Care E-Vac

Evacuator
Manual

Fannin

Fannin

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Rx ONLY CE

IFU 1ea / Box

Date. 2022-12-20 REV.001
PK-ESUP215-IFU001
Made in Korea.

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Original

NO	REVISION RECORD	DATE	APPROVE
1	MDR 적용, 온도표기 변경	221220	
0	도면 최초 제정	220428	승인완료

DSND	CHKD	APPD	Q'TY	
			SCALE	
PROJECT	EQM-U(Care E-vac)		DATE	2022. 12. 20
DESCRIPTION	Manual		PART NO	
	FANNIN		DWG NO	PK-ESUP215-IFU001-1

BIOPROTECH., INC

Care E-Vac

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System Description

Section 1.0

1.1 Introduction

Indications for use of the Care E-Vac Smoke Evacuation System include:
To remove and filter smoke and aerosols from a surgical site produced during electrosurgical and laser procedures.

The Care E-Vac Smoke Evacuation System has 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 Care E-Vac 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. Each Care E-Vac filter contains four different stages within to capture the smoke plume.

The first stage of filtration is a pre-filter whose function is to trap and remove gross particulate.

The second stage of filtration is the ULPA grade (Ultra Low Penetration Air) filter design that captures particulates and micro-organisms from 0.1 to 0.2 microns at an efficiency of 99.999%.

The third stage of filtration is comprised of virgin activated carbon.

The fourth stage of 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 Care E-Vac Smoke Evacuation System have been designed “user friendly” and facilitate unit set-up and operation. Please refer to Section 2.0 for Operating Instructions.

1.2 Inspection

The Care E-Vac Smoke Evacuation System has been thoroughly tested and inspected before shipment from the factory. Please check the unit before using it to ensure that no damage has occurred in transit. If damage is evident, please contact your local representative.
In addition, please compare the accessories you receive with the standard accessories list below.
If an item is missing, please notify your local distributors Customer Service.

Standard Accessories:
- Operator’s Manual
- Power Cord
- Pneumatic Footswitch

Please contact your local representative to purchase the following accessories:
• Replacement Filters
• Care E-Vac Auto Automatic Activation Device
• Hoses, Tubing, Adapters, 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 Care E-Vac Smoke Evacuation System complies with IEC60601-1 electrical specifications in the following systems:
   110~ VAC, 50/60 Hz, 10Amps
2. Type of protection against electrical shock: Class I
3. Degree of protection against electric shock: Type CF Applied Part (Open Tubing, ESU Pencil, Laparoscopic Tubing)
4. Degree of protection against ingress of water: IPX1(Foot Switch Only)
5. Method of sterilization or disinfection recommended by FANNIN:
   Unplug Unit. Wipe unit with a damp cloth containing mild disinfectant solution or soapy water. Wipe dry with a clean cloth. Do not use steam to 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. This equipment is intended only for attended use.
9. This equipment needs special precautions regarding Electro Magnetic Compatibility and needs to be installed according to EMC information found in this manual.
10. This equipment utilizes mobile RF communications equipment that can affect medical electrical equipment.
11. 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.
12. 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
13. 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.
14. Potential Equalization Conductor: Terminal located on back panel for connection of potential equalization. The conductor complies with requirements per IEC 60601-1.

The Care E-Vac Smoke Evacuation System 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 Care E-Vac 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 Care E-Vac 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 Care E-Vac Smoke Evacuation System 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.**

· **The user that the device must be started at the lowest power possible.**

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

· The Care E-Vac filters and single-use accessories are completely disposable. Please dispose of them 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 Care E-Vac Auto Automatic Activation Device cable 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 the risk of electric shock, this equipment must only be connected to a supply main with protective earth.

· The use of ACCESSORIES other than those specified by FANNIN, or sold by FANNIN as replacement parts for internal components, may result in increased emissions or decreased immunity of the Care E-Vac.

· This equipment should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the Care E-Vac 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 FANNIN 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 Care E-Vac 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 Care E-Vac filters were demonstrated to be compatible with the Care E-Vac Smoke Evacuation System. 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 Care E-Vac Filter should be changed according to the life of the filter. The Care E-Vac Filter, used with the Care E-Vac Smoke Evacuation System, 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. The filter life gauge 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%.

· The operator must not touch any part of ME equipment or electrical connector and patient simultaneously.

· The product has a lower breaking capacity type. So do not install at the building power system prospective short-circuit current exceeding 35 A.

There are no user-serviceable components in the Care E-Vac Smoke Evacuation System. Refer service to qualified service personnel.

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

1.4.3 Contraindication:

· **Care E-Vac is contraindicated from suctioning of fluid**

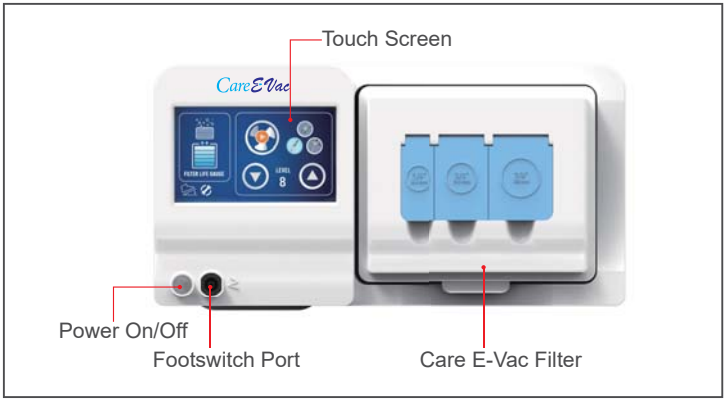
Symbols	Description / Meaning
	Warning
	Caution
	TYPE CF Applied Part
IPX1	Protection Against Ingress of Water As Detailed In IEC 60529
	Protective Earth(Ground)
	Alternating current
	Denotes The Date The Equipment was Manufactured
	Denotes The Manufacturer of The Device
	Non-Ionizing Radiation
	Consult Instructions
	Automatic Activation Device
	Footswitch
	“ON” / “OFF” (push-push) NOTE Each position, “ON” or “OFF”, is a stable position
	Equipotentialiy
Rx ONLY	Prescription Only
	Certification body's CE mark and identification number
	Do not use if packaging damaged
	Consult instructions for use
	Medical device
	Latex Free
	Keep away from sunlight
	Keep dry
	Temperature limit

Section 2.0

2.1 System Controls

The electronic system controls on the Care E-Vac Smoke Evacuation System 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 and turns on power button, the unit's touch screen will illuminate, and a startup process will begin. This will take about 10 seconds to complete. During this time, Care E-Vac's logo will appear on the touch screen.

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 Power On/Off button located on the front of the panel of the Care E-Vac system will activate or deactivate the touch screen control panel as well as any unit functionality.

MODE OF OPERATION

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

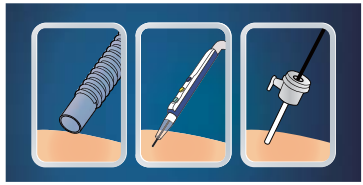


Figure 1.

Please select the mode that is appropriate for your clinical application.
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 Care E-VacPencils, please select the Electrosurgical Pencil Mode Button. Finally, when attaching to a surgical cannula during laparoscopic procedures, please select the Laparoscopic Button.

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 right 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 2

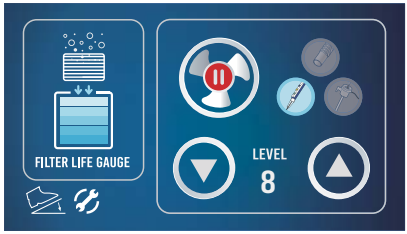


Figure 2.

SUCTION CONTROL

The amount of suction may be adjusted by pressing the suction control buttons located under the fan image. Each time the suction controls 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 3.

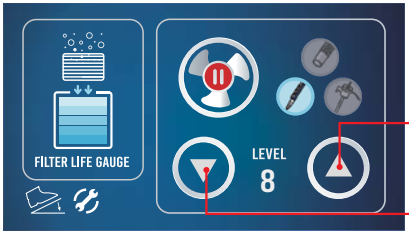


Figure 3.

FOOTSWITCH / Care E-Vac-Auto AUTOMATIC ACTIVATION DEVICE

The Care E-Vac Smoke Evacuation System also comes equipped with a pneumatic footswitch. A footswitch or a Care E-Vac Auto Automatic Activation Device may be added to any system by simply plugging in an activation accessory into the appropriate jack on either the front (footswitch) or back (Care E-Vac Auto) panel of the unit. When the footswitch is plugged in, the motor may be started or stopped by depressing the footswitch pedal once for each operation. For directions on using the Care E-Vac Auto 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.

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

All Mode (Laparoscopic mode, Electrosurgical Pencil mode, Open tubing mode) = 50 hours of filter life. The Care E-Vac Filter Life Indicator is factory set. All filter life timing is automatic. See Figure 4

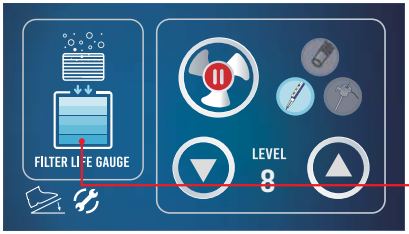


Figure 4.

When the maximum filter life is consumed, the following warning screen will appear indicating that a filter replacement is needed. See Figure 5.

Figure 5.

After inserting a new Care E-Vac Filter, 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.
* By pressing the button Indicates ERROR ICON, you can check the available operating time. See Figure 6.

Figure 6.

At that point, the Care E-Vac 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.

OFF TIME DELAY CONTROL SETTINGS
The Care E-Vac allows you to increase or decrease the amount of time the Care E-Vac System remains on after the release of the electrosurgical button when the system is coupled with our Care E-Vac Auto Automatic Activation Device. This delay is to capture any residual smoke plume that may linger after the electrosurgical unit is deactivated. By pressing the button indicated a clock icon, you can adjust the delay from 0-10 seconds by pressing the down sign to decrease the delay or the up sign to increase the delay. If the Care E-Vac Auto is set to 3 seconds and the Care E-Vac is set to +5 the actual delay time will be 8 seconds.
See Figures 7. You may press the X Button to return to the previous menu.

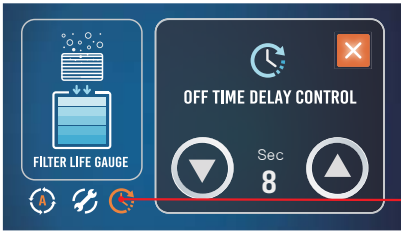


Figure 7.

FUSES (circuit board)
Two 10 AMP fuses (8 AMP for 220/240 Care E-Vac 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.

2.2 Care E-Vac Filter Instructions

Care E-Vac 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:
1. Remove the Care E-Vac 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 Care E-Vac Filter into the 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 the evacuation of fluid. If fluid is expected to be aspirated using the Care E-Vac Filter or the Care E-Vac 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 Care E-Vac 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 Care E-Vac Filter from the smoke evacuation system and dispose of it in accordance with hospital policy. The Care E-Vac 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 Care E-Vac Filter.

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

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 the smoke evacuator.

2.3 Performance References*

Performance		
Model Number		Care E-Vac
Standard Hose I.D.		
	7/8” (22mm)	25 CFM (708 LPM)
	3/8” (9.5mm)	4.5 CFM (130 LPM)
	1/4” (6.4mm)	2 CFM (57 LPM)
Dimensions (H x W x D)	inches	6 x 11 x 15.5
Dimensions (H x W x D)	centimeters	15.2 x 27.9 x 39.4
Weight	lbs (kg)	12.0 lbs (5.0 kg): with filter installed
Noise Level, dBA	MAXIMUM	55.0 dBA
Footswitch Pneumatic		Standard
Remote Control Activation		Yes (option)
Safety Features		FDA
		CE Marked
		Fuse protection
Display		Touch Screen
		Filter Status
		Flow Rate
Voltage Available		110 ~ VAC
Frequency, auto sensed		50/60 Hz
Variable Flow Control		Yes
Motor (Watts)		800 ± 5%
Motor Static Suction (6.5mm Orifice)		21.10 kpa

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

2.4 Electromagnetic Compatibility Information per IEC60601-1-2

Table 1

Guidance and manufacturer's declaration – electromagnetic emissions		
The Surgical Smoke Evacuator Model Care E-Vac is intended for use in the electromagnetic environment specified below. The customer or user of the Care E-Vac should assure that it is used in such an environment.		
Emissions Test	Compliance	
RF Emissions CISPR 11	Group 1	The Care E-Vac 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 Care E-Vac 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	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 Care E-Vac is intended for use in the electromagnetic environment specified below. The customer or user of the model Care E-Vac 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	+6kV contact +8kV air	+6kV contact +8kV 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	+2kV for power supply lines +1kV for input/ output lines	+2kV for power supply lines +1kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+1kV differential mode +2kV common mode	+1kV differential mode +2kV 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% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5cycles 70% UT (30% dip in UT) or 25cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5cycles 70% UT (30% dip in UT) or 25cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Model Care E-Vac requires continued operation during power mains interruptions, it is recommended that the Model Care E-Vac be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/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 Care E-Vac is intended for use in the electromagnetic environment specified below. The customer or user of the model Care E-Vac 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	3V/m		d = 1.7 √P 80MHz to 800MHz
IEC 61000-4-3	80MHz to 2.5GHz	3V/m	d = 2.3 √P 800 MHz to 2.5 GHz
Conducted RF			
IEC 61000-4-6	150kHz to 80MHz		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 Care E-Vac should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model Care E-Vac. Over the frequency range of 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 Care E-Vac is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the model Care E-Vac can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model Care E-Vac as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to the frequency of transmitter m		
	150kHz to 80MHz $d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$	80kHz to 800MHz $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$	800kHz to 2.5GHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$
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 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structure, objects, and people.

Maintenance

Section 3.0

3.1 General Maintenance Information

This section contains information for the ordinary upkeep of Care E-Vac.
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 the unit prior to cleaning. Wipe the unit with a damp cloth containing mild disinfectant solution. Do not clean the 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 use steam to sterilize.

3.3 Periodic Inspection

The Care E-Vac Surgical Smoke 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 Care E-Vac Filter, press firmly into place and fully engage clip. 2. Replace filter with a genuine Care E-Vac Filter. 3. Replace vacuum hose or tube with genuine FANNIN products. 4. Call your local representative
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 your local representative. Replace the filter with a genuine Care E-Vac Filter.

Customer Service

Section 4.0

4.1 Equipment Return

For the quickest response to your service needs, please follow these procedures:
Step 1: Write down the model and the serial number of the Care E-Vac 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 Care E-Vac 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 the return shipment.
Step 5: Freight for all returned goods should be prepaid by the shipper. The Address will be supplied by Customer Service.

4.2 Ordering Information

To reorder, obtain replacement parts or return a unit for service, call Customer Service or contact your authorized FANNIN Distributor or Representative.

Care E-Vac Smoke Evacuation System versions available:
• 220~ 240 VAC 50/60Hz

Available accessories:
• Care E-Vac Filters
• Suction Canister
• Care E-Vac Auto Automatic Activation Device
• Hoses & Tubing
• Reducer Fittings
• Electrosurgical Smoke Pencil

Terms & Warranty

Section 5.0

5.1 Specifications

Specifications are subject to change without notice.

SHIPMENT OF ORDER:

FANNIN will try to accommodate individual customer requests for shipping method. FANNIN reserves the right to decide the 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. FANNIN'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. FANNIN will assist customers in pursuing these claims.

RETURN OF MATERIAL:

Return merchandise must have a pre-authorized return number from FANNIN 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. An 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 your local representative before shipping back merchandise.
2. Incorrectly shipped merchandise is exempt from restocking fees. Please contact your local representative before shipping back merchandise.

5.2 Warranty

FANNIN warrants that the filter system manufactured by FANNIN shall be free from defects in material and workmanship. Products are warranted only to the extent that FANNIN will replace without charge any filter systems proved to have defects within one (1) year of the date of delivery for Care E-Vac and provided FANNIN 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 FANNIN 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 FANNIN have been developed at FANNIN'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:
FANNIN shall not in any case whatsoever be liable for special, incidental, indirect or consequential damages of any kind. In no case shall FANNIN's liability exceed the amount paid FANNIN by the purchaser for the specific system giving rise to the liability. Purchaser agrees to indemnify and hold FANNIN 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 FANNIN'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 the State of California. Using any filter not manufactured by FANNIN may cause damage to the systems and will be cause for voiding the warranty.

JURISDICTION:
Purchaser hereby consents to the jurisdiction of the Courts of England & Wales with respect to any controversy or dispute arising out of this agreement or the merchandise sold hereunder.

MEMO

Fannin

Local Representative/ Distributor (Label / Information)

Name

Tel

Email

Manufactured for:

Fannin UK Ltd.

Fannin (UK) Limited, DCC Vital,
Repton Road, Measham, Swadlincote,
Derbyshire, England, DE12 7DT

Rx ONLY CE

Bio Protech Inc. (in Korea)

151-3, Donghwagongdan-ro, Munmak-eup,
Wonju-si, Gangwon-do, 26365 Korea
Tel : 82-33-735-7720, Fax : 82-33-735-7736

www.protechsite.com
Please refer to the website for more product information.

IFU | 1ea / Box

EC REP

Meridius Medical Europe Ltd

Unit 3D North Point House,
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Date. 2022-12-20 REV.001
PK-ESUP215-IFU001
Made in Korea.