I. C. MEDICAL, INC.

CRYSTAL VISION®
Model 450D

REF ICM-450-0000

OPERATING AND INSTALLATION MANUAL

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Document#: ICM-450-9000 Rev. N Date: 2021-03

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LIMITED WARRANTY:

For the periods and the conditions specified below, I.C. Medical, Inc. warrants to the original purchaser that I.C. Medical, Inc.'s products will perform to our published specifications when used and maintained in accordance with our written instructions.

If due to a defect in materials or workmanship a Product fails to perform to our published specification, or if a Consumable is not free from defects in materials and workmanship when shipped from our factory, I.C. Medical will, at its option, repair or replace the defective Product or Consumable without charge, using new or remanufactured parts. I.C. Medical reserves the right to make a repair in its factory, at any authorized repair facility, or at the purchaser's premises. Factory return shipping charges, if any, shall be paid by the purchaser.

With respect to the Crystal Vision, the warranty period is one (1) year from delivery. The warranty for the Crystal Vision smoke evacuator is null and void if 1) the purchaser, including any I.C. Medical, Inc. authorized service provider, attempts to service or repair the smoke evacuator (other than the performance of routine maintenance as described in the Operator's Manual), 2) the smoke evacuator is used other than as specified in the Operator's Manual, or 3) the smoke evacuator is used without I.C. Medical's **SAFEGUARD BLUE®** Hydrophobic ULPA (Ultra Low Penetration Air) Filter with Built-in Fluid Trap*. Without limitation, this warranty does not cover damage caused by customer misuse of the smoke evacuator.

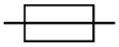
*WARNING: **This warranty will only apply when the smoke evacuator is used in conjunction with I.C. Medical's SAFEGUARD BLUE® Hydrophobic ULPA Filter with Built-in Fluid Trap.** I.C. Medical's **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap includes a hydrophobic filtration media, and advanced sealing methods, to prevent contaminated fluid and air from leaking into, and out of, the smoke evacuator. Use of the Crystal Vision smoke evacuator without I.C. Medical's **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap can result in particle, air, and fluid leakage that contaminates the smoke evacuator and affects the efficiency and operation of the smoke evacuator. In addition, particle, fluid and air leakage resulting from use of the smoke evacuator without I.C. Medical's **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap can compromise user and patient safety, especially in laparoscopy where maintaining patient intra-abdominal pressure is critical. I.C. Medical's limited warranty applies to all I.C. Medical branded smoke evacuators and those for which I.C. Medical is the original equipment manufacturer (OEM). In no event will I.C. Medical repair any of its smoke evacuators that have been contaminated by using **non**- I.C. Medical Hydrophobic ULPA filters either during or after the warranty period.

THIS WARRANTY IS IN LIEU OF ANY OTHER WARRANTIES EXPRESSED OR IMPLIED, AND ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE IS EXPRESSLY DISCLAIMED. Purchaser's exclusive remedy for any failure of any Product or Consumable is as provided in this Limited Warranty, and in no event shall I.C. Medical be liable for any special, incidental, consequential, indirect or other similar damages arising from breach of warranty, breach of contract, negligence or any other legal theory.

IMPORTANT SAFEGUARDS AND NOTICES

The following pages provide important guidelines for operators and service personnel. Specific warnings and cautions appear throughout the manual where they apply. Please read and follow this important information, especially those instructions related to risk of electric shock or injury to patient or staff members.

Any instructions in this manual that require opening the equipment cover or enclosure are for use by I.C. Medical, Inc. qualified service personnel only. To reduce the risk of electric shock, do not perform any other service than that contained in the operating instructions unless you are determined by I.C. Medical, Inc. to be qualified to do so.

Symbol	Description:
	**"ON" (power)**
	**"OFF" (power)**
	Caution
	The device is Class 1, Type BF applied part
	Fuse
	Earth (ground)

SERIOUS ADVERSE EVENTS

Any serious adverse event or incident that occurs in relation to the device or accessory should be reported to the manufacturer, I.C. Medical, Inc., at complaints@icmedical.com and to the FDA. In addition, European customers should also report to the Authorized Representative at the address listed on the label or IFU and to the competent authority in the member state.

GENERAL WARNINGS

A warning indicates a possible hazard to personnel, which may cause injury. Observe the following general warnings when using or working on this equipment:

1. Heed all warnings on the unit and in the operating instructions.
2. Do not use this equipment in or near water.
3. This equipment is grounded through the grounding conductor of the power cord. To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
4. Route power cords so they are not likely to be damaged.
5. Disconnect power before cleaning the equipment. Do not use aerosol cleaners, use a damp cloth.
6. Dangerous voltages may exist at several points in this equipment. To avoid injury, do not touch exposed connections and components while power is on.
7. Do not wear rings or wristwatches when troubleshooting the equipment.
8. To avoid fire hazard, use only specified fuse(s) with the correct type number, voltage, and current ratings as referenced on the equipment. Qualified service personnel should replace fuses.
9. Not intended to be used in an Oxygen Rich Environment. Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
10. Qualified service personnel should perform safety checks periodically and after any service.
11. If the equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.
12. Keep the back of the unit away from the patient vicinity (which is commonly defined as the space within 1.8m/6 feet of the patient/operating table), or otherwise be generally inaccessible to the patient.
13. Use only smoke evacuator accessories manufactures by I.C. Medical, as **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap, Large Coconut Charcoal Output Filter, RF Sensor(s), smoke tubing disposable and other accessories.
14. Using any other filters, sensors, or accessory, not manufactured or supplied by I.C. Medical, may cause damage and/or cause the system to be inoperable and may void the warranty.
15. Do not operate unit without **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap (for a complete list of products contact I.C. Medical sales representative).
16. To prevent contamination and for proper operation I.C. Medical **SAFEGUARD BLUE®** Hydrophobic ULPA Filter must be properly installed and used at all times.
17. Do not operate machine without Large Coconut Charcoal Output Filter.
18. Turn OFF the unit when replacing the Large Coconut Charcoal Output Filter. Replace the Large Coconut Charcoal Output Filter as soon as odors become noticeable, or every three months, whichever occurs first.
19. Do not block exhaust.

CONTRAINDICATIONS

A contraindication is a specific situation in which a drug, procedure, or surgery should not be used because it may be harmful to the person. Observe the following contraindications when using or working on this equipment.

DO NOT use this device for the suction of liquids.

GENERAL CAUTIONS

A caution indicates a possible hazard to equipment that could result in equipment damage. Observe the following cautions when operating or working on this equipment.

1. When installing this equipment, do not attach the power cord to building surfaces.
2. To prevent damage to equipment when replacing fuses, locate and correct the problem that caused the fuse to blow before re-applying power.
3. Use only specified replacement parts.
4. Use only smoke evacuator accessories manufactured by I.C. Medical, as **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap, Large Coconut Charcoal Output Filter, RF Sensor(s), smoke tubing disposable and other accessories. Using any other filters, sensors, or accessory, not manufactured or supplied by I.C. Medical, may cause damage and/or cause the system to be inoperable and may void the warranty.
5. Follow precautions for static sensitive devices when handling this equipment.

6. This product should only be powered as described in the manual. To prevent equipment damage, select the proper voltage outlet.
7. To prevent damage to the equipment, read the instructions in the equipment manual for proper input voltage.
8. Keep unit at operating environment for at least 6(six) hours before use, if unit was exposed to extreme shipping and storage conditions.
9. Make sure the unit is in a safe and stable environment as to prevent falling or being dropped, which may cause damage.

COMPATIBILITY

Refer to below compatibility information, Specifications Section, and Installation/Operations Instructions to confirm that this Crystal Vision Model is compatible with the accessories being used.

The Smoke Evacuator was tested electrically to meet the requirements ANSI/AAMI ES 60601-1 Medical electrical equipment— Part 1: General requirements for basic safety and essential performance. This unit is compatible with other IEC 60601-1 certified units.
Electrosurgical equipment (ESU) connected to the auxiliary Mains outlet must be certified according to IEC60601-1, including Medical Electrical System aspects. Everybody who connects additional equipment to the auxiliary mains outlet configures a medical system and is therefore responsible that the system complies with the requirements of IEC 60601-1.

For the electromagnetic compatibility (EMC), this smoke evacuator complies with EMC standard for medical electrical equipment (IEC 60601-1-2).

List of compatible I.C. Medical products:
1. ESU Sensor
2. RF Sensor, Shielded
3. **UNIVERSAL BLUE™** RF Sensor
4. Laser Sensor
5. Foot Switch
6. **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap
7. Large Coconut Charcoal Output Filter
8. Intra-Abdominal Plume Eliminator Tubing Set
9. Speculum Tubing
10. Smoke Evacuator Wand
11. Smoke Evacuator Tube
12. ESU Shroud
13. PenEvac1
14. Non-Telescopic PenEvac
15. The power cords for smoke evacuator units should be grounded, medical-grade type

In addition, new products released after the introduction of this product may also become compatible with this Crystal Vision Model. For further details, contact I.C. Medical.

WARNING
If combinations of equipment other than those shown within this manual are used, the full responsibility is assumed by the medical facility.
Connecting additional equipment, other than one found compatible with, to the auxiliary mains outlet or other inputs (ESU, Laser) will increase chassis leakage.
Using incompatible equipment can result in patient injury and/or equipment damage.

Crystal Vision® Model 450D
SPECIFICATIONS

INDICATION FOR USE: USED FOR:	The CRYSTAL VISION® 450D is intended to remove smoke created in surgical procedure. The CRYSTAL VISION® 450D is intended to remove smoke created in surgical procedure. The Model 450D can be used to remove smoke produced by lasers, electrosurgical devices, argon beam coagulators, LEEP devices, and other devices that create smoke during surgical procedures. During internal surgical procedures such as laparoscopy, it helps to maintain the desired internal pressure (pneumoperitoneum). The smoke evacuator removes up to 20 liters-per-minute of smoke produced. The Model 450D automatically activates when active (smoke producing) devices that are coupled to the Model 450D with special sensors are turned on. The Model 450D automatically turns off, at a time predetermined by the operator, after the active device turns off. The Model 450D also automatically activates when the high pressure limit is exceeded in the pneumoperitoneum and it remains running to remove smoke, vapors, and gases until the internal pressure returns to levels below the preset maximum. The Model 450D can also be used to evacuate CO_2 gas from the pneumoperitoneum at the end of laparoscopic procedures.
PRODUCT DISPOSITION:	At the end of service life, dispose of product in accordance with your institutional protocol for capital equipment. I.C. Medical, Inc. has defined the service life for the Crystal Vision® as 10 years from date of manufacture.
SIZE:	7.2"H x 14.07"W x 15.05"D (18.28cm H x 35.73cm W x 38.22cm D). Allow an additional 1.0" (2.5 cm) on both sides and 6.0" (15.2 cm) behind the device for the Large Coconut Charcoal Output Filter and adequate cooling.
WEIGHT:	Approximately 17 pounds (7.7 kg).
SHIPPING/STORAGE ENVIRONMENT:	An ambient temperature range of -40ºC to +70ºC; A relative humidity range of 10% to 100%, including condensation; An atmospheric pressure range of 500 hPa to 1060 hPa.
OPERATING ENVIRONMENT:	10º - 25º C, 30-75%RH, 700-1060hPa.
POWER REQUIREMENTS:	100-240 VAC, single phase, and 4.0 A, 47-63 Hz
LEAKAGE CURRENT:	<100 μamps
FUSE RATING:	F4AH 250V.
FLOW RATE:	
OPEN RANGE:	Minimum: N/A Maximum: At least 90 Liters/Minute.
LAP RANGE:	Minimum: 4 (±1) lpm Maximum: At least 18 Liters/Minute
ACCURACY:	±10%
MAXIMUM VACUUM:	Will not be more negative than -350mmHg.
MANUAL START SWITCH:	YES

INDICATORS:

POWER ON	Visual Indicator
OPEN FLOW ON	Visual Indicator
LAP FLOW ON	Visual Indicator
OCCLUSION	Visual & Audio Indicators
CHANGE FILTER	Visual Indicator
NO PATIENT	Visual Indicator
OVER PRESSURE	Visual & Audio Indicators
OPEN FLOW RATE	LED Meter
LAP FLOW RATE	LED Meter
OPEN FLOW SET POINT	LED Display
LAP FLOW SET POINT	LED Display
TIME SETTING	LED Meter
FLOW READING	LED Meter

SAFEGUARD BLUE® HYDROPHOBIC ULPA FILTER WITH BUILT-IN FLUID TRAP:

Multiple Use: Change when CHANGE FILTER illuminates on front panel; replace cap on input connector when **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap not in use.

Filtration Efficiency:

Mode		Particles at: (in microns)		
		0.03	**0.12**	**0.3**
LAP	**Efficiency (%)**	**>99.9999**	**>99.9999**	**>99.9999**
OPEN	**Efficiency (%)**	**>99.9999**	**>99.9999**	**>99.9999**

LARGE COCONUT CHARCOAL OUTPUT FILTER:

Re-usable: Change when noticeable odor is detected, or every three months, whichever occurs first.

TURN OFF THE UNIT WHEN REPLACING THE FILTER.

Filtration Efficiency:

Mode		Particles at: (in microns)		
		0.03	**0.12**	**0.3**
LAP	**Efficiency (%)**	**99.86**	**94.38**	**91.58**
OPEN	**Efficiency (%)**	**98.39**	**85.34**	**86.80**

Studies shows that approximately 77% of the particulate matter in the plume was less than 1.1 microns in size.

(Mihashi, Ueda, Hirano, Tomita, & Hirohata, 1975);

(Coronaviruses: An Overview of Their Replication and Pathogenesis, Helena Jane Maier, Erica Bickerton, and Paul Britton; 2015 Feb 12);

The following particulates has a typical size of:

0.01 to 0.1 micron for viruses;

0.01 to 1.0 microns for tabacco smoke;

0.01 to 3.0 microns for combustion gases;

0.06 to 0.14 microns for SARS-CoV-2;

0.1 to 1.0 microns for fumes;

0.1 to 1.0 microns for dust mite feces;

0.1 to 10.0 microns for insecticide dust;

0.1 to 50.0 microns for face powder;

0.4 to 15.0 microns for bacteria;

0.8 to 9.0 microns for lung-damaging dust;

1.0 to 10.0 microns for skin flakes;

1.0 to 10.0 microns for dust mites;

8.0 to 100.0 microns for human hair;

9.0 to 15.0 microns for spores;

10.0 to 100.0 microns for sneezes;

10.0 to 15.0 microns for pollen;

INSTALLATION/OPERATIONS INSTRUCTIONS

1. ***Use only under the direction of a licensed physician.***
2. ***Do not exceed 27-mmHg intra-abdominal pressure.***
3. ***Do not use OPEN MODE in Laparoscopic Procedure***
4. ***Do not re-use, disposable Sterile Tubing Sets, PenEvac1®, and Disposable ESU Shrouds that are SINGLE USE ONLY.***

The CRYSTAL VISION® Model 450D is intended to remove smoke created in surgical procedure. The Model 450D can be used to remove smoke produced by lasers, electrosurgical devices, argon beam coagulators, LEEP devices, and other devices that create smoke during surgical procedures.
During internal surgical procedures such as laparoscopy, it helps to maintain the desired internal pressure (pneumoperitoneum). The smoke evacuator removes at least 18 liters-per-minute of smoke produced.
The Model 450D automatically activates when active (smoke producing) devices that are coupled to the Model 450D with special sensors are turned on. The Model 450D automatically turns off, at a time predetermined by the operator, after the active device turns off.
The Model 450D also automatically activates when the high pressure limit is exceeded in the pneumoperitoneum and it remains running to remove smoke, vapors, and gases until the internal pressure returns to levels below the preset maximum.

The Model 450D can also be used to evacuate CO_2 gas from the pneumoperitoneum at the end of laparoscopic procedures.

During laparoscopic procedures, the CRYSTAL VISION® is designed to remove automatically smoke plume and water vapor from the peritoneal cavity while maintaining the pneumoperitoneal pressure that the surgeon has selected on the insufflator. Therefore, the volume of smoke that can be removed by the CRYSTAL VISION® is directly dependent on the flow rate of the insufflator.

The following I.C. Medical's accessories are compatible, and need to be use with your CRYSTAL VISION®, be sure to inspect them for any sign of damage:

1. ESU Sensor
2. RF Sensor, Shielded
3. **UNIVERSAL BLUE™** RF Sensor
4. Laser Sensor
5. Foot Switch
6. **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap
7. Large Coconut Charcoal Output Filter

The power cords for smoke evacuator units should be grounded, medical-grade type

For a complete list of compatible finish product reference number, please contact I.C. Medical, Inc.

CAUTIONS: Use only smoke evacuator accessories manufactured by I.C. Medical, Inc. as **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap, Large Coconut Charcoal Output Filter, RF Sensor(s), smoke tubing disposable and other accessories.

Using any other filters, sensors, or accessory, not manufactured or supplied by I.C. Medical, Inc. may cause damage and/or cause the system to be inoperable and may void the warranty.

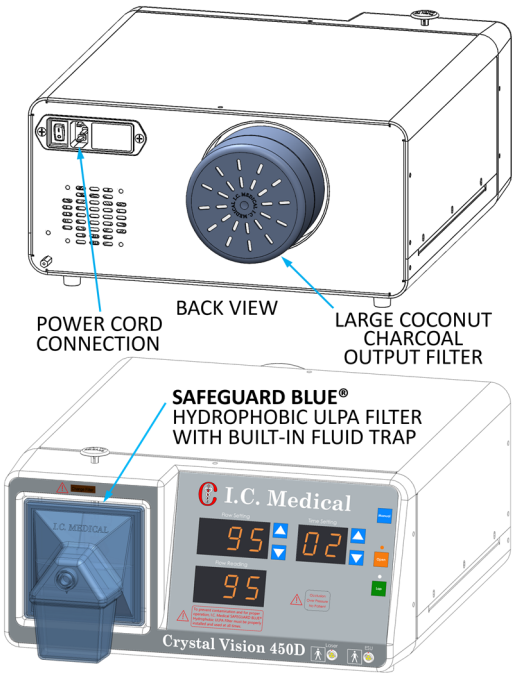


Figure 1: Filters and Power Cord Installation

FILTERS and POWER CORD INSTALLATION:

1. Attach the Large Coconut Charcoal Output Filter to the connector on the back of the CRYSTAL VISION®.
2. Attach the **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap to the connector on the front of the CRYSTAL VISION®.
3. Attach the power cord to the CRYSTAL VISION®.
4. Refer to Figure 1.

ESU, RF, or UNIVERSAL SENSOR INSTALLATION:

If you are going to use your CRYSTAL VISION® with an electrosurgical unit (ESU) monopolar or bipolar, ultrasonic device, harmonic scalpel, proceed with the following:

RF SENSOR
For use with all Crystal Vision® Models.
INSTALLATION/OPERATION:

RF Sensor when used with Monopolar Devices
(Figure 2; Option 2; Placement 1 or 2):

1. Plug the RF Sensor's connector into Crystal Vision Smoke Evacuator's ESU/Laser port.
2. Place the RF Sensor, on the monopolar device's cable (e.g. PenEvac), by running it through the sensor's wire clip.
3. Make sure the sensor is installed on top of the wire, with the clip side facing down, close to the monopolar device's plug, to prevent capture of residual RF signal from surrounding devices.
4. Plug the monopolar device (e.g. PenEvac), into the Monopolar port of the ESU Generator.
5. Select the "Monopolar" option on ESU Generator.
6. Set ESU Generator's Cut and Coag value.
7. Activate the monopolar device by depressing cut or coag button. When the monopolar device activates, the RF Sensor should turn ON the Crystal Vision Smoke Evacuator, automatically.
8. When not in use, put away the RF Sensor by attaching the Velcro side of the RF Sensor to the smoke evacuator. Perform first-time installation by peeling the back film from the Velcro loop tape, pressing it firmly to a clean and dry area on the side of the Smoke Evacuator.

To reuse the RF Sensor simply pull it off from the Smoke Evacuator's side.

RF Sensor when used with Bipolar Devices
(Figure 2; Option 1; Placement 1 or 2):

1. Plug the RF Sensor's connector into Crystal Vision Smoke Evacuator's ESU/Laser port.
2. Place the RF Sensor, on the bipolar device's cable, by running it through the sensor's wire clip.
3. Make sure the sensor is installed on top of the wire, with the clip side facing down, close to the bipolar device's plug, to prevent capture of residual RF signal from surrounding devices.
4. Plug the bipolar device into the Bipolar Port of the ESU Generator.
5. Select the "Bipolar" option on ESU Generator.
6. Activate the bipolar device. When the bipolar device activates, the RF Sensor should turn ON the Crystal Vision Smoke Evacuator, automatically.

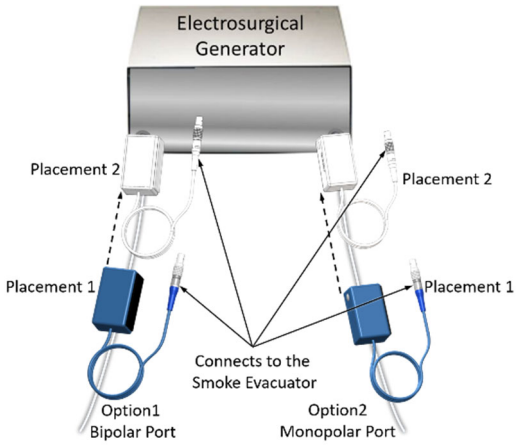


Figure 2: ESU and RF Sensor installation when used with an electrosurgical generator (ESU)

7. When not in use, put away the RF Sensor by attaching the Velcro side of the RF Sensor to the smoke evacuator. Perform first-time installation by peeling the back film from the Velcro loop tape, pressing it firmly to a clean and dry area on the side of the Smoke Evacuator.

To reuse the RF Sensor simply pull it off from the Smoke Evacuator's side.

UNIVERSAL BLUE RF SENSOR
For use with all Crystal Vision® Models
INSTALLATION/OPERATION:

UNIVERSAL BLUE™ RF Sensor when used with Monopolar Devices

(Figure 3; Option 2; Placement 1 or 2):

1. Plug the **UNIVERSAL BLUE™** RF Sensor's connector into Crystal Vision Smoke Evacuator's ESU/Laser port.
2. Place the UNIVERSAL BLUE™ RF Sensor, on the monopolar device's cable (e.g. PenEvac), making sure the sensor is installed on top of the cable, facing down, to prevent capture of residual RF signal from surrounding devices.
3. Use both of the self-adhering Velcro straps to wrap around the sensor and over the monopolar device's cable, to secure the cable to the sensor at both ends of the sensor.
4. Plug the monopolar device (e.g. PenEvac), into the Monopolar port of the ESU Generator.
5. Select the "Monopolar" option on ESU Generator.
6. Set ESU Generator's Cut and Coag value.
7. Activate the monopolar device by depressing cut or coag button. When the monopolar device activates, the RF Sensor should turn ON the Crystal Vision Smoke Evacuator, automatically.

UNIVERSAL BLUE™ RF Sensor when used with Bipolar Devices

(Figure 3; Option 1; Placement 1 or 2):

1. Plug the **UNIVERSAL BLUE™** RF Sensor's connector into Crystal Vision Smoke Evacuator's ESU/Laser port.
2. Place the **UNIVERSAL BLUE™** RF Sensor, on the bipolar device's cable, making sure the sensor is installed on top of the cable, facing down, to prevent capture of residual RF signal from surrounding devices.
3. Use both of the self-adhering Velcro straps to wrap around the sensor and over the bipolar device's cable, to secure the cable to the sensor at both ends of the sensor.
4. Plug the bipolar device into the ESU Generator.
5. Select the "Bipolar" option on ESU Generator.
6. Activate the bipolar device. When the bipolar device activates, the RF Sensor should turn ON the Crystal Vision Smoke Evacuator, automatically.

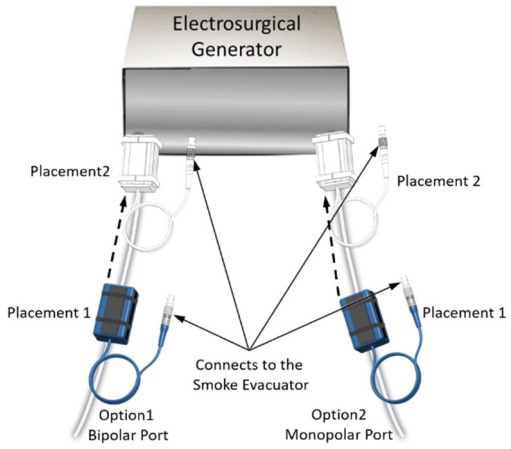


Figure 3: **UNIVERSAL BLUE** RF Sensor installation when used with an electrosurgical generator (ESU)

UNIVERSAL BLUE™ RF Sensor when used with Harmonic Scalpel Generator
(Figure 4; Placement 1 or 2):

1. Plug the **UNIVERSAL BLUE™** RF Sensor's connector into Crystal Vision Smoke Evacuator's ESU/Laser port.
2. Place the **UNIVERSAL BLUE™** RF Sensor on the hand piece cable, making sure the sensor is installed on top of the cable, facing down, to prevent capture of residual RF signal from surrounding devices.
3. Use both of the self-adhering Velcro straps to wrap around the sensor and over the hand piece cable, to secure the cable to the sensor at both ends of the sensor.
4. Plug the handpiece into the Harmonic Scalpel Generator.
5. Set the Harmonic Scalpel Generator
6. Activate the handpiece. When the handpiece is activated, the **UNIVERSAL BLUE™** RF Sensor should turn ON the Crystal Vision Smoke Evacuator automatically.

CAUTIONS: Use only smoke evacuator accessories manufactured by I.C. Medical, Inc. as **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap, Large Coconut Charcoal Output Filter, RF Sensor(s), smoke tubing disposable and other accessories. Using any other filters, sensors, or accessory, not manufactured or supplied by I.C. Medical, Inc. may cause damage and/or cause the system to be inoperable and may void the warranty.

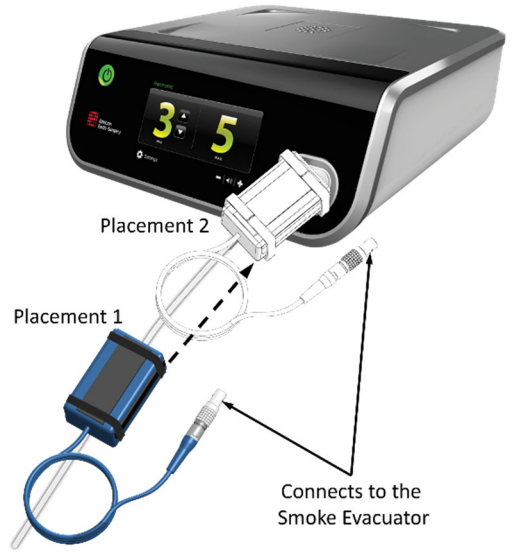


Figure 4: **UNIVERSAL BLUE** RF Sensor installation when used with Harmonic Scalpel generator

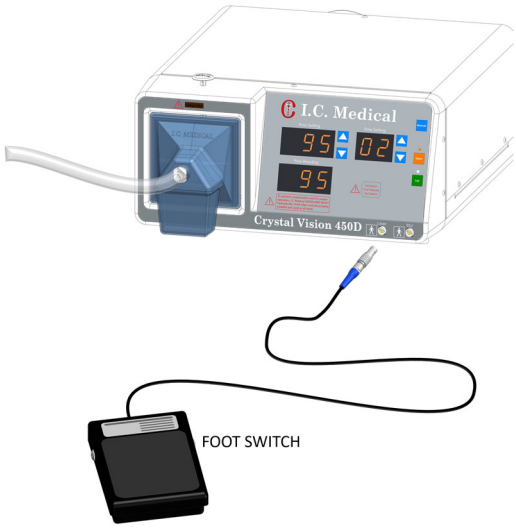


Figure 5: Foot Switch Installation

FOOT SWITCH INSTALLATION/OPERATION

If you would like to use your Smoke Evacuator independent to other devices, proceed with the following:

1. Plug the Foot Switch's connector into the Smoke Evacuator's ESU/Laser port as per Figure 5.
2. Depress/Release Foot Switch to activate/deactivate the Smoke Evacuator.

LASER SENSOR INSTALLATION

If you are going to use your CRYSTAL VISION® with a laser, proceed with the following:

1. Attach the Sensor Cable (Figure 6) to the LASER connector on the CRYSTAL VISION® and to the Sensor Connector Box.
2. The Sensor Assembly has three parts: the Sensor Connector Box, the Transmit Sensor, and the Receive Sensor. Both Sensors have double-backed tape on one side and an infrared lens on the side opposite the tape. The Receive Sensor has a red indicator lamp that will light when the sensor assembly is plugged into the operating CRYSTAL VISION®.

   (**NOTE**: When the red light goes off, CRYSTAL VISION® will start to operate).

   Test the Sensor Assembly for proper operation:

   a) Plug the Sensor Cable into the Sensor Connector Box and the LASER connector of the CRYSTAL VISION®.
   b) Plug the CRYSTAL VISION® into an AC outlet and turn on the Power Switch on the Control Box back panel and front panel.
   c) Align the Transmit Sensor Lens and the Receive Sensor Lens until the red light goes off and the CRYSTAL VISION® starts.
   d) Move the Sensor until the red light comes on. The pump in the CRYSTAL VISION® will stop operating sometime within 30 seconds after the light goes out. (**NOTE**: the actual amount of time that is required for the pump to cease operation is determined by the TIME adjustment on the CRYSTAL VISION® front panel).

3. Place the foot switch for the laser on an easily accessible work surface (Figures 7 & 8).
4. Inside the foot switch housing (Figure 8), position the Transmit Sensor and the Receive Sensor on opposite sides of the foot switch. Do not position the sensors on the sides of the foot switch.

   WITHOUT REMOVING THE PROTECTIVE COVERING ON THE TAPE, position them so that the red light comes on.

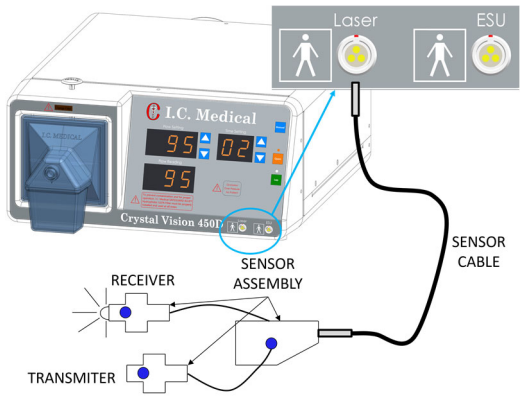


Figure 6: Laser Sensor Installation

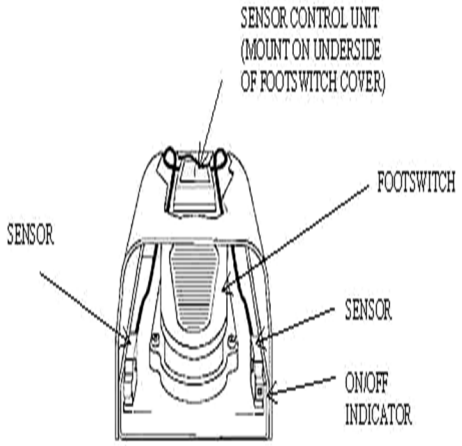


Figure 7: Laser Sensor Installation to the SIDE of the laser foot switch HOUSING.

5. Keep the Sensors in the same position and press the Laser Foot Pedal down. The red light should go out. If it does not, reposition the Sensors until the red light goes out when the Laser Foot Pedal is depressed and it remains on when the pedal is not depressed.
   THE LIGHT SHOULD GO OUT FOR THE SLIGHTEST MOVEMENT OF THE FOOT PEDAL. If it does not, move both sensors higher up the wall of the protective housing of the laser pedal.
   Carefully mark the location of both sensors.

6. Remove the protective backing from one Sensor and place it in the correct position on the side of the Laser Foot Switch Assembly. (**NOTE**: It is usually very helpful to only LIGHTLY position the sensors at first and only after you are certain that they are in the exact position press them firmly into place.)

   Repositioning either sensor after it has been firmly set in place can easily destroy it.

7. Repeat the process for the other Sensor.

8. Move the Sensor Connector Box to a convenient location inside the Laser Foot Switch Assembly. Be sure that the cables from the Sensors to the Sensor Connector Box do not interfere with the operation of the foot switch or with the surgeon's foot. Carefully mark this location

9. Remove the protective covering from the tape on the Sensor Connector Box and attach it to the previously marked location inside the Laser Foot Switch Assembly.

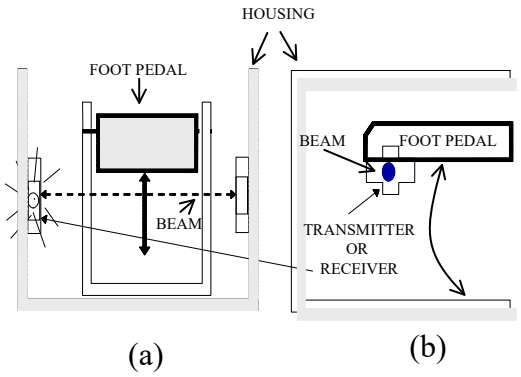


Figure 8: Sensors should be positioned so that ANY movement of the pedal interrupts the beam.

CHECK PROPER OPERATION OF THE CRYSTAL VISION®

1. The CRYSTAL VISION®. power switch (Figure 9) is located on the back panel, next to the power cord. Place this in the "ON" [I] position. When unit is turned ON, the FLOW SET, indicators and display for TIME and FLOW should illuminate.
2. Adjust the TIME by pressing the push buttons (Figure 10) until the TIME display reads 2 SECONDS. The pump should operate when the ESU Sensor or Laser Foot Switch is activated and stops within approximately 2 seconds after the foot switch is released.
3. The pump should operate when the MANUAL push button (Figure 10) on front panel is depressed and stop operating within approximately 2 seconds after the button was released.
4. Adjust TIME by pressing the push button arrow Up to maximum, it should read 30 seconds. Press the MANUAL button. The pump should start and then stop approximately 30 seconds after the button was released
5. Adjust TIME by pressing the push button arrow Down until the TIME display reads 2 seconds. Press and release the MANUAL button. The pump should start and then stop approximately 2 seconds after the button was released.

The Up and Down arrow buttons adjust the desired FLOW rate on the Flow Setting display. The digital FLOW READING displays the actual flow through the Crystal Vision®.

The OPEN (Orange) button and LAP (Green) button changes the operating mode of the unit the operating mode of Crystal Vision® is indicated by the LED situated above OPEN and LAP push buttons.

Figure 9: ON/OFF power switch description.

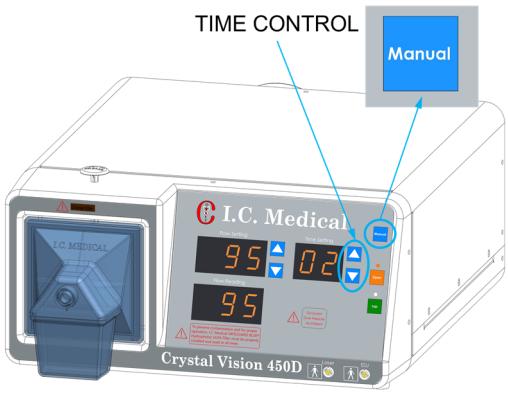


Figure 10: Manual and Time Control locations.

6. The FLOW SETTING buttons (Up and Down arrows), (Figure 11), adjusts the desired Flow level on the Flow Setting display. The Flow Reading digital meter indicates the actual Flow through the unit. Some RF noise may cause the Flow Set and Flow Reading to flicker; however, it will not affect the actual flow or the functionality of the CRYSTAL VISION®.

7. Push OPEN Button. Orange LED indicator should light up. Adjust Flow setting to maximum (95 l/min) by pushing Flow Setting Up arrow button. Press Manual button, pump should start. Flow Reading display should indicate at least 90 l/min.

8. Push LAP button. Green LED indicator should lit up. Set the Flow Setting to minimum (4 l/min) by pushing Flow Setting arrow button down. Press Manual button, pump should start. Flow reading display should indicate 4 (±1) l/min. Repeat the process for maximum flow. The Flow Reading display should indicate at least 18 l/ min.

9. Place a finger over the **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap input and press the MANUAL button. The CHANGE FILTER and OCCLUSION LEDs should lit up. **The OVER PRESSURE indicator requires special test equipment and should be tested only by trained qualified personnel**.

10. For any problems, or if the CRYSTAL VISION® fails to perform as indicated, contact I. C. Medical, Inc.

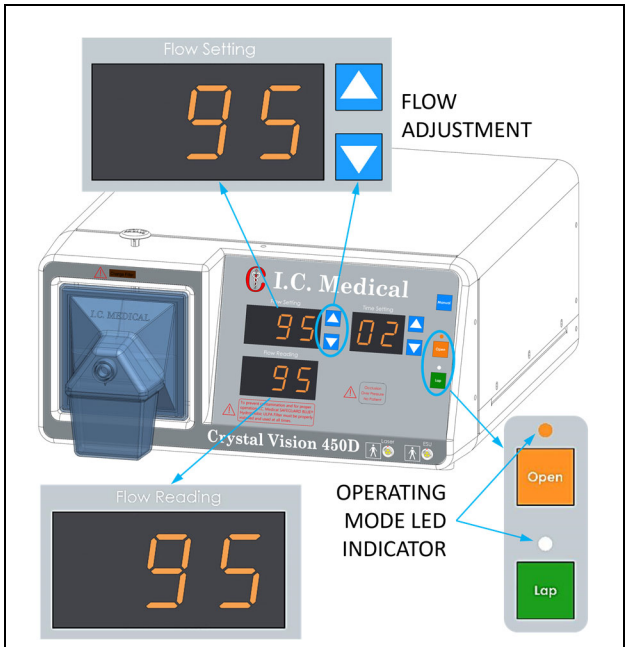


Figure 11: Flow buttons.

DESCRIPTION OF SWITCHES, CONTROL BUTTONS & INDICATORS

The Sensor Assembly and the Large Coconut Charcoal Output Filter should already be installed according to the INSTALLATION INSTRUCTIONS.

1. ON/OFF SWITCH is located on the back panel (Figure 12) next to the power cord. This switch controls the power to the CRYSTAL VISION®. International symbols are used. The [I] symbol indicates power "ON" and [O] indicates "OFF." This switch also controls the cooling fan.
2. MANUAL button (Figure 13) used to turn the CRYSTAL VISION® ON when the surgeon is not activating a smoke-producing device. The MANUAL button can be used to clear residual plume during these situations in (LAP) procedures. It can also be used to clear smoke and plume if more than one device is used and only one sensor is available. This frequently occurs during laser cases when a sensor is attached to the laser foot pedal and other sensors are not available to be attached to an Electrosurgical Unit (ESU).
3. LASER CONNECTOR (Figure 13) is the input for the LASER SENSOR CABLE. In reality, both LASER & ESU connectors are identical and either will accept all standard I.C. Medical sensor assemblies.
4. ESU CONNECTOR (Figure 13) is the input for the ESU SENSOR CABLE. This sensor can be used to activate the CRYSTAL VISION®.

Figure 12: ON/OFF power switch location.

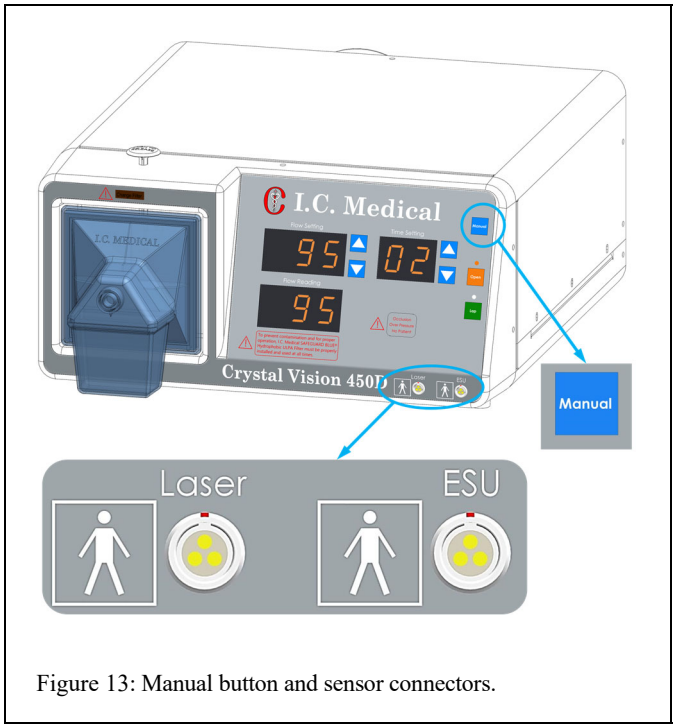


Figure 13: Manual button and sensor connectors.

5. TIME SETTING Buttons (Up and Down arrows) (Figure 14) varies the amount of time that the CRYSTAL VISION® continues to draw smoke, vapor, and gases from the surgical site. The low flows into the pneumoperitoneum limit the amount of gas that can be evacuated from the pneumoperitoneum without causing the abdomen to deflate. In cases such as this, it is very useful to limit the flow rate to a value that can be supplied by the insufflator. To extend the amount of time that the CRYSTAL VISION® operates after the foot pedal (or hand switch) is released. This allows for a greater volume of gas to be eliminated from the abdomen and therefore reduces the amount of residual smoke that is left in the abdomen. The ideal situation is to increase the amount of flow into the abdomen. See the highlighted box titled "FOR BEST RESULTS" in the LAPAROSCOPIC OPERATION section that follows.

   TIME DISPLAY (METER) (Figure 14) indicates the amount of time that the CRYSTAL VISION® will operate after the foot switch, or hand switch, is deactivated (2 sec min- 30 sec max)

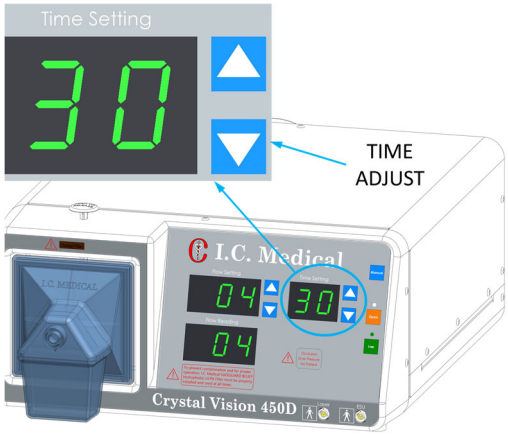


Figure 14: Adjustment for time setting.

6. OPEN and LAP buttons (Figure 15) select the flow range of the vacuum pump. The operator, according to the type of procedure selects the range**. LAP MODE SHOULD BE SELECTED FOR ALL LAPAROSCOPIC PROCEDURES** and the readouts are GREEN. OPEN MODE should be used during open and external cases when plume is being eliminated through a handpiece. Using OPEN MODE during laparoscopy will quickly deflate the pneumoperitoneum. The OPEN and LAP buttons also select the corresponding FLOW SETTING.

7. Only one of the LED mode indicators is illuminated at a time. This eliminates confusion of which mode is used.

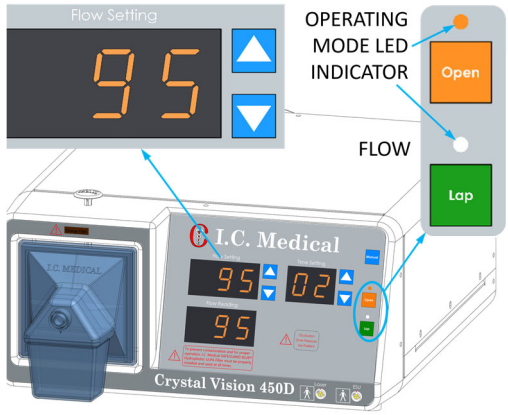


Figure 15: Setting the flow RANGE.

8. FLOW SETTING control buttons (Figure 16) sets the maximum flow that is desired by the surgeon. This value is indicated on the FLOW SETTING display.
9. FLOW READING (Figure 16) is registering the amount of gas and vapor that is actually flowing at the present time. This value should be zero, when the vacuum pump is not turned on.
10. CHANGE FILTER indicator is located above filter (Fig. 17). It illuminates when there is a reduced flow into the CRYSTAL VISION®. The **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap should be changed when this light first illuminates. Do not attempt to clean, or re-use the **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap. Dispose of the **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap according to your institution's biological waste protocol. This indicator will also come ON when there is a total occlusion. If the OCCLUSION indicator is also lit, be sure to clear the obstruction that caused it first and then check the CHANGE FILTER indicator. If it is still illuminated and the OCCLUSION indicator is not, then the **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap needs to be changed.
11. OCCLUSION indicates that flow into the CRYSTAL VISION® has stopped (Figure 17). The CHANGE FILTER light will also come ON at this time. The operator should check for kinked tubing, stopcocks that are turned OFF, clogged insufflator, use by date of Large Coconut Charcoal Output Filter, or a completely clogged **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap. In order to prevent pump failure, the CRYSTAL VISION® pump will not activate when this lamp is illuminated.
12. OVER PRESSURE indicates pressure exceeding 27 mmHg in the pneumoperitoneum (Figure 17). At pressures over 30 mmHg, the vacuum pump starts in order to reduce the pressure in the pneumoperitoneum. This situation can be caused by many factors. Frequently, the surgeon presses on the abdomen and this causes intra-abdominal pressure to rise. Correct the cause before continuing.
13. The "NO PATIENT" indicator (Figure 17) turns on when the CRYSTAL VISION® is in the LAP MODE, when zero pressure, or atmospheric pressure, is present at the **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap. The tubing set may not be connected to the Trocar sheath or to the **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap; the valve on the Trocar sheath may be turned off; or the **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap may not be attached to the **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap connector.

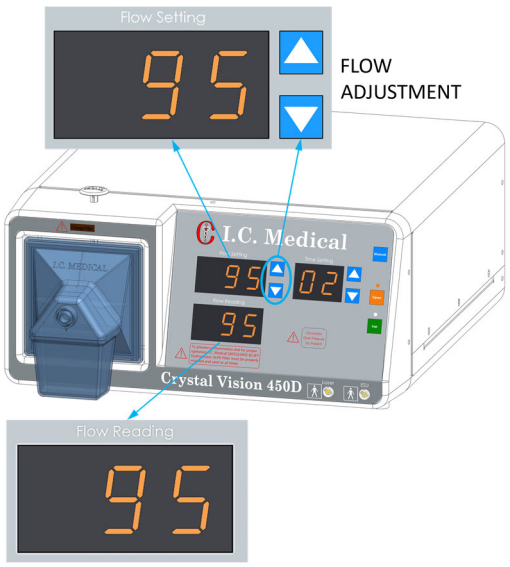


Figure 16: Selecting the desired flow.

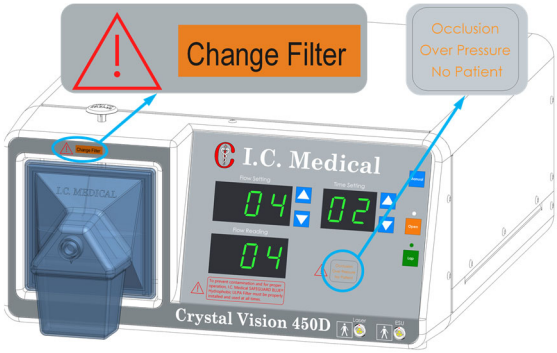


Figure 17: Front Panel Indicators.

14. **INPUT FILTER CONNECTOR** (Figure 18) holds the **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap. The metal ring is pushed down to allow the **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap, to be released. Replace cap on end of **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap between uses. Change the **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap when CHANGE FILTER indicator illuminates.
15. **Large Coconut Charcoal OUTPUT FILTER CONNECTOR (connector not shown)** (Figure 18). The Large Coconut Charcoal OUTPUT FILTER CONNECTOR is located on the back panel of the CRYSTAL VISION®. The Large Coconut Charcoal Output filter- is reusable for several cases. The Large Coconut Charcoal Output filter has a functional life of three months. The Large Coconut Charcoal Output filter provides odor control and reduces vacuum pump noise.

Do not operate the unit without a Large Coconut Charcoal Output filter.

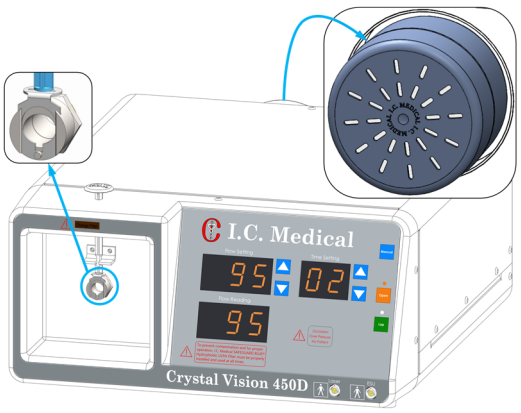


Figure 18: Input Filter Connector holds **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap. Large Coconut Charcoal Output Filter

LAPAROSCOPIC OPERATION

FOR BEST RESULTS:

1. Installation of Crystal Vision should already be completed according to the installation instructions. Connect **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap to CRYSTAL VISION® front panel. Connect sensor LASER SENSOR and/or the ESU/RF/Universal SENSOR, as desired, to CRYSTAL VISION® front panel.
2. Be familiar with all operating controls as described in Description of Switches, Control Buttons, and Indicators.

SET-UP when using ESU in Laparoscopic Procedures:

1. Install and connect a 10mm Laparoscope CANULA (TROCAR) to the insufflator.
2. Install and connect the I/A tubing to Crystal Vision on one end, and other end to the CANULA (TROCAR).
3. Install a second 10mm CANULA (TROCAR) to use with 5mm ESU instrument.
4. Upon installation the user may detach the laparoscopic tubing from Laparoscope/Canula and attach to 10mm CANULA (TROCAR) used for ESU instrument and install SMOKE EVACUATOR TUBING to the 10 mm Laparoscope CANULA (TROCAR).
5. The insufflator FLOW should be set to Maximum, and the pressure should be set to surgeon's needs. Refer to Figure 19.

At the end of procedure remove all instruments and CANULA except the one with Smoke Evacuator attached. Set the Smoke Evacuator Flow at maximum in LAP mode, time at 30 seconds and press the manual button-the entire quantity of CO_2 from the abdomen is filtered and removed safety so no gas will escape in OR, protecting the surgeon and OR stuff from bacteria and viruses.

SET-UP when using CO_2 Laser in Laparoscopic Procedures:

1. Install and connect the Laser Laparoscope luer lock to the insufflator.
2. Install and connect the I/A tubing, to Crystal Vision on one end, and to the CANULA (TROCAR) on the other end. Refer to Figure 20.

At the end of procedure remove all trocars and instruments except the one with Smoke Evacuator attached.
Set the Smoke Evacuator Flow at maximum in LAP mode, time at 30 seconds and press manual button-in few seconds the abdomen will be deflated, the gas will pass through the SAFEGUARD BLUE® Hydrophobic ULPA Filter with Built-in Fluid Trap, filtered, and no bacteria and viruses will escape in OR.

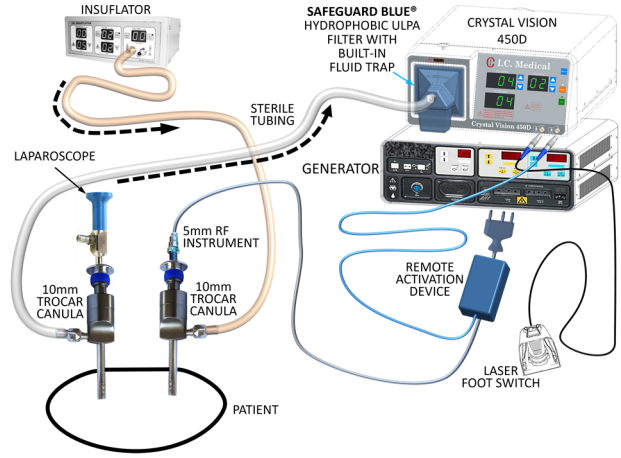


Figure 19: Laparoscopy Set up when using ESU and Crystal Vision

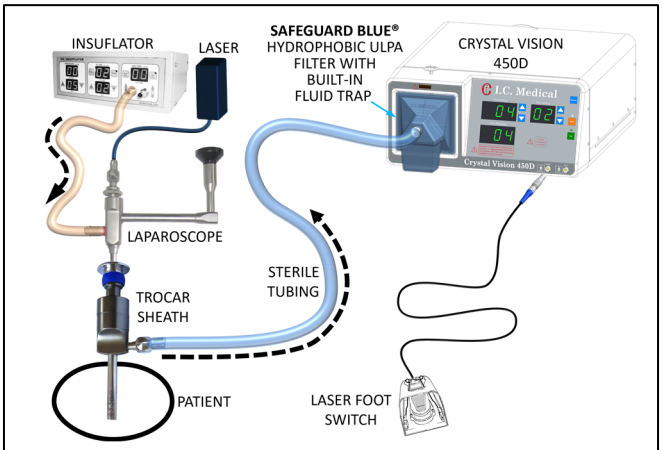


Figure 20: Laparoscopy Set up when using CO_2 Laser and Crystal Vision

Set the FLOW SETTING for a flow slightly **LESS** than the flow that the insufflator can provide.
Push the MANUAL button.
Observe the effect of a complete cycle by noting the pneumoperitoneal pressure on insufflator gauge/indicator before the CRYSTAL VISION® starts to operate and immediately after the pump stops. The intra- abdominal pressure should not drop more than 1-2 mmHg. If it does, reduce the flow on the CRYSTAL VISION® FLOW SETTING and repeat the process until the pressure drops very slightly. It is important to set the CRYSTAL VISION® flow as high as possible without diminishing the pneumoperitoneal pressure.

The FLOW SETTING indicates the desired maximum Flow. The FLOW READING display indicates the actual Flow occurring at that moment. The meter will read zero when the pump is off. The meters are ORANGE in OPEN Mode and GREEN in LAP Mode.

3. The MANUAL button can be used to start the vacuum pump if smoke still exists when the TIME SETTING is set for the maximum amount of time. Be sure to monitor the pneumoperitoneal pressure so that it does not fall more than a few mmHg (adjust the FLOW SETTING, if necessary).

OPERATIONAL HINTS:

The TIME SETTING can be used to conserve insufflator gas by reducing the amount of time that the Crystal Vision pumps after lasing stops. This process requires more attention from the circulating nurse, or the laser operator.

4. CHANGE FILTER illuminates when the **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap needs to be changed.
5. OCCLUSION indicator lights when flow virtually ceases from the pneumoperitoneum. Check for kinked tubing, closed Luer lock on the Trocar sheath, severely clogged **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap, heavy fluid accumulation in the fluid trap, or obstructions in the Trocar sheath. The CHANGE FILTER indicator always lights when the OCCLUSION indicator comes on.
6. OVER PRESSURE occurs when a pressure more than 27 mmHg (±10% and 1 digit) is detected by the CRYSTAL VISION. When this happens, the OVER PRESSURE lamp and audio indicators turn ON. If the pressure exceeds 30 mmHg (±10% and 1 digit) the CRYSTAL VISION pump starts and attempts to reduce the over pressure situation. DO NOT EXCEED 30 mmHg PRESSURE!
7. NO PRESSURE indicator illuminates when the Trocar sheath is turned off, the tubing set is not connected to the Trocar sheath, or the **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap is not connected to the **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap connector.

IF SMOKE PERSISTS WHEN THE PUMP STOPS BE SURE THAT:

1. Luer lock on the cannula is open,
2. Tubing is not crimped,
3. **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap is clean, may need to be replaced if it is clogged,
4. Inspect for leaks at the Trocar sheaths, tubing, or instruments,
5. Increase the TIME SETTING if there are no leaks.
6. If TIME SETTING is set to maximum time, use the MANUAL button until the abdominal cavity is smoke free. Do not use it excessively, or the pneumoperitoneum will collapse.

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NON-LAPAROSCOPIC GYNECOLOGY PROCEDURES:

1. Installation should already be completed according to the installation instructions.
2. Be familiar with all operating controls as described in Description of Switches, Control Buttons, and Indicators.
3. Refer to Figure 21 for set-up.
4. Connect **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap to the CRYSTAL VISION®.
5. Connect Disposable Sterile Tubing Set to laser speculum port and to the **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap.
6. Connect ESU and/or LASER SENSOR CABLE to SENSOR ASSEMBLY and the CRYSTAL VISION®.
7. Plug CRYSTAL VISION® into power outlet and turn on POWER SWITCH on back panel.
8. Push OPEN (Orange) button.
9. Adjust FLOW SETTING for the desired flow rate indicated on the display.
10. Push MANUAL button and observe the actual flow indicated by FLOW READING display. Adjust FLOW SETTING if necessary.
11. Adjust TIME SETTING for the desired amount of time that the CRYSTAL VISION® runs after the smoke producing equipment is shut off.
12. Increase the FLOW SETTING and/or the TIME SETTING if smoke is not eliminated from the uterus.
13. **CHANGE FILTER** light may indicate a partially obstructed speculum port or smoke tubing. Check and clean them, if necessary. **The SAFEGUARD BLUE® Hydrophobic ULPA Filter with Built-in Fluid Trap may also need to be changed.**
14. **OCCLUSION** alarm indicates obstructed speculum port, kinked, or obstructed tubing. Check and clean as necessary. **It may also mean that the SAFEGUARD BLUE® Hydrophobic ULPA Filter with Built-in Fluid Trap has become extremely filled with smoke particles. Replace it, if required.**

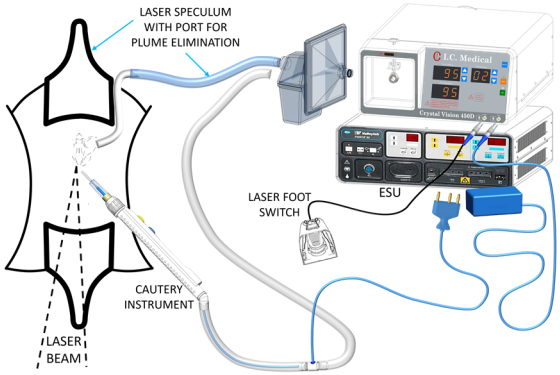

Figure 21: Set up for gynecology procedure for either ESU or CO_2 laser delivered through a colposcope or Micromanipulator

OTHER NON-LAPAROSCOPIC PROCEDURES:

1. Installation should already be completed according to the installation instructions.
2. Be familiar with all operating controls as described in Description of Switches, Control Buttons, and Indicators.
3. Refer to Figure 22 or 23 for set-up.
4. Connect **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap to CRYSTAL VISION®.
5. Connect Laser Hand piece Accessory or ESU Handpiece Accessory to the **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap .
6. Connect ESU sensor to ESU port of the CRYSTAL VISION® or Laser Sensor Cable to Sensor Assembly and the CRYSTAL VISION®.
7. Plug CRYSTAL VISION® into power outlet.
8. Turn ON POWER switch on back panel.
9. Push OPEN (Orange) button. Indicator should illuminate.
10. Adjust FLOW SETTING for the desired flow.
11. Push MANUAL button and observe that desired flow is shown on the digital FLOW meter display
12. Adjust TIME SETTING for the desired amount of time that the CRYSTAL VISION® runs after the smoke producing equipment is deactivated.

IF SMOKE PERSISTS DURING THE SURGICAL PROCEDURE, TRY THE FOLLOWING:

13. Increase the FLOW SETTING and/or the TIME SETTING if smoke is not eliminated from the surgical site.
14. CHANGE FILTER light may indicate a partially obstructed speculum port or tubing. Check and clean them, if necessary. The **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap may also need to be changed.
15. **OCCLUSION** alarm indicates an obstructed smoke collection nozzle, kinked or obstructed smoke tubing. Check and clean as necessary. **It may also mean that the SAFEGUARD BLUE® Hydrophobic ULPA Filter with Built-in Fluid Trap has become extremely filled with smoke particles. Replace it, if required.**

IF SMOKE PERSISTS WHEN THE PUMP STOPS BE SURE THAT:

16. Tubing is not crimped
17. **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap is clean, may need to be replaced if it is clogged
18. Be sure there are no leaks in the tubing, or instruments:
19. Increase the TIME SETTING if there are no leaks.

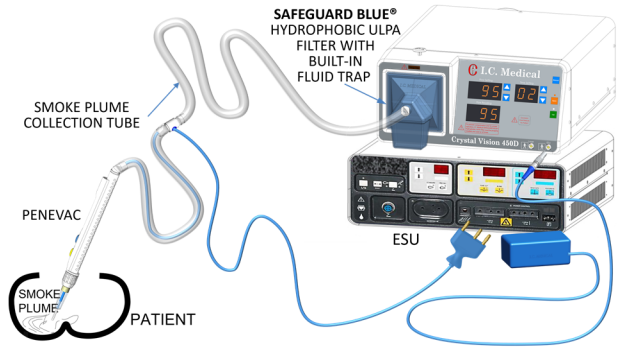

Figure 22: Set up for using CRYSTAL VISION® with an ESU system during an open procedure.

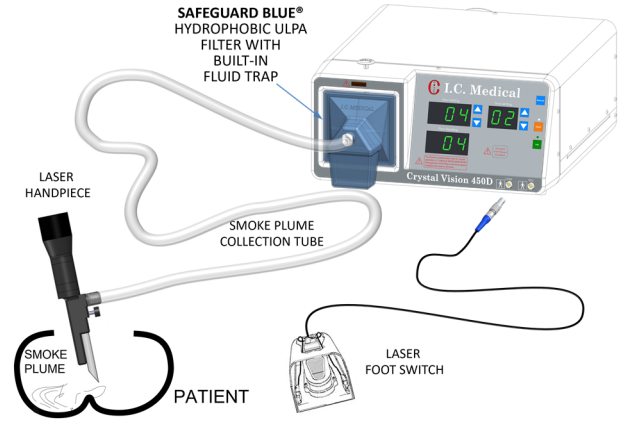

Figure 23: Set-up for using a CRYSTAL VISION® with a laser hand piece.

PENEVAC1®, NON-TELESCOPIC PenEvac and OTHER ACCESSORIES USED WITH CRYSTAL VISION:

PenEvac Accessories:
PenEvac® accessories (PenEvac1 and Non-telescopic PenEvac) may also be used with the CRYSTAL VISION® Model 450D. The PenEvac1® combines the function of an ESU pencil and smoke evacuator into a single hand-held device. The PenEvac1® also has a telescoping tip that enables the surgeon to change the length of the electrode without actually replacing the electrode. Several styles of electrodes are available.
The Non-Telescopic PenEvac has the same function as the PenEvac1 however its electrode is non telescopic.

The PenEvac® products are available as disposable single-use.

ESU Shroud Accessories:
The ESU Shroud, slips over standard electrosurgery (ESU) hand switching pencil and is used to evacuate smoke and other airborne debris that is created when the ESU pencil is in use.

Intra-Abdominal Tubing Set:
I/A Tubing is used to eliminate smoke and any airborne debris that are generated during laparoscopic procedures.

Speculum Tubing:
Smoke Accessories are intended to evacuate smoke plume produced during surgical procedures

Smoke Tubing:
Smoke Tubing Accessories are intended to evacuate smoke plume produced during surgical procedures.

Please refer to http://www.icmedical.com for further information.

For a complete list of compatible finish product reference number, please contact I.C. Medical, Inc.

CAUTIONS: Use only smoke evacuator accessories manufactured by I.C. Medical, Inc. as **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap, Large Coconut Charcoal Output Filter, RF Sensor(s), smoke tubing disposable and other accessories. Using any other filters, sensors, or accessory, not manufactured or supplied by I.C. Medical, Inc. may cause damage and/or cause the system to be inoperable and may void the warranty.

THEORY OF OPERATION

The CRYSTAL VISION® Model 450D was designed to effectively remove smoke during surgical procedures and to eliminate problems associated with other types of smoke evacuators. The CRYSTAL VISION® automatically turns on when the surgeon activates a smoke-producing device and it turns itself off when it is not needed to remove surgical smoke. The Model 450D has two flow ranges to provide optimal performance under a variety of surgical conditions. In addition, the evacuator notifies the operator of conditions that may limit the effective removal of smoke.

PNEUMATIC CIRCUITS

Surgical Smoke collection devices are used to remove smoke from the surgical site and deliver it through the fluid trap and into the **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap rated 0.1-micron input filter. The filtered air then travels from the **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap , through either the OPEN or LAP pneumatic circuits, into the pump, then through the output charcoal 0.5-micron filter and finally delivered back into the operating room.

ELECTRONIC CIRCUITS

START PUMP:

There are three ways to start the pump: trigger a remote sensor, push the MANUAL button on the front panel, or an OVER PRESSURE condition.

1. **Remote Sensors**: Remote sensors are attached to the front panel at the ESU or LASER plug. Both plugs are electrically identical and can be used interchangeably with either sensor.

   a) The **LASER sensor** consists of an infrared transmitter and receiver that are carefully positioned on a foot switch that activates a surgical laser. Placement is critical because it is very important to position the infrared beam so that it is interrupted at the first movement of the foot pedal. In this manner, the evacuator is started before the laser actually activates and the air stream is already moving when the laser beam first strikes tissue.

   b) The **ESU sensor** is placed on, or near the input connector of the electrocautery pencil cable and the other end is plugged into the evacuator front panel. Activation of the ESU pencil is detected by the sensor. The remote sensor (ESU or Laser) sends a trigger, through the front panel board, to the Master Board, and then to the motor controller.

2. The **Manual button** also starts the pump if it is pushed. This push button is used during procedures to activate the pump if a remote sensor is not used with all of the active smoke producing devices. The switch can also be used when very low flow insufflators are used during laparoscopic procedures. It is helpful in this circumstance because increasing the flow rate would deflate the pneumoperitoneal pressure. Instead, the flow TIME can be set to 30 seconds and if additional purging is required, the MANUAL button will continue the evacuation.

3. An **OVER PRESSURE condition**: When the evacuator is in the **LAP Mode,** the pressure in the pneumoperitoneum is monitored. When the pressure reaches approximately 27 mmHg, a light alert is activated. If the pressure continues to build to 30 mmHg, the pump is started and it continues to operate until the pressure drops below 30 mmHg. The pressure is not monitored in **OPEN Mode** because this range is not intended to be used during laparoscopic procedures.

STOP PUMP:

When the smoke producing device is deactivated, MANUAL button not pressed, or the OVER PRESSURE condition is not present, the pump will continue to operate for the amount time shown on the TIME SETTING on the front panel.

Whenever an **OCCLUSION** condition is sensed, the pump will stop. After a brief period of time, if any start condition exists, it will attempt to restart to see if the occlusion has been cleared. If it has not, the pump will again stop. This will continue until the occlusion is cleared, or until TIME expires.

TIME SETTING:

The **TIME SETTING** buttons are used to adjust the amount of time that the evacuator continues to pump after the active smoke producing device (laser, ESU, etc.) is deactivated. This lag in the deactivation of the evacuator is necessary in order to remove any residual smoke from the surgical site. The control is variable from approximately 2 to 30 seconds.

FLOW SETTING:

The **FLOW SETTING** control buttons vary the speed of the vacuum pump depending on the flow range in use. **OPEN Mode** flow is adjustable to at least **90 lpm** and **LAP Mode** flow from **4 ± 1** to at least **18 lpm**.

The **FLOW SETTING** is used only as a general indicator of what the flow will be when the pump is started. The purpose of the display is to allow the operator to preset the desired flow when the pump is not running. The **FLOW READING** is meant to provide a more accurate measure of the flow actually occurring. There may be relatively large differences between the FLOW SETTING and the FLOW READING.

The **FLOW READING** display provides a good measure of the actual flow when the pump is running. The **FLOW READING** displays 00.0 (Zero) when the pump is not running. Measuring flow is a very complicated process. The actual flow through the pump will vary significantly depending on the accessories, and the measuring devices used. Be sure to follow the procedures listed in the Calibration section explicitly when trying to calibrate, or measure, the flow through the evacuator.

OPEN MODE:

The **OPEN MODE** is used with the PenEvac1®, ESU Pencil Shroud™, or other types of surgical smoke collection 10mm or greater tubing sets. These procedures are considered "**open**" in that the flow of air and vapor to the surgical site is not restricted like it is during a laparoscopic or other "**closed**" procedure. During the open procedures, higher flow rates are very desirable to remove effectively all smoke from the site and to keep it from permeating the operating room. When the **OPEN** button is pushed, the high flow solenoid is activated to select the high flow air circuit.

The flow circuit is monitored by a vacuum sensor in order to detect an occluded air stream. If an occlusion is detected, the pump immediately stops to prevent tissue damage. Within a few seconds, the pump will attempt to restart. If the occlusion has been cleared, the pump will run. If the occlusion is still present the pump will not start and will again attempt a restart in a few seconds. The restart attempts will continue until the occlusion is cleared, or until **TIME SETTING** expires.

The flow resistance is also monitored for changes in restrictions in the air stream that do not represent an occlusion.

When the set point is exceeded, sensing that the **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap is no longer effectively capturing particles, the **CHANGE FILTER** light is illuminated. The pump is not stopped unless the restrictions are allowed to continue (**filter gets fuller**) and an occlusion is sensed.

LAP MODE:

LAP flow range is used during laparoscopic ("**closed**") procedures, they are characterized by a limited amount of gas (air, carbon dioxide, etc.) being available for evacuation. **LAP MODE** is used as many insufflators can only provide 4 - 6 lpm to the cavity. If the **FLOW SETTING** is set to evacuate much higher rates, the pneumoperitoneum will collapse. Therefore, the operator needs to balance the **FLOW** and **TIME SETTINGS** to optimize the amount of gas removed at any one time.

The **LAP MODE** is also monitored for Occlusion and Change Filter conditions. These are monitored by the same vacuum sensor and uses parallel circuits to those in the **OPEN MODE**. For more information, refer to the **OPEN MODE** description.

The **LAP MODE** is also monitored for two other conditions. The CRYSTAL VISION®, in **LAP** flow only, monitors the pressure in the flow circuit when the pump is **NOT** running. The **NO PATIENT** circuit looks for the presence of a positive pressure to indicate that the evacuator is attached to the pneumoperitoneum correctly and that there are no occlusions (typically closed stopcocks) in the circuit. If the circuit is not attached to the patient, or a stopcock is closed, or the filter is completely clogged, the positive pressure in the pneumoperitoneum cannot be sensed by the CRYSTAL VISION®. Under these circumstances, the **NO PATIENT** lamp comes on. Whenever this light comes on, it is important to correct the problem because the evacuator will not be able to monitor the pressure in the pneumoperitoneum for **OVER PRESSURE** conditions nor will it be able to evacuate smoke when it is generated.

The pneumoperitoneal pressure is monitored (if the circuit is connected properly and the **NO PATIENT** light is out) when the pump is not running. If the pressure sensed is approximately 27 mmHg, the **OVER PRESSURE** light alert is activated until the pressure drops to below 27 mmHg. If the pressure exceeds approximately 30 mmHg, then the pump will start and run for the set time.

TROUBLE SHOOTING GUIDE

SYMPTOM	PROBLEM/RESOLUTION:
CRYSTAL VISION® **Won't Turn ON**	Be sure power cord is plugged in. Check power switch on back panel to see if it is turned on. Blown Fuse. (Have technically qualified personnel replace as follows: Remove fuse cover with small screw driver, remove fuse holder, replace fuse with F4AH 250V fuse; replace fuse holder and replace fuse cover). Check Outlet for voltage reset circuit breaker if needed. If none of the suggestions resolves this problem, then Unit is malfunctioning, please have technically qualified personnel check and correct or contact I. C. Medical, Inc.
Pump Won't Start	Occlusion Indicator is on. See solutions under "**Occlusion Indicator."** Press the manual button, if pump starts then check the following; Activation Sensor assembly is not installed, or it is not installed correctly. If **Laser Sensor** is used, be sure the red light is "on" and that it goes out as soon as the foot pedal is depressed. If Electrosurgical Sensor is used, **see "ESU SENSOR INSTALLATION."** Sensor cable not connected to CRYSTAL VISION® front panel (and connected to foot switch if Laser Sensor is used). Press the manual button, if pump does not start then Unit is malfunctioning, please have technically qualified personnel check and correct or contact I. C. Medical, Inc.
Pump Runs Continuously	Unplug Sensor from the Unit, adjust TIME SETTING to minimum. If after 2 seconds pump turns off then the following may apply; **Laser Sensor** assembly not installed correctly. Be sure red light on the sensor is "ON" when the pedal is NOT depressed and that it goes out when the pedal is depressed. Debris blocking the light beam at the sensor assembly. **ESU Sensor** is defective and will need to be repaired. Unplug Sensor from the Unit, adjust TIME SETTING to minimum. If after 2 seconds pump does not turn off then Unit is malfunctioning, please have technically qualified personnel check and correct or contact I. C. Medical, Inc.
OCCLUSION Indicator Is ON	**For Laparoscopic procedures,** Gas is not allowed to flow freely from the pneumoperitoneum to the CRYSTAL VISION®. Check Trocar sheath stopcock, pinched tubing, tissue/fluids blocking the Trocar channel, or a severely clogged **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap. Clear obstruction before continuing. **For open procedures,** Blockage is occurring during the procedure, determine the blockage and clear away. Check calibration of Occlusion Indicator (**LAP** flow & **OPEN** flow). See **Hospital Level Calibration Instructions**. If none of the suggestions resolves this problem, then Unit is malfunctioning, please have technically qualified personnel check and correct or contact I. C. Medical, Inc.
OVER PRESSURE Indicator Is ON	**Pressure exceeds 27 mmHg (±10% and 1 digit) in the pneumoperitoneum**. Insufflator or argon beam coagulator supplying too much gas. External Pressure (i.e., from physician's arm, etc.) to the pneumoperitoneum is raising the internal pressure. **Correct the problem before continuing.** Check calibration of Over Pressure Indicator. Also check adjustment of the Over Pressure Threshold to Start Pump. See **Hospital Level Calibration Instructions**. If none of the suggestions resolves this problem, then Unit is malfunctioning, please have technically qualified personnel check and correct or contact I. C. Medical, Inc.
NO PATIENT Indicator Is ON	The CRYSTAL VISION® is not sensing pneumoperitoneal pressure. Be sure tubing set and **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap are properly connected. Also, be sure the stopcock on the Trocar sheath is open. Pneumoperitoneum may be at room pressure (no action required). Check calibration of No Patient Indicator. See **Hospital Level Calibration Instructions**. If none of the suggestions resolves this problem, then Unit is malfunctioning, please have technically qualified personnel check and correct or contact I. C. Medical, Inc.

SYMPTOM	PROBLEM/RESOLUTION:
CHANGE FILTER Indicator Is ON	Airflow through the **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap is being reduced. This may indicate a partial obstruction for the following reasons depending upon the procedure, speculum port, partially obstructed smoke collection nozzle, or smoke tubing. Check and clean them, if necessary. The **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap may also need to be changed. **Do not attempt to clean or re-use SAFEGUARD BLUE® Hydrophobic ULPA Filter with Built-in Fluid Trap. Dispose of according to your institution's protocol for biological waste disposal.** If problem persists, check calibration of Change Filter (**LAP Mode** flow minimum, & **OPEN Mode** flow maximum) adjustments. See **Hospital Level Calibration Instructions**. If none of the suggestions resolves this problem, then Unit is malfunctioning, please have technically qualified personnel check and correct or contact I. C. Medical, Inc.
Pneumoperitoneum Collapses	Gas is leaving the abdominal cavity faster than it is being supplied from the insufflator. (Insufflator flow should be at maximum). Tubing from insufflator to patient may have an internal diameter that is too small to allow full flow of gas from the insufflator. Check for leaks when instruments are removed from Trocars and for leaks around Trocar sheaths. Stop the leaks. Flow Rate on the CRYSTAL VISION® may be too high. Reduce flow. **INSUFFLATOR** output filter may have gotten dirty. Change filter. Time adjusted on the CRYSTAL VISION® may be too long. Reduce the amount of time, which the CRYSTAL VISION®` runs after the smoke producing device has been deactivated. If none of the suggestions resolves this problem, then Unit is malfunctioning, please have technically qualified personnel check and correct or contact I. C. Medical, Inc.
Smoke Remains In Pneumoperitoneum	CRYSTAL VISION® not starting soon enough. Be sure that the Laser Sensor is positioned so that it starts the CRYSTAL VISION® `when the foot pedal is just starting to be depressed. The slightest downward motion of the pedal should turn the red light off on the Laser Sensor. FLOW rate may be too low. The object is to have the highest flow that does not deflate the pneumoperitoneum. Increase the flow rate on the CRYSTAL VISION® `and ensure that it does not cause a loss of pneumoperitoneal pressure. If it does, increase the flow from the insufflator, if possible. If the insufflator flow cannot be increased to provide satisfactory results, use an insufflator that provides higher flows. See the **Important Notice** located on the first page of the Installation Instructions and Operating Instructions. Time adjustment can be increased to allow continued operation of the CRYSTAL VISION® `pump under circumstances when a higher flow rate from the insufflator is not possible. The output filter on the insufflator (when used) may have become clogged, or dirty. Replace it, if necessary. Be sure the any output filters used on the insufflators do not significantly reduce the flow going to the patient. Use high flow filters. An electrocautery device, or other smoke producing device, is in use without a sensor being attached, or attached properly. Use the **MANUAL** button to eliminate smoke in these circumstances. If none of the suggestions resolves this problem, then Unit is malfunctioning, please have technically qualified personnel check and correct or contact I. C. Medical, Inc.
Smoke Odor In Operating Room	Smoke is leaking from pneumoperitoneum, tubing set, or the **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap . Check for leaks and eliminate them. They most frequently occur at the Trocar sheaths when instruments are removed and gas is allowed to vent into the room. Leaks also occur between the outside of the Trocar sheath and the patient. Tubing connections might be loose. Large Coconut Charcoal Output Filter needs to be replaced if odor is emanating from it. If none of the suggestions resolves this problem, then Unit is malfunctioning, please have technically qualified personnel check and correct or contact I. C. Medical, Inc.

PREVENTIVE MAINTENANCE

The CRYSTAL VISION® has minimal routine preventive maintenance and calibration requirements.

EVERY SIX MONTHS:
Perform standard electrical leakage tests.

Perform "**Check Proper Operation of the Crystal Vision**" as directed in a previous section.

Perform "**Hospital Level Calibration**" only if the flow does not meet the specifications.

The service personnel should be properly trained and have the correct test equipment. If adjustments are made without the correct test equipment or by a properly trained person, damage or maladjustment may occur to the unit. This can pose a threat to patient safety

ANNUALLY:
Perform items listed under "**Every Six Months**."

Check the pump operation with a flow meter. Your reading should be 90 liters per minute or greater. Please remember to factor in air temperature and pressure. If you experience any problems performing this test or the actual flow is less than 90 liters per minute, please have contact I. C. Medical, Inc.

CLEANING INSTRUCTIONS:

Cleaning should only be done to the external case of the smoke evacuator.
To reduce the possibility of being electrically shocked smoke evacuator should be unplugged before cleaning.

1. Follow your facility's approved clean policy
2. Use your facility's approved cleaning agent for cleaning electronic medical equipment.
3. Dampen a cloth with your facility's approved cleaning agent.
4. Gently wipe the external surfaces of the smoke evacuator until clean.

HOSPITAL LEVEL CALIBRATION INSTRUCTIONS

Fully trained and knowledgeable individuals must only accomplish the following procedures with extensive experience in calibrating surgical and life support electromechanical devices. They should be aware of the importance of medical devices in the operating room environment, and physiological parameters of the patient during surgery.

Only the following adjustments should be attempted. I. C. Medical, Inc. personnel or those individuals, who have been fully trained by I. C. Medical, Inc. only, should make all other adjustments.

If the equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.

When making adjustments or troubleshooting the electronics be careful to avoid any electrical shock or damage to the equipment with the smoke evacuator cover off.

Refer to the attached diagram for adjustment locations.

Adjustments are made on the Master Board only.

SECTION 1

Leak Test:

Note:
The leak test needs to be done before any other calibration is attempted.

1. Make sure power is off to the CRYSTAL VISION®
2. Attach a disposable clean **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap .
3. Connect a calibrated bulb manometer to the filter-input connector of the **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap.
4. Increase the pressure on the bulb manometer to 100 mmHg.
5. System should not lose more than 3-mmHg pressure for 5 seconds.
6. If it fails this test, open the unit to locate and repair the leak.
7. Repeat test after each repair.

SECTION 2

SETUP FOR SECTION 2:

1. Turn on power switch (back panel)
2. CRYSTAL VISION® MUST be in LAP MODE.
3. Set the unit to minimum flow.
4. The timer set for 2 seconds.
5. Attach a **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap and an Intra-Abdominal (I/A) tubing set to the filter input connector of the CRYSTAL VISION®
6. Connect a calibrated bulb manometer to the end of the tubing.
7. The pump should not be running.

NO PATIENT Indicator Adjustment:

Test:

1. Set Up unit to **SETUP FOR SECTION 2.**
2. When at room pressure the NO PATIENT Indicator lamp should be on.
3. Slowly increase the pressure with the manometer and the lamp should go out when approximately 3 mmHg is reached.

Adjustment:

Only make adjustments when necessary.

1. Set Up unit to **SETUP FOR SECTION 2.**
2. Turn **VR2** on the master board clock-wise until the NO PATIENT Indicator light turns off.
3. Then turn **VR2** counter clock-wise until the NO PATIENT Indicator light lights.
4. Then turn **VR2** counter clock-wise 1/2 turn more.
5. The pump should not be running during these adjustments.

OVER PRESSURE Lamp Adjustment:

Test:

1. Set up unit to **SETUP FOR SECTION 2.**
2. With the CRYSTAL VISION® set as listed above, increase the pressure on the bulb manometer.
3. The OVER PRESSURE lamp should come between 26 or 28 mmHg.

Adjustment:

Only make adjustments when necessary.

1. Set Up unit to **SETUP FOR SECTION 2.**
2. Slowly apply 27 mmHg of pressure.
3. The over pressure light should come on at 27 mmHg.
4. If not, adjust turn **VR3** clock-wise to increase sensitivity or counter clock-wise to decrease sensitivity.

THIS IS AN IMPORTANT PATIENT SAFETY ADJUSTMENT. IT MUST NEVER BE ADJUSTED FOR OVER 28 mmHg.

OVER PRESSURE Threshold to Start Pump:

Test:

1. Set up unit according to **SETUP FOR SECTION 2.**
2. With the CRYSTAL VISION® set as listed above, increase the pressure on the bulb manometer until the pump starts to pump.
3. Observe the pressure when the pump starts, it must be 30 mmHg or less.

Adjustment:

Only make adjustments when necessary.

1. Set Up unit to **SETUP FOR SECTION 2.**
2. Set the unit to LAP MODE, Flow Setting adjusted to minimum.
3. Slowly apply 30 mmHg of pressure.
4. The over pressure light should come on.
5. The pump should now activate.
6. If it needs adjustment turn **VR4** clock-wise to increase sensitivity or counter clock-wise to decrease sensitivity.

THIS IS AN IMPORTANT PATIENT SAFETY ADJUSTMENT IT MUST NEVER BE ADJUSTED FOR OVER 30 mmHg.

SECTION 3

SETUP FOR SECTION 3

1. Turn on power switch (back panel).
2. Crystal Vision **MUST** be in LAP Mode.
3. Set the unit to 4 LPM, LAP flow.
4. The timer set for 30 seconds.
5. Attach a **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap and an Intra-Abdominal (I/A) tubing set to the filter input connector of the **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap .
6. Attach a 10-mm Trocar to the Intra-Abdominal (I/A) tubing set.
7. Insert a 10mm laparoscope (or equivalent) into the Trocar.

CHANGE FILTER: LAP MODE (minimum Flow Setting):

Test:

1. Set up unit according to **SETUP FOR SECTION 3.**
2. In the LAP MODE (all indicators green): set the flow 6 & 7, activate the pump with the Manual switch.
3. With laparoscope in the Trocar slowly pinch, the intra-abdominal tube to a ¾ occlusion of the tube.
4. The CHANGE FILTER lamp should come on.

The CHANGE FILTER light should always come on before the OCCLUSION LAMP.

5. Repeat for maximum flow in the LAP MODE.

Adjustment:

Only make adjustments when necessary.

1. Set up unit according to **SETUP FOR SECTION 3.**
2. In the LAP MODE: set the flow at minimum, activate the pump with the Manual push button.
3. Adjust **VR5** until the change filter indicator turns on and back off until it just turns off.
4. Adjust **VR5** clock-wise to increase sensitivity or counter clock-wise to decrease sensitivity.

OCCLUSION: LAP MODE

Test:

1. Set up unit according to **SETUP FOR SECTION 3.**
2. With the same setup as above turn the flow to minimum.
3. Activate the pump with the Manual push button.
4. Completely pinch the intra-abdominal tubing. (If your Trocar port has a stopcock, slowly close the stopcock until the airway is closed.
5. The **OCCLUSION** lamp should come on.
6. Repeat for 7 l/min on FLOW SETTING and maximum flow in LAP MODE.

Adjustment:

Only make adjustments when necessary.

1. Set up unit according to **SETUP FOR SECTION 3.**
2. In LAP MODE: set the flow to minimum, activate the pump with the Manual push button.
3. Activate the unit.
4. Completely pinch the intra-abdominal tubing. (If your Trocar port has a stopcock, slowly close the stopcock until the airway is closed.
5. Adjust **VR6** until the OCCLUSION lamp comes on.
6. Turn **VR6** clock-wise to increase sensitivity or counter clock-wise to decrease sensitivity.
7. Adjust **VR6** until the OCCLUSION lamp works throughout the flow range. Based on the characteristics of the smoke evacuator, some units will only alarm between 4 to 8 and 16 to 20 on FLOW SETTING display. This is acceptable.

SECTION 4

SETUP FOR SECTION 4

1. Change unit to OPEN MODE.
2. Set the flow at maximum.
3. Set the time at 30 seconds.
4. Attach a clean **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap.
5. Attach smoke tube to the **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap .

CHANGE FILTER: OPEN MODE (maximum):

Test:

1. Set up unit according to **SETUP FOR SECTION 4.**
2. Obstruct about ¾ of the smoke tube opening with your thumb.
3. The CHANGE FILTER lamp should come on.

The CHANGE FILTER light should always come on before the OCCLUSION LAMP.

4. Repeat for medium and maximum flows in the OPEN MODE.

Adjustment:

Only make adjustments when necessary.

1. Set up unit according to **SETUP FOR SECTION 4.**
2. Activate the unit.
3. Adjust **VR8** clock-wise (to increase sensitivity), until the CHANGE FILTER lamp just comes on.
4. Adjust **VR8** counter clock-wise (to decrease sensitivity), until the CHANGE FILTER lamp just turns off.

Adjust until the CHANGE FILTER lamp works throughout the flow range

OCCLUSION: OPEN MODE (maximum):

Test:

1. Set up unit according to **SETUP FOR SECTION 4.**
2. Now activate the unit.
3. Completely occlude the smoke tube with your finger.
4. The OCCLUSION lamp comes on.
5. Check the OCCLUSION at minimum, medium, and maximum flows.

Adjustment:

Only make adjustments when necessary.

1. Set up unit according to **SETUP FOR SECTION 4.**
2. Activate the unit.
3. Completely occlude the smoke tube with your finger.
4. Adjust **VR7** until the OCCLUSION lamp comes on.
5. Adjust **VR7** clock-wise to increase sensitivity or counter clock-wise to decrease sensitivity.
6. Adjust **VR7** until the OCCLUSION lamp works throughout the flow range.

For emergency procedures, when occlusion occurs prematurely turn VR6 for LAP MODE or VR7 for OPEN MODE counter clock-wise ½ turn. This should solve the problem.

I. C. Medical, Inc. personnel or those individuals, who have been fully trained by I. C. Medical, Inc., should only make any other adjustments.

Declaration for Electromagnetic Immunity

CRYSTAL VISION® Model 450D is intended for use in the electromagnetic environment specified below. The user of the CRYSTAL VISION® Model 450D should assure that the CRYSTAL VISION® Model 450D is used in such environment.

IEC 60601-1-2 Requirements:

Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6kv contact 8kv air	Full compliance	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	Full compliance	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kv line(s) to line(s) ± 2kv line(s) to earth	Full compliance	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 UT=230 Vac	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT for 25 cycles <5% UT (>95% dip in UT for 5 sec	Full compliance	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operations during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50 Hz) magnetic field. IEC 61000-4-8	3 A/m	Full compliance	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6 Radiated RF	3Vrms	Full compliance	Portable and mobile RF communications equipment should be used no closer to any part of the equipment including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\left[\frac{3,5}{V1}\right]\right]\sqrt{P}$ $d = \left[\left[\frac{3,5}{E1}\right]\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\left[\frac{7}{E1}\right]\right]\sqrt{P}$ 800 MHz to 2,5 GHz 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[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of known RF transmitting devices and 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 equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

CRYSTAL VISION® Model 450D is intended for use in the electromagnetic environment specified below. The user of the CRYSTAL VISION® Model 450D should assure that the CRYSTAL VISION® Model 450D is used in such environment. **IEC 60601-1-2 Requirements:**		
Emissions test	**Compliance Level**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The equipment 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 equipment is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system 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 equipment or shielding the location
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Full compliance	