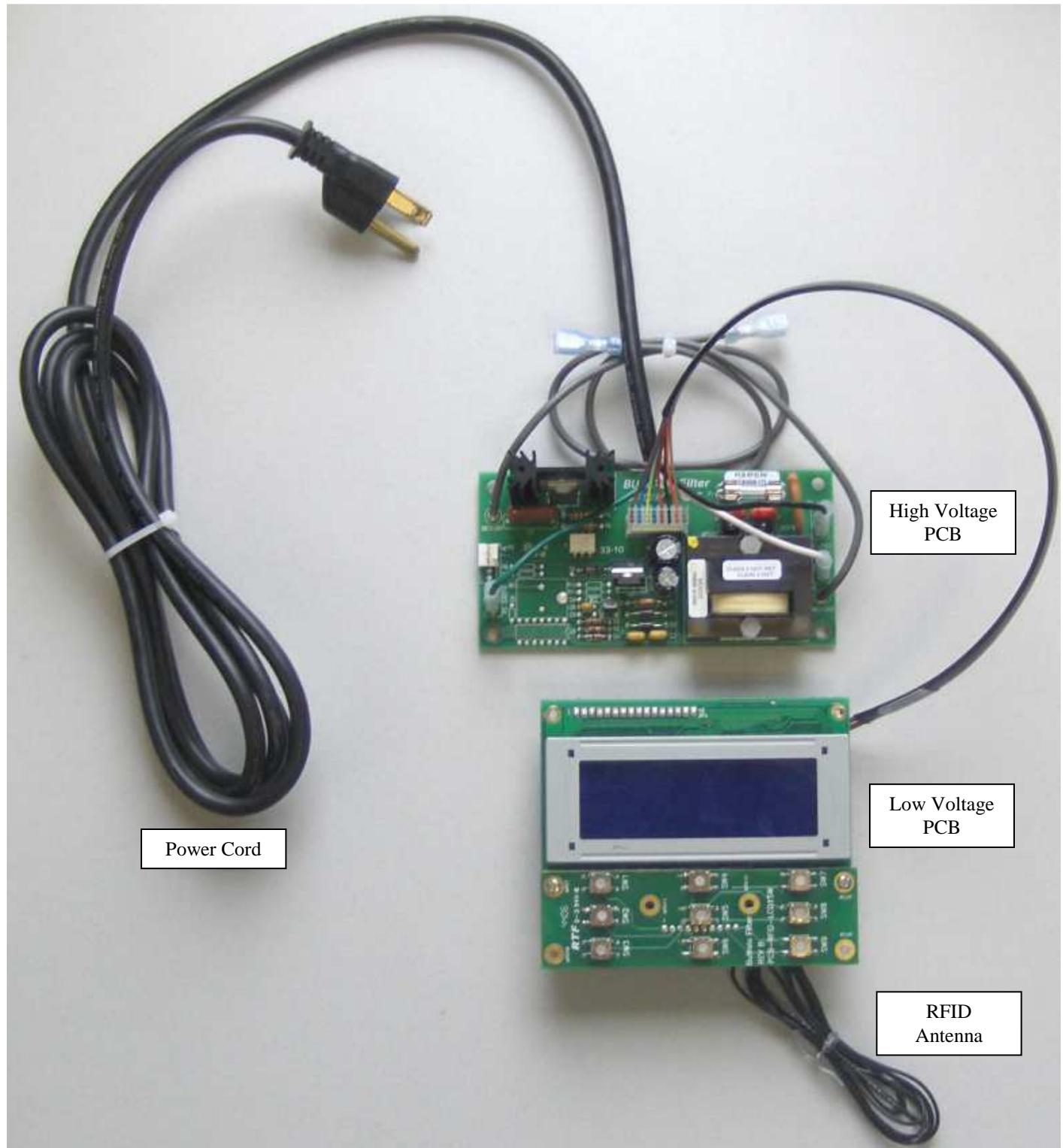
TX Frequencies: Manchester encoded,

A = fc +/- 423.75kHz, B = fc +/- 484.29kHz

Low bit: transition A to B

High bit: transition B to A

RFID Modular Components



Cautions and Warnings

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



Attention, consult Accompanying Documents (Manual)

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 system is only intended and suitable for the applications that are mentioned in the operating instructions.
- Do not operate this module 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 smoke evacuator 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 system.
- This equipment should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use in necessary, the smoke evacuator 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.

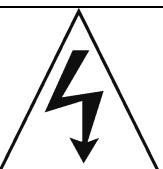
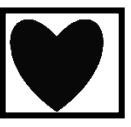
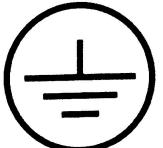
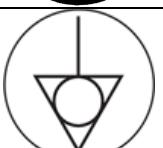
The warranty on this product is void if any of these warnings are disregarded.

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 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 BF0001™ 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.
	ATTENTION, CONSULT, ACCOMPANYING DOCUMENTS (MANUAL)
	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

Operating Instructions

Section 2.0

2.1 System Controls

The RFID control is integrated into the host system through the low voltage control circuit and its firmware. There are not operator controls required for this module as it is integrated into the system below the operator level.

2.3 Performance References*

<i>PERFORMANCE</i>	
Model Number	BF0001™
Safety Features	UL Classified
	CE Marked
	Fuse Protection
Voltage Available	100/120 VAC, 220/240 VAC
Frequency, auto sensed	50/60 Hz

2.4 Electromagnetic Compatibility Information per IEC60601-1-2

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions		
The Smoke Evacuation System model BF0001™ is intended for use in the electromagnetic environment specified below. The customer or the user of the Advantage Light should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The BF0001™ 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 BF0001™ 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 BF0001 is intended for use in the electromagnet environment specified below. The customer or the end user of the Model BF0001 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) 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 BF0001™ requires continued operation during power mains interruptions, it is recommended that the Model BF0001™ be powered from an uninterruptible power supply or a 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 6

Guidance and manufacturer's declaration - electromagnetic emissions			
The Model BF0001™ is intended for use in the electromagnetic environment specified below. The customer or the user of the Model BF0001™ should assure that it is used in such an environment.			
Immunity test	IEC 60601 Test level	Compliance Level	Electromagnetic environment - guidance
Radiated RF	3 V/m		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. $d = 1.7 \sqrt{P}$ 80 MHz to 800 MHz
IEC 61000-4-3	80MHz to 2.5 GHz	3 V/m	$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz
Conducted RF		3 Vrms	$d = [3.5/V1] \sqrt{P}$
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 structures, objects and people.			
a 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 BF0001™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Model BF0001™			
b 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 @ 3Vrms			
The model BF0001™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model BF0001™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model BF0001™ 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 MHz to 800 MHz $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$
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 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Maintenance

Section 3.0

3.1 General Maintenance Information

This section contains information for ordinary upkeep of the BUFFALO FILTER BF0001™ 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

See cleaning instruction for Host Device.

3.3 Periodic Inspection

The BF0001™ 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.
- Obvious external or internal damage to the system.

3.4 Troubleshooting the System – see below.

PROBLEM	POTENTIAL CAUSE	CORRECTIVE ACTION
1. RFID Tag not reading correctly	<ol style="list-style-type: none">1. Invalid RFID Tag2. Disconnected Antenna3. RFID module not connected properly	<ol style="list-style-type: none">1. Install properly pre-programmed RFID tag2. Check all module connections3. BUFFALO FILTER Technical Services at: 1-800-343-2324 or (716) 835-7000

Customer Service

Section 4.0

3.1 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 BF0001™ 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 BF0001™ 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.

3.2 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 BF0001™ Smoke Evacuation System versions available:

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

Available accessories:

- Filters
- Suction Canister
- Remote Switch Activator
- 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 one (1) year of the date of delivery for P/N VV120 & VV220 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.