I. C. MEDICAL, INC.

CRYSTAL VISION®
Model 460

REF ICM-460-0000

OPERATING AND INSTALLATION MANUAL

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MADE IN USA
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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.

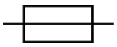
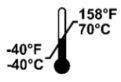
*WARNING: **This warranty will only apply when the smoke evacuator is used in conjunction with I.C. Medical's SAFEGUARD BLUE® Hydrophobic ULPA Filter with Built-in Fluid Trap.** I.C. Medical's **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap includes a hydrophobic filtration media, 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 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 IC. Medical, Inc. to be qualified to do so.

Symbol	Description:
	"ON" (power)
	"OFF" (power)
	Caution
	Fuse
	Earth(ground)
	Catalogue number
	Manufacturer
	Authorized Representative
	CE Mark
	UK-Responsible Person
	UKCA Mark
	Date of manufacture
	Serial Number
	Quantity per package (Qty/pkg=1)
	Consult electronic instructions for use
	Prescription Only
	Medical Device
	Temperature limit
	Humidity limitation

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 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.
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. The SAFEGUARD BLUE® Hydrophobic ULPA Filter with Built-in Fluid Trap includes a hydrophobic barrier to protect the smoke evacuator from fluid ingress. Do not exceed the fluid trap capacity. Monitor fluid levels regularly and replace the filter promptly to prevent overflow.
18. Do not operate machine without Large Coconut Charcoal Output Filter.
19. Turn OFF the unit when replacing the filter. Replace the Large Coconut Charcoal Output Filter as soon as odors become noticeable, or every three months, whichever occurs first.
20. Do not block exhaust.
21. Use Environment: The medical device is intended to be used in a hospital – operating room(s); surgical suite setting. The device is not intended for home use or mobile use.
22. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
23. Use of accessories, transducers, and cables other than those specified or provided by I.C. Medical, Inc. could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
24. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the CRYSTAL VISION® 460, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."
25. The Emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A).

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.

None.

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. The power cords for smoke evacuator units should be grounded, medical-grade type.
3. To prevent damage to equipment when replacing fuses, locate and correct the problem that caused the fuse to blow before re-applying power.
4. Use only specified replacement parts.
5. 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.
6. Follow precautions for static sensitive devices when handling this equipment.
7. This product should only be powered as described in the manual. To prevent equipment damage, select the proper voltage outlet.
8. To prevent damage to the equipment, read the instructions in the equipment manual for proper input voltage.
9. Keep unit at operating environment for at least 6(six) hours before use, if unit was exposed to extreme shipping and storage conditions.
10. Make sure the unit is in a safe and stable environment as to prevent falling or being dropped, which may cause damage.

COMPATIBILITY

The medical device is intended to be used in a hospital–operating room(s), surgical suite setting. The device is not intended for home use or mobile use.

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 meets the requirements of 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 Immunity requirements of the EMC standard for medical electrical equipment IEC 60601-1-2 for Professional healthcare facility environment.
For the electromagnetic compatibility (EMC), this smoke evacuator complies with Group 1 Class A Emissions requirements of the EMC standard for medical electrical equipment IEC 60601-1-2 for Professional healthcare facility environment.

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. Speculum Tubing
9. Smoke Evacuator Wand
10. Smoke Evacuator Tube
11. ESU Shroud

12. PenEvac1
13. Non-Telescopic PenEvac
14. 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 460
SPECIFICATIONS

INDICATION FOR USE:	The CRYSTAL VISION® 460 is intended to remove smoke created in surgical procedure.
USED FOR:	The CRYSTAL VISION® 460 is intended to remove smoke created in surgical procedure. The Model 460 can be used to remove smoke produced by lasers, electrosurgical devices, and other devices that create smoke during surgical procedures. The Model 460 automatically activates when active (smoke producing) devices that are coupled to the Model 460 with special sensors are turned on. The Model 460 automatically turns off, at a time predetermined by the operator, after the active device turns off.
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 15 pounds (6.80 kg).
SHIPPING/STORAGE ENVIRONMENT	An ambient temperature range of -40ºC(-40°F) to +70ºC(158°F); 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.
POWER CORD	This unit was equipped with a 110VAC hospital grade power cord. Should the AC power cord need to be replaced to match another plug configuration, the replacement plug/cable/receptacle configuration must meet or exceed the following specification: 100-120 VAC Plug: Hospital Grade NEMA 5/15P Clear Cordage: SJT 18AWG x 3, 105º Gray Connector: EN60320 C13 Clear 10 Ft. (3M) Overall Length. Rating: 10A/125V 220-240VAC Plug: CEE 7/7 Cable: H05VVF3G1.0mm Connector: EN60320 C13 2.5M (8.2 Ft.) Overall Length Rating: 10A/250V
FLOW RATE:	Minimum: N/A Maximum: At least 90 Liters/Minute
ACCURACY	±10%
MAXIMUM VACUUM:	Will not be more negative than -350mmHg.
MANUAL START SWITCH:	YES
INDICATORS:	POWER ON — Visual Indicator OCCLUSION — Visual & Audio Indicators CHANGE FILTER — Visual Indicator FLOW RATE — LED Meter FLOW SET POINT — LED Display TIME SETTING — 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**
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**
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 use in Laparoscopic Procedure.***
3. ***Do not re-use, disposable Sterile Tubing Sets, PenEvac1®, and Disposable ESU Shrouds that are SINGLE USE ONLY.***

The CRYSTAL VISION® Model 460 is intended to remove smoke created in any surgical procedure. The Model 460 can be used to remove smoke produced by lasers, electrosurgical devices, and other devices that create smoke during surgical procedures.

The Model 460 automatically activates when active (smoke producing) devices that are coupled to the Model 460 with special sensors are turned on. The Model 460 automatically turns off, at a time predetermined by the operator, after the active device turns off.

The following I.C. Medical's accessories are compatible, and needed 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.

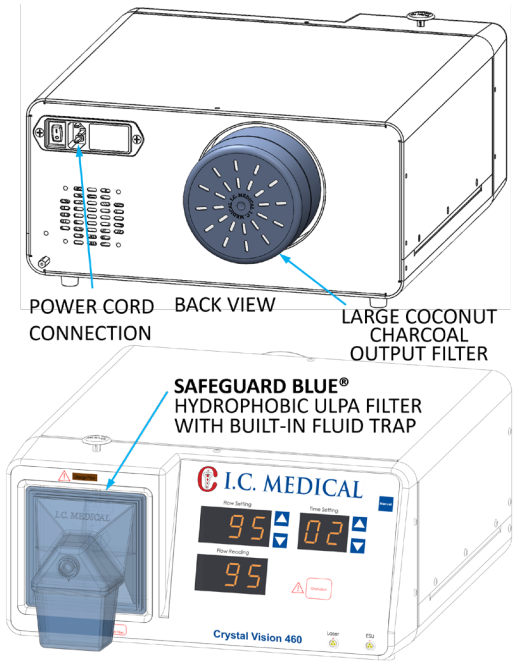


Figure 1: Filters and Power Cord Installation

FILTERS and POWER CORD INSTALLATION:

1. Attach 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.

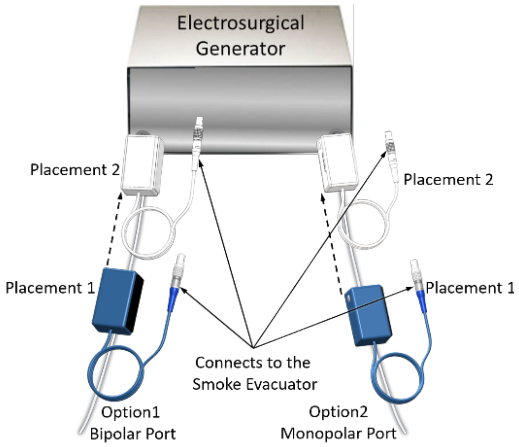


Figure 2: ESU and RF Sensor installation when used with an electrosurgical generator (ESU)

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 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.

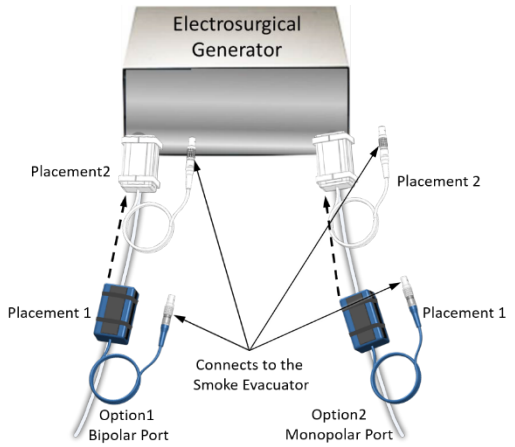


Figure 3: **UNIVERSAL BLUE** RF Sensor installation when used with an electrosurgical generator (ESU)

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 overthe 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.

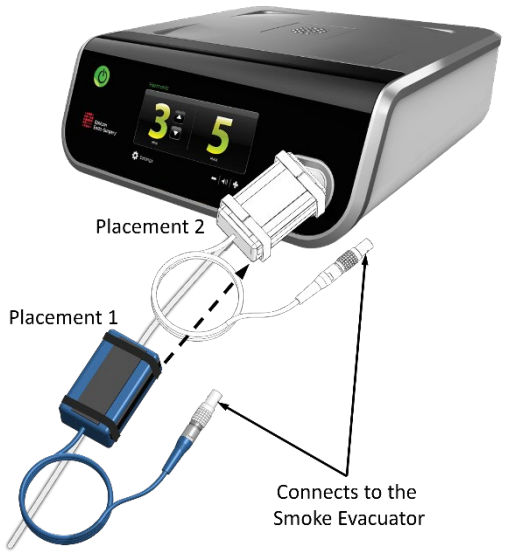


Figure 4: **UNIVERSAL BLUE** RF Sensor installation when used with Harmonic Scalpel generator

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

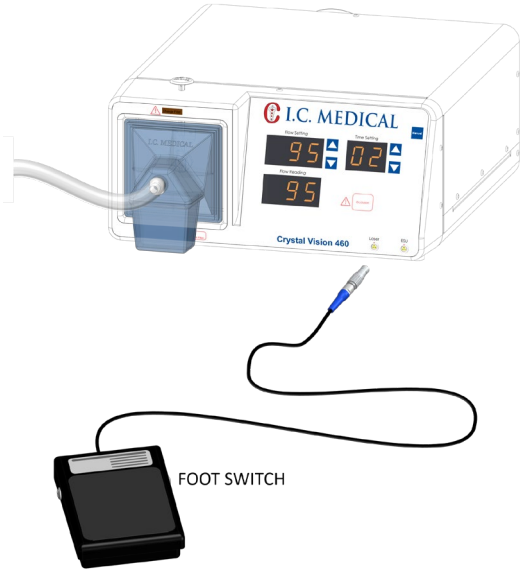


Figure 5: Foot Switch Installation

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.

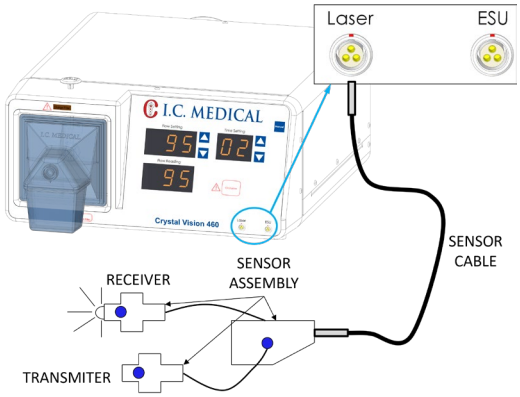


Figure 6: Laser Sensor Installation

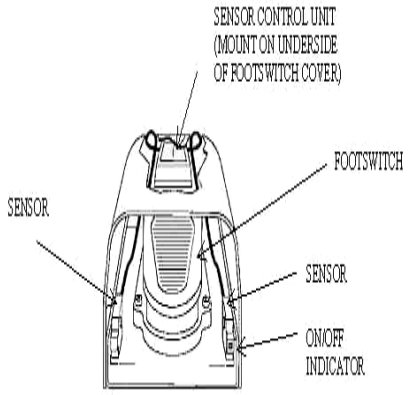


Figure 7: Laser Sensor Installation to the SIDE of the laser foot switch HOUSING.

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.

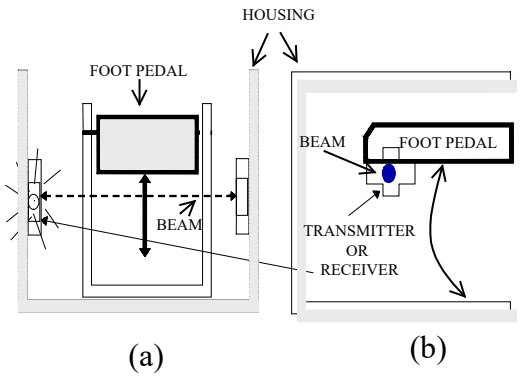


Figure 8: Sensors should be positioned so that ANY movement of the pedal interrupts the beam.

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®.

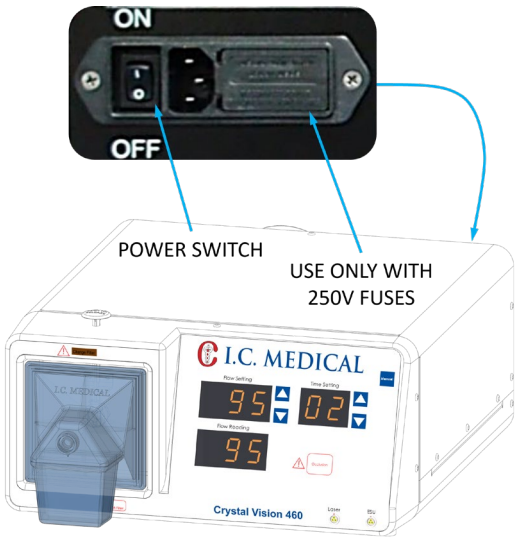


Figure 9: ON/OFF power switch description.

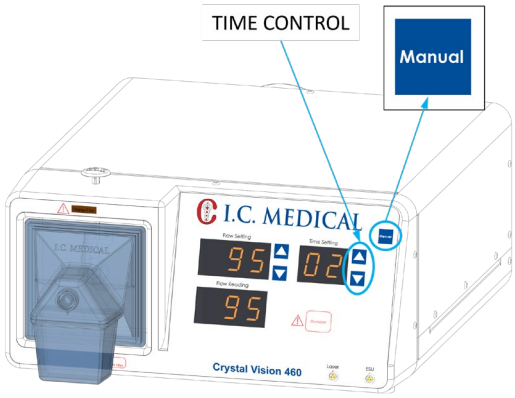


Figure 10: Manual and Time Control locations.

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. 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.
   A (+/-)10% difference between Flow Setting and Flow Reading is acceptable.

8. Place a finger over the **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap and press the MANUAL button. The CHANGE FILTER and OCCLUSION LEDs should lit-up.

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

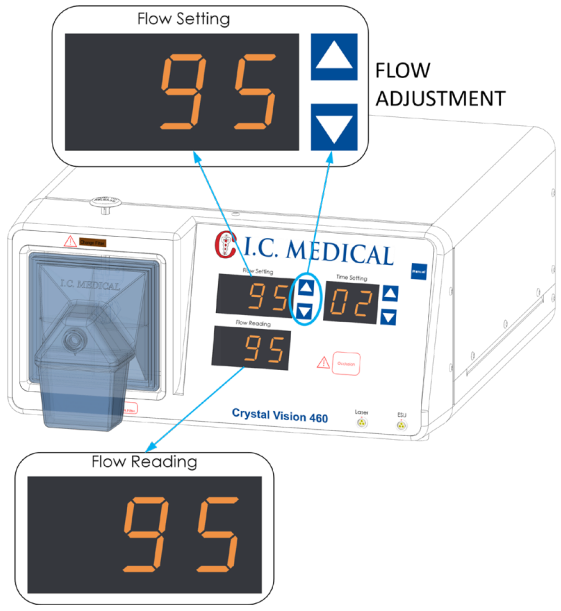


Figure 11: Flow adjustment buttons.

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. It can 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®.
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.

   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)

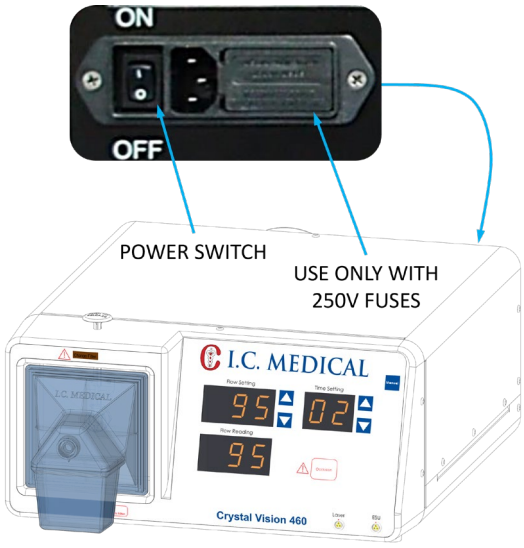


Figure 12: ON/OFF power switch location.

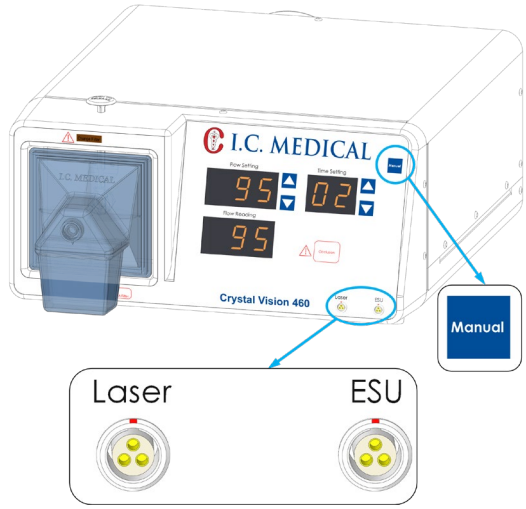


Figure 13: Manual button and sensor connectors.

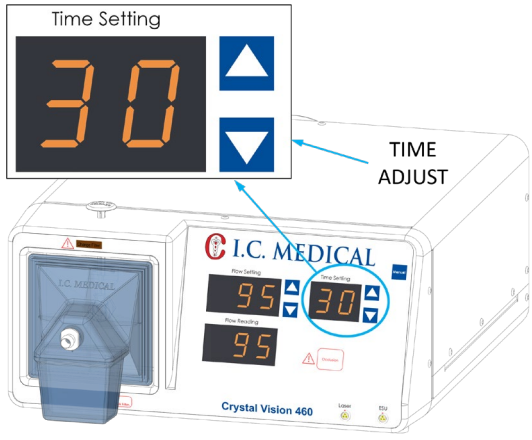


Figure 14: Adjustment for time setting.

6. FLOW SETTING control buttons (Figure 15) sets the maximum flow that is desired by the surgeon. This value is indicated on the FLOW SETTING display.

7. FLOW READING (Figure 15) 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.

8. CHANGE FILTER indicator is located above filter (Figure 16). 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.

9. OCCLUSION indicates that flow into the CRYSTAL VISION® has stopped (Figure 16). 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 Large Coconut Charcoal Output Filter, or a completely clogged or full fluid trap in the **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.

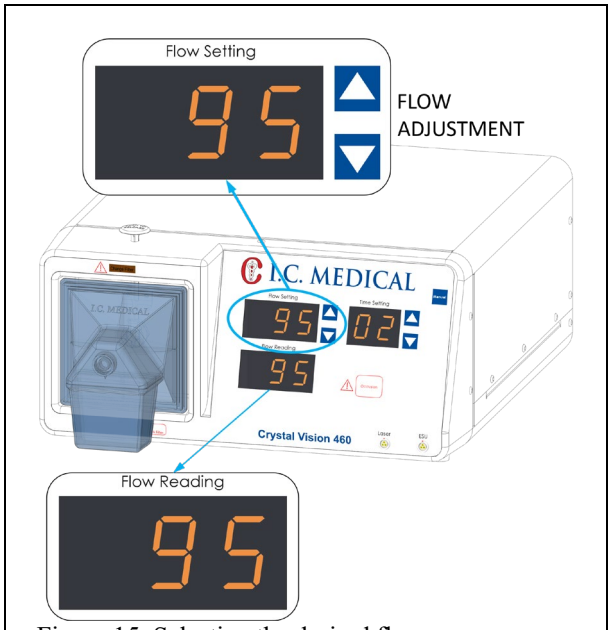


Figure 15: Selecting the desired flow.

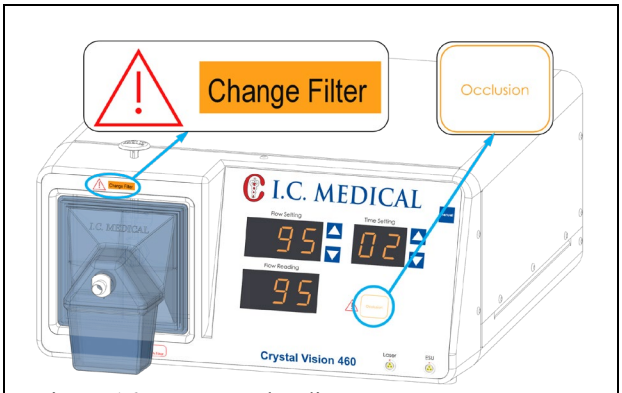


Figure 16: Front Panel Indicators.

10. **INPUT FILTER CONNECTOR** (Figure 17) 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.

11. **Large Coconut Charcoal OUTPUT FILTER CONNECTOR (connector not shown)** (Figure 17). The Large Coconut Charcoal OUTPUT FILTER CONNECTOR is located on the back panel of the CRYSTAL VISION® and holds the Large Coconut Charcoal Output Filter. 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.

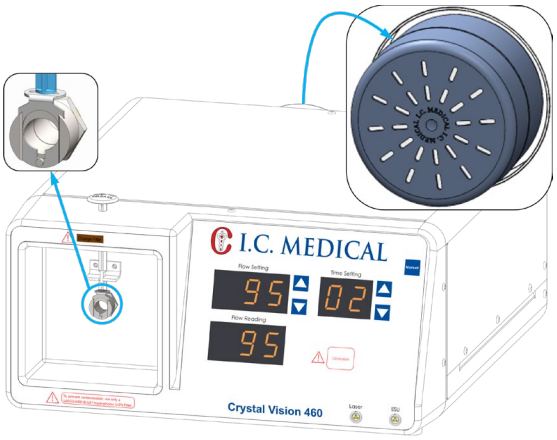


Figure 17: Input Filter Connector holds **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap .

Large Coconut Charcoal Output Filter Connector

OPERATING 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, controls, and indicators.
3. Refer to Figure 18 or 19 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. Front Panel should turn on (illuminate orange).
10. Adjust FLOW SETTING for the desired flow.
11. Push MANUAL button and observe that desired flow is shown on FLOW READING 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.

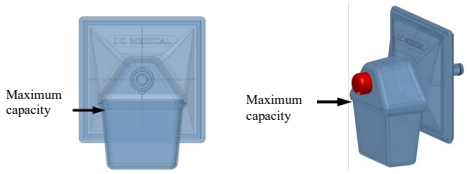
- Increase the FLOW SWTTING and/or the TIME SETTING if smoke is not eliminated from the surgical site.

- **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.**

- **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:

- Tubing is not crimped.
- **SAFEGUARD BLUE®** Hydrophobic ULPA Filter with Built-in Fluid Trap is clean. Replace if clogged or before fluid reaches the trap's capacity.



- Be sure there are no leaks in the tubing, or instruments.
- Increase the TIME SETTING if there are no leaks.

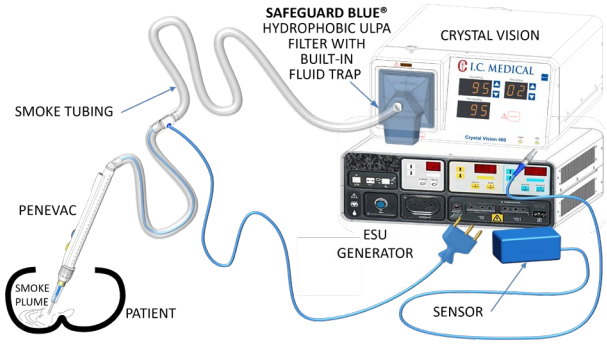


Figure 18: Set up for using CRYSTAL VISION® with an ESU system during an open procedure.

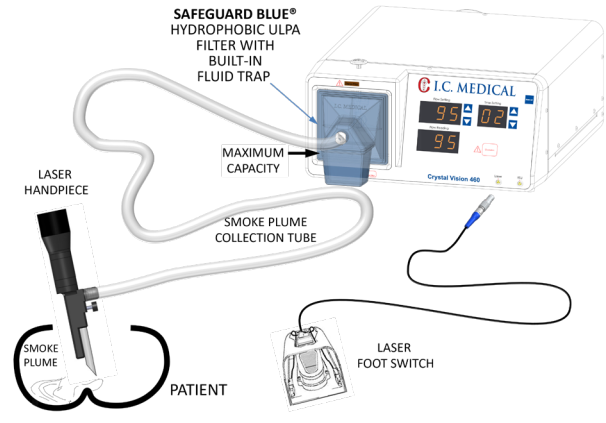


Figure 19: Set-up for using CRYSTAL VISION® with a laser hand piece.

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

PenEvac Accessories:
PenEvac1® accessories (PenEvac1 and Non-telescopic PenEvac) may also be used with the CRYSTAL VISION® Model 460. 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.

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.

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, controls, and indicators.
3. Refer to Figure 20 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. FRONT PANEL should turn on.
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.**

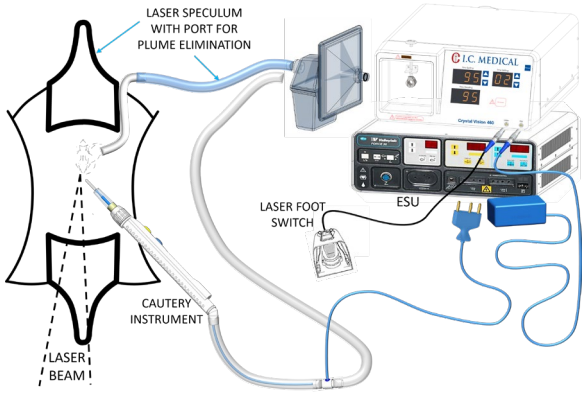


Figure 20: Set up for gynecology procedure for either ESU or CO_2 laser delivered through a colposcope or Micromanipulator.

TROUBLESHOOTING 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 starts 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	Blockage is occurring during the procedure, determine the blockage and clear away. Check calibration of Occlusion 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.
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 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.
Smoke Remains	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. Increase the flow rate if possible. Time adjustment can be increased to allow continued operation of the CRYSTAL VISION® `pump under circumstances when a higher flow rate cannot be increased. 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, damaged or maladjusted 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.

SETUP FOR SECTION 1

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

CHANGE FILTER INDICATOR TEST:

Adjustments are made on the Master Board.

Test:

1. Set up unit according to **SETUP FOR SECTION 1.**
2. Obstruct about 3/4 of the smoke tube opening with your thumb.
3. The CHANGE FILTER lamp should come on. **NOTE: The CHANGE FILTER light should always come on before the OCCLUSION lamp and alarm.**
1. Check the CHANGE FILTER at minimum, medium, and maximum flows**.**

Adjustment:

1. **Only make adjustments when necessary.**
2. Keep the flow and time set as above.
3. Activate the unit.
4. Adjust **VR8** until the change filter indicator just turns on.
5. Adjust **VR8** counter clockwise until the change filter light turns off.
6. Then give it another 1/2 turn counter clockwise.

Adjust until the CHANGE FILTER lamp works throughout the flow range.

OCCLUSION ALARM TEST:

Adjustments are made on the Master Board.

Test:

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

Adjustment:

1. **Only make adjustments when necessary.**
2. With the Crystal Vision® set as described above, activate the unit.
3. Completely occlude the smoke tube with your finger.
4. Adjust **VR7** until the OCCLUSION lamp comes on.
5. Adjust **VR7** counter clockwise for higher pressure (decrease sensitivity) or clockwise for lower pressure (increase sensitivity).
   Adjust **VR7** until the OCCLUSION lamp works throughout the flow range.

For emergency procedures, when occlusion occurs prematurely turn, VR7 for high flow counter clockwise 1/2 turn. This should solve the problem.

I. C. Medical, Inc. personnel or those I. C. Medical, Inc. fully trained individuals should make any other adjustments.