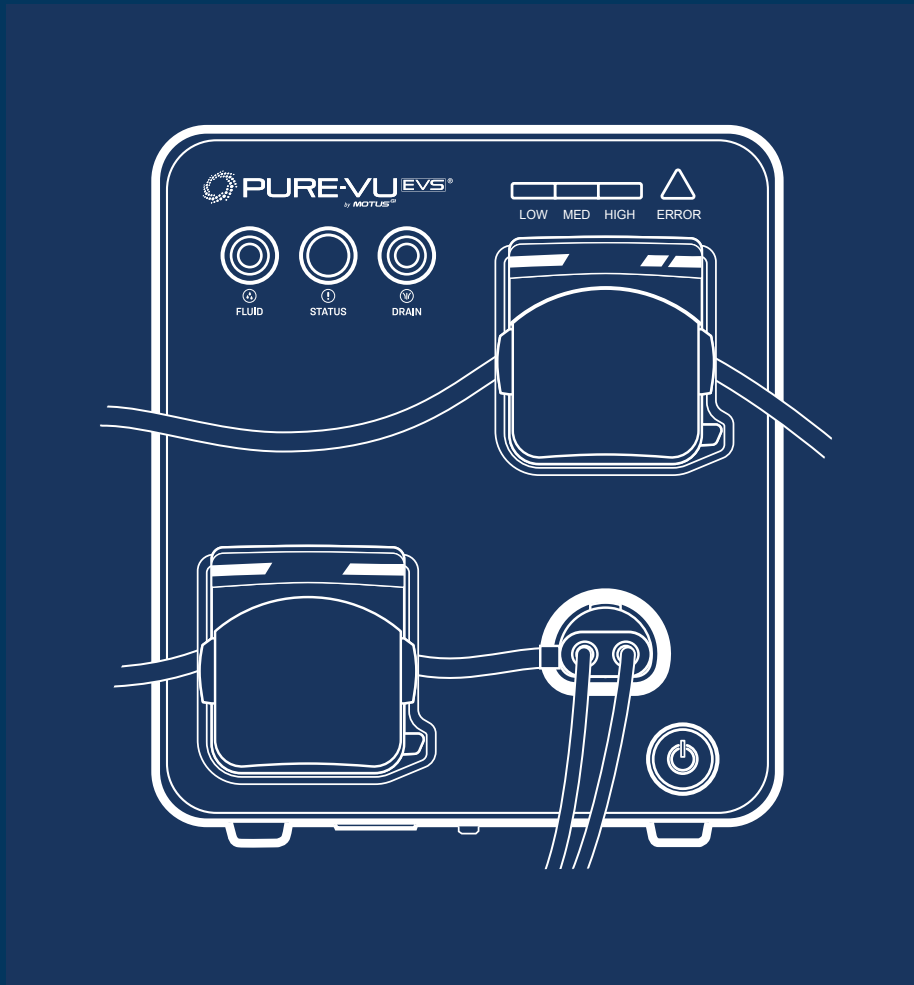




# Instructions For Use



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## 1.0 WARNINGS AND PRECAUTIONS

**Please read this manual and follow its instructions carefully.**

### **Warnings:**

















- This device shall only be used by order of a licensed physician as governed by the FDA.
- The Pure-Vu System shall only be used according to the instructions and operating conditions described in this manual. Failure to do so could impact the performance and safety profile of the device, damage the device or the endoscope.
- The Pure-Vu System shall only be used under the supervision of a licensed physician. Do not use Pure Vu system for any purpose other than the intended use.
- The Pure-Vu System shall be used only by trained medical personnel.
- The Pure-Vu Disposable Kits are provided clean and intended for single patient use. Do not sterilize, clean or re-use the disposables. Discard all of the disposable device sections properly after use.
- Confirm that the other devices used with the Pure-Vu System function properly to their intended use and that their operation or safety is not compromised and is compatible with the Pure-Vu System as noted in these instructions. If any component of the endoscopic system is not functioning properly, the procedure should not be performed.
- The Pure-Vu System should only be used with APPROVED medical devices, complying with IEC 60601-1.
- The Pure-Vu System shall be connected only to a supply main with protective earthing.
- Check and confirm that all cords or cables are connected correctly and securely.
- Continually monitor the Pure-Vu System and the patient for any signs of irregularity.
- The Pure-Vu System is compatible with EMC regulations, but may cause radio interference or may disrupt the operation of nearby equipment.
- If the system does not function properly, turn the Workstation off, abort the procedure, and follow the instructions noted in section “Operating the Pure-Vu Workstation”.
- The Pure-Vu System shall never be stored in areas where the unit could get wet or be exposed to high temperature, humidity, direct sunlight, dust, or salt, which could adversely affect the equipment.
- The Pure-Vu System shall never be installed, used or transported in an inclined position nor should it be subjected to impact.
- The Pure-Vu Workstation shall be maintained in a clean condition during storage and be ready for subsequent use.
- The Pure-Vu disposables , as well as the Workstation (WS), shall be used only with the Pure-Vu System recommended equipment and accessories.
- Avoid using the cleansing mode on the same area of tissue for an extended period of time.
- New, single use waste containers shall be used for each patient (Hospital approved canisters or Motus GI Waste Bag).
- A New, single use irrigation bag (IB) or Irrigation bottle (water or saline) shall be used for each patient.

### **Precautions:**

- Advance cautiously when performing retroflexion, entering the pylorus, duodenum, or ileocecal valve.
- Care shall be taken to avoid pinching the tubing during advancement through the GI tract and/or when applying torque to the endoscope.
- Only Motus GI personnel or a trained Motus GI designee are allowed to service the Pure-Vu System.

## 1.1. Symbols Used

The Pure-Vu System has a safety warning and compliance label located on the Workstation and Disposable Kit. For a definition of individual symbols, see table below:

| SYMBOL  | DESCRIPTION   |
|---|---|
|    | FDA (USA) law restricts this device to sale by or on order of a physician                       |
|    | Non-sterile   |
|    | Do not use if package is damaged  |
|    | Caution! Consult accompanying documents for safety instructions                                 |
|    | General warning sign  |
|    | Do not re-use   |
|    | Batch code (adjacent to the lot symbol)   |
|   | Manufacturer  |
|  | Date of manufacture   |
|  | Follow Instructions for Use   |
|  | Consult Instructions for Use, symbols are meant to support, not replace, operating instructions |
|  | Must not be treated as unsorted municipal waste   |
|  | Type BF equipment   |
|  | Temperature limit   |
|  | Use-by-date   |
|  | Serial number   |

## 2.0 INTENDED USE

The Pure-Vu System is intended to connect to standard or slim colonoscopes and gastroscopes to help facilitate intraprocedural cleansing of the GI tract by irrigating or cleaning and evacuating irrigation fluid (water), feces, and other bodily fluids and matter, e.g. blood.

It is for use only by trained medical personnel located in hospitals, clinics, and doctors' offices.

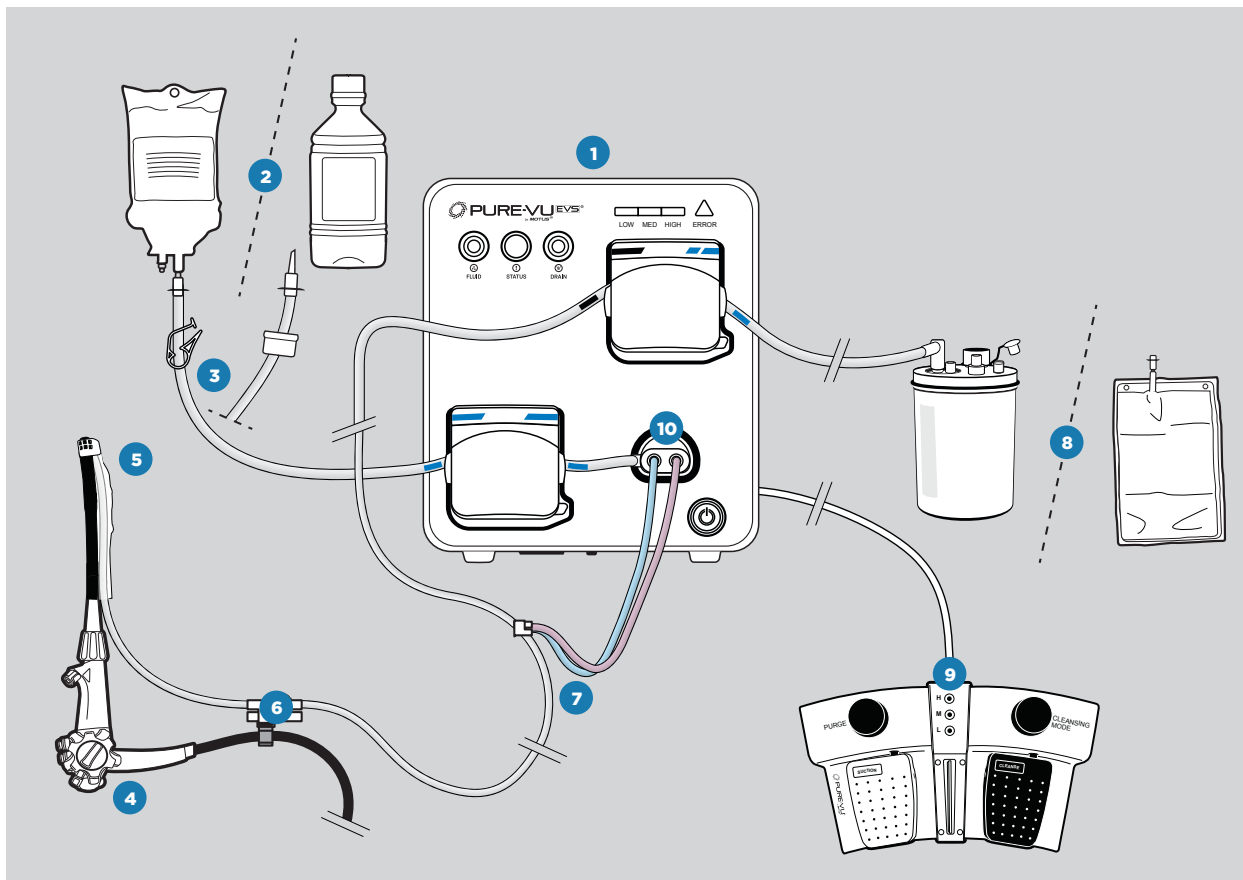
### 3.0 PRODUCT DESCRIPTION

The Pure-Vu System enables cleansing of the GI tract during endoscopy using a standard or slim colonoscope with a length of 1630mm - 1710mm and an outer diameter range of 11.7mm - 13.2mm or gastroscopes with length of 950-1030mm and an outer diameter of 9.2-10 mm . The EVS Flex Channel, which fits alongside the endoscope and is connected to an external Workstation, generates fluid and gas to break up debris. The debris & fluids are removed through the suction channel of the EVS Flex Channel into an external waste container/bag.

The Pure-Vu System consists of the following main components:

- Disposable device which includes an Flex Channel section and an Umbilical Section. The EVS Flex Channel fits over the endoscope. The Umbilical Section connects the Flex Channel to the external Workstation.
- Workstation that is reusable and supplies an irrigation mixture of water or saline and gas, and evacuates debris & fluids.

Below is a drawing showing the various components of the system and where they connect to each other.

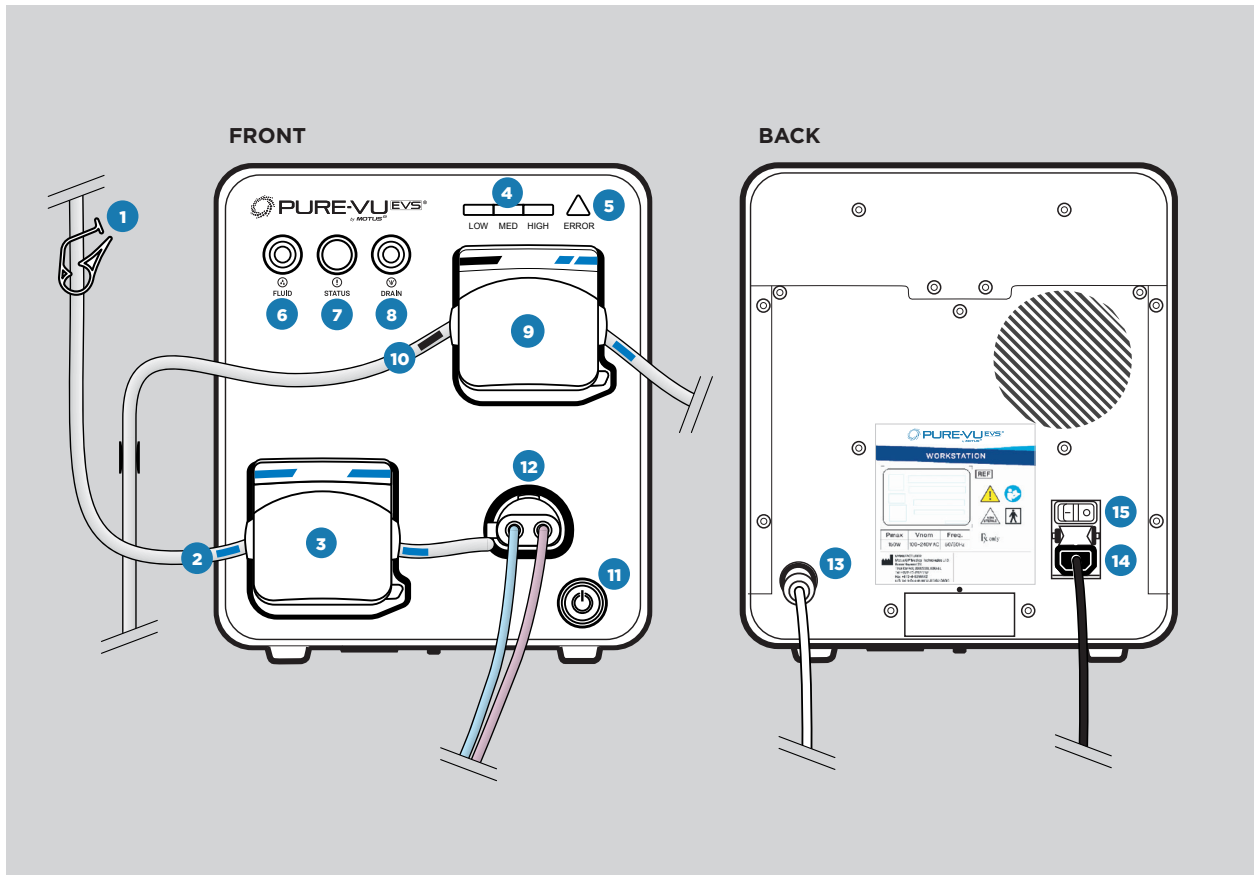


**FIGURE 1:** Pure-Vu Workstation - General Design & Components

- |                               |                     |                              |                   |
|-------------------------------|---------------------|------------------------------|-------------------|
| 1 Workstation                 | 4 Endoscope         | 7 Umbilical Section          | 10 Main Connector |
| 2 Irrigation Bag/Water Bottle | 5 EVS Flex Channel  | 8 Waste Containers/Waste Bag |                   |
| 3 Irrigation Line Clamp       | 6 In-Line Connector | 9 Foot Pedal                 |                   |

### 3.1. Pure-Vu® Workstation

The Workstation is designed to supply water or saline and gas for irrigation and provide suction to evacuate debris & fluids out of the body during the endoscopy procedure. Care should be taken when removing the Workstation from the package so as not to damage any components.



**FIGURE 2:** Pure-Vu Workstation

- |  |                                      |
|--|--------------------------------------|
| 1 Irrigation Line Clamp                        | 9 Suction Pump (Blue/Black Markers)  |
| 2 Irrigation Line (Blue Markers)               | 10 Suction Tube (Blue/Black Markers) |
| 3 Irrigation Pump (Blue Markers)               | 11 On/Off Power Button               |
| 4 Cleansing Mode Indicators (Low / Med / High) | 12 Main Connector                    |
| 5 Error Light                                  | 13 Foot Pedal Connector              |
| 6 Fluid Button                                 | 14 Power Cord                        |
| 7 Status Light                                 | 15 Main Power Switch                 |
| 8 Drain Button                                 |                                      |

### **3.1.1. Pure-Vu® Workstation Components:**

- Monitoring & Control Unit control the delivery of irrigation fluids and gas into the colon, and suction of fluids and debris from the GI tract.
- Irrigation Bag/Bottle (saline or water) which is connected to the irrigation line.
- Waste Containers/Bag for collecting the GI tract content & fluids that are suctioned from the GI tract through the suction lines.
- Foot Pedal that activates the cleansing, suction and purging functions, and enables switching between cleansing modes used by the physician.

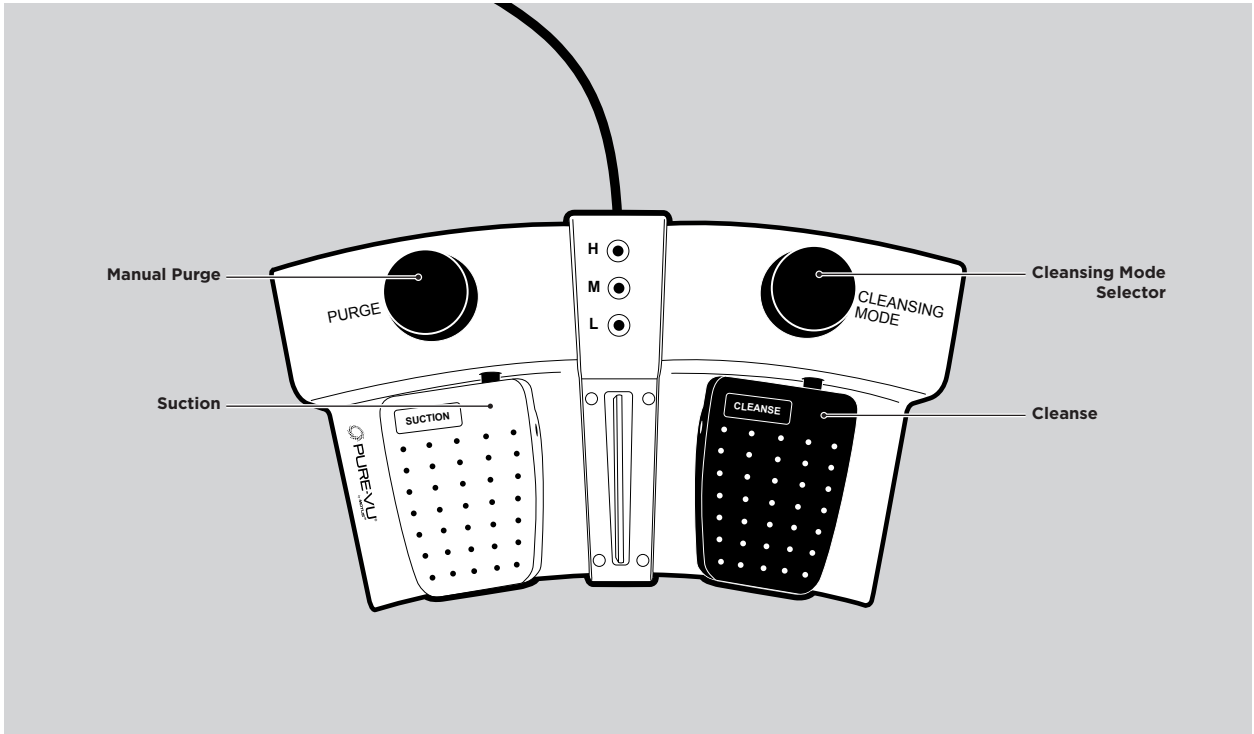
### **3.1.2. Front Panel:**

- On/Off Power Button - powers Workstation On/Off.
- Irrigation Pump - pumps room temperature water or saline.
- Cleansing Mode Indicator - indicates the mode you are in and is activated by using the cleansing mode selector button on the Foot Pedal (shown in Figure 2). The system can be operated in three cleansing modes; low, medium (default mode) and high.
- One Suction Pump - removes debris, gas & fluids and other debris into the waste container/bag
- Main Connector - connects the Umbilical Section to the Workstation and supplies gas to the irrigation line
- Fluid Button - activates “irrigation Only” mode without simultaneous suction activity when depressing the cleansing pedal.
- Drain Button - activates the draining of the fluids from the disposable prior to unloading from the Workstation.
- Status Light - indicates status of the system; green light means ready to go and yellow light indicates the setup is not performed properly as well as indicates the end of drain routine.
- Error Light (Triangle) - turns red when there is a non-recoverable system error where the Workstation stops its operation automatically.

### 3.1.3. Foot Pedal

The Foot Pedal allows the physician to select the operating modes during the procedure. The operating modes are as follows (Figure 3: Pure-Vu Foot Pedal Unit):

- Cleanse - simultaneous irrigation and suction, activated by the right foot pedal. (If FLUID button is pressed and lit blue, only the irrigation is activated.)
- Suction - activated by the left pedal.
- Manual Purge - activated by the left button.
- Cleansing Mode Selector - activated by the right button. User can toggle between three cleansing modes; low, medium (default mode) and high where the pedal LEDs indicate the modes in parallel to the Workstation LED panel.



**FIGURE 3:** Pure-Vu Foot Pedal

## 3.2. Pure-Vu® Disposable Kits

The Pure-Vu® Disposable Kits are comprised of an EVS Flex Channel, and the Umbilical Section. The Pure-Vu Disposable is a single use device, which fits over a standard and slim colonoscope or gastroscope. The Pure-Vu EVS Flex Channel consists of an irrigation lumen and a suction lumen. The EVS Flex Channel strips allow for a secure connection to the endoscope. Proximal to the scope grip is the in-line connector that enables attachment to the Umbilical Section.

The Umbilical Section connects the Pure-Vu EVS Flex Channel to the Workstation via its Main Connector.

## 3.3. Accessories for Use with Pure-Vu® System

The following water bottles, Motus waste bag, waste containers, and disposable liners are recommended for use with the Pure-Vu System.

| MANUFACTURER    | REFERENCE CODE | DESCRIPTION                                   |
|-----------------|----------------|---|
| Cardinal Health | 65651-530      | CRD disposable liner 3000cc                   |
| Cardinal Health | 65652-531      | Wall to outer edge canister (10 ¾ in.) 3000cc |
| Braun           | R5000-01       | Sterile water for irrigation 1000mL bottle    |
| Baxter          | 2F7114         | Sterile water for irrigation 1000mL bottle    |
| Motus           | PV-WST-03-1    | Pure-Vu EVS Waste Bag 3L                      |

## 4.0 SETUP AND INTERCONNECTIONS

### 4.1. Unpacking

#### 4.1.1. Unpacking the Disposables

Prior to unpacking the Disposable units, verify that the packaging is not compromised. If the packaging is open and/or damaged, DO NOT use the device.

Verify the date of expiry on the label.

Verify that the type of Disposable as indicated by its specifications is compatible with the endoscope to be used (refer to compatible endoscope dimensions in section 3.0).

During set up, ensure that no packaging material remains on the device and that the device does not touch the floor or other unclean surfaces that could compromise the cleanliness or intended use of the product.

#### 4.1.2. Unpacking the Workstation

Prior to unpacking the Workstation, verify that the packaging is not compromised. If the packaging is open or damaged, DO NOT use the device.

During set-up ensure that no packaging material remains on the device and that the device does not touch the floor or other unclean surfaces that could compromise the cleanliness or intended use of the product.

## 4.2. Assembly of the EVS Flex Channel to the Workstation

### 4.2.1. EVS Flex Channel Assembly

**STEP 1:** Secure endoscope handle onto a scope holder or solid surface.

**Attention:** Make sure the endoscope is clean and dry before attaching the EVS Flex Channel.



**STEP 2:** Open the Tyvek lid (A) and remove the tray retainer (B).



## 4.2.1. EVS Flex Channel Assembly (cont...)

**STEP 3:** Lift out the EVS Flex Channel from the tray and unfold it.



**STEP 4:** Attach the EVS Flex Channel's Tube Holder on the side of the endoscope with the control wheels as shown in image below.



**STEP 5:** Lubricate the distal end of the endoscope with a lubricating gel.



## 4.2.1. EVS Flex Channel Assembly (cont...)

**STEP 6:** Bring the endoscope tip to the rear opening of the Flexible Head (A) and orient the endoscope's working/biopsy channel next to the flexible head suction channel (B). Insert endoscope into the EVS Flex Channel flexible head so that the tip of the endoscope passes the ring on the Flexible Head (C)

Ensure the endoscope's working/biopsy channel is aligned above the suction lumen of the Pure-Vu EVS Flex Channel as shown (B). If needed, fine adjustments can be made.

Please note the distal end of the colon and gastro heads are slightly different when positioning the tip of the scope (C).



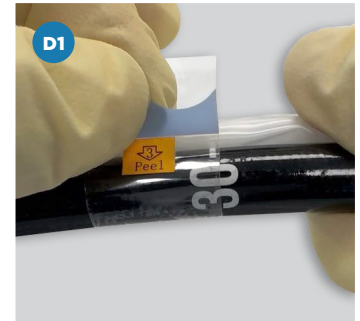
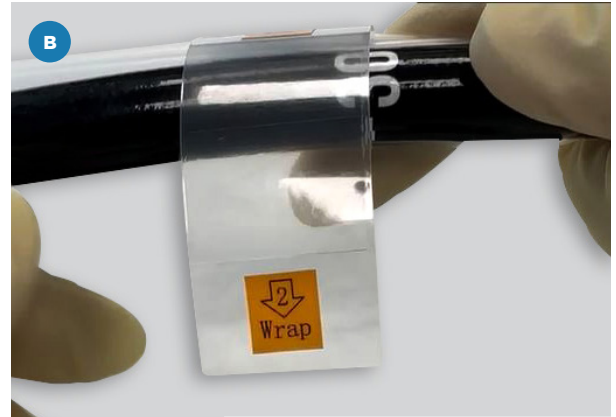
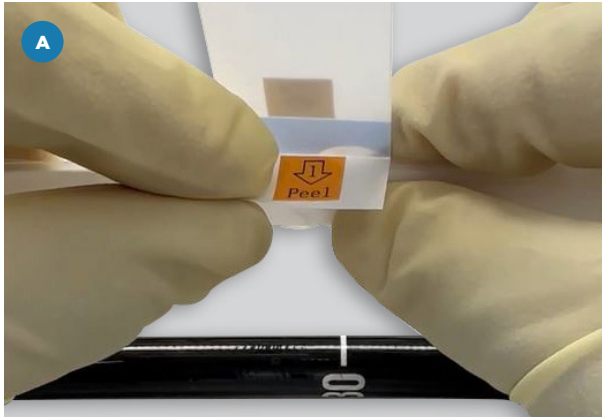
## 4.2.1. EVS Flex Channel Assembly (cont...)

**STEP 7:** Attach strip to the endoscope by aligning the EVS Flex Channel next to the endoscope.

Peel backing filament # 1 (A) and wrap strip # 2 (B) around the endoscope (C) and then back onto the EVS Flex Channel, then peel off “#3” filament (D).

Rub the strip on the scope and the EVS Flex Channel to make sure that all surfaces are well adhered (E).

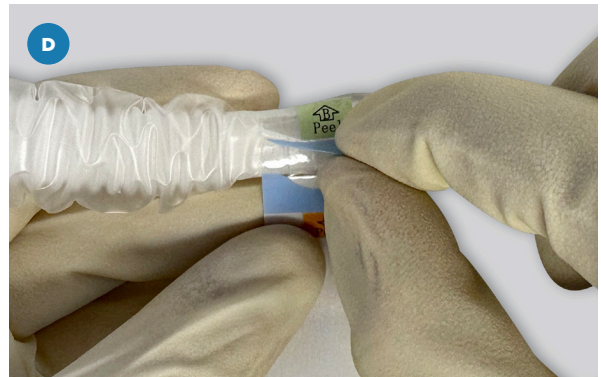
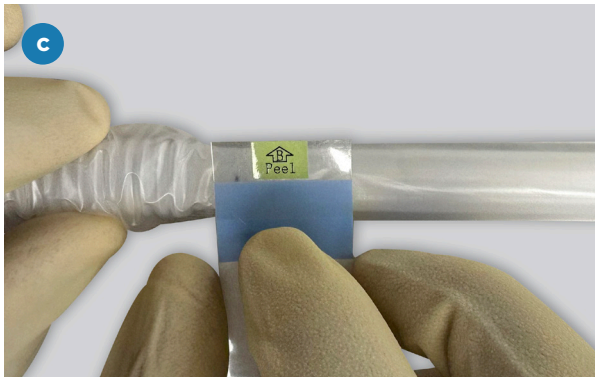
Repeat this action for additional strips.



## 4.2.1. EVS Flex Channel Assembly (cont...)

**STEP 8:** In case of extra strips needed, use the strips from the bag (A).

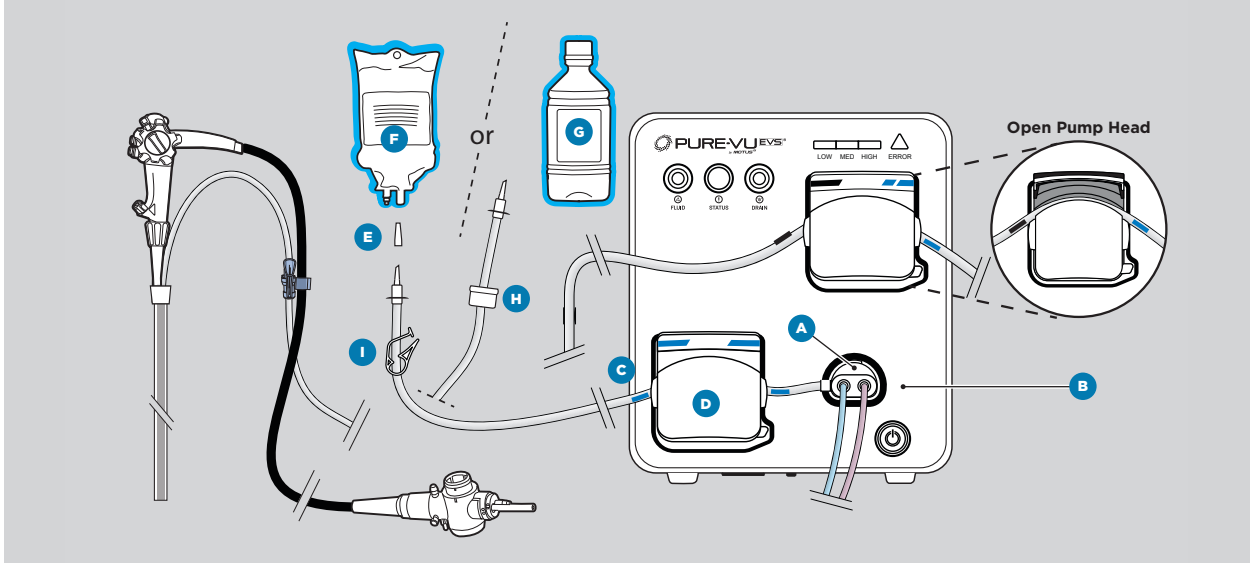
Remove "Peel A" (B), attach it to the EVS Flex Channel (C) and rub the strip on the EVS Flex Channel to make sure it's well attached, remove "Peel B" (D) and repeat STEP 7.



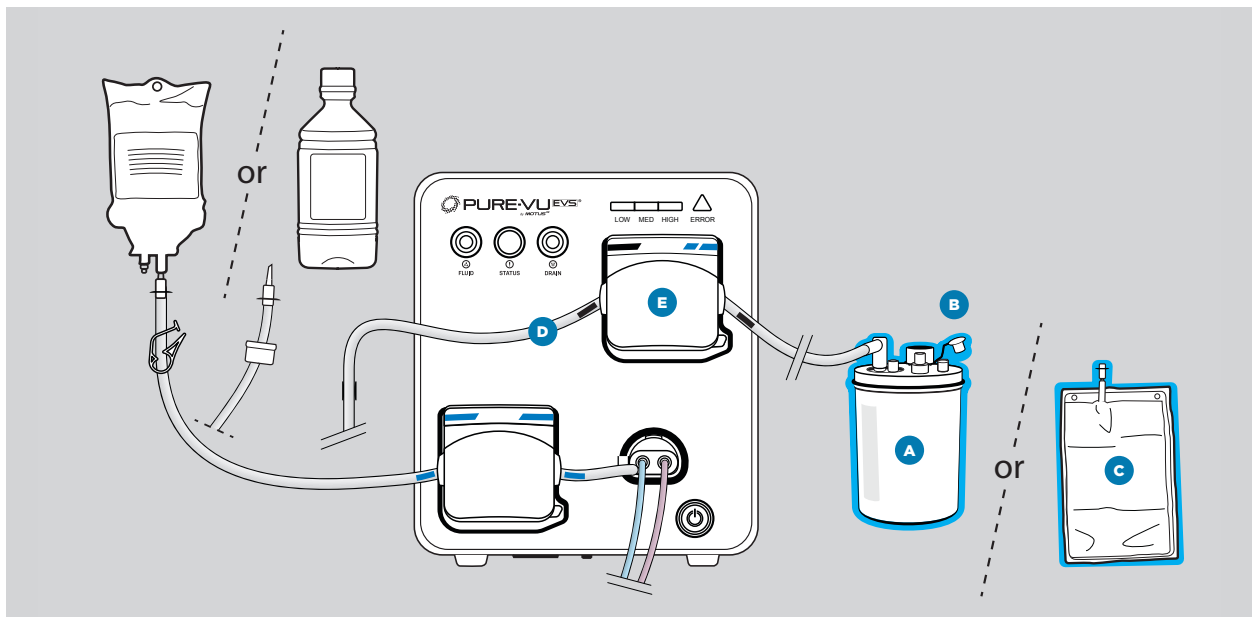
## 4.2.2. Attaching the Umbilical Section to the Workstation

The Workstation should be cleaned prior to attaching the Umbilical Section to the Workstation by thoroughly wiping down the Workstation with a viricidal cloth (Opti-cide, Cavicide or similar surface disinfectant of choice) that has an active ingredient of isopropyl alcohol (17% - 21%).

Remove the Umbilical Section from the tray. To attach the Umbilical Section to the Workstation complete the following steps:

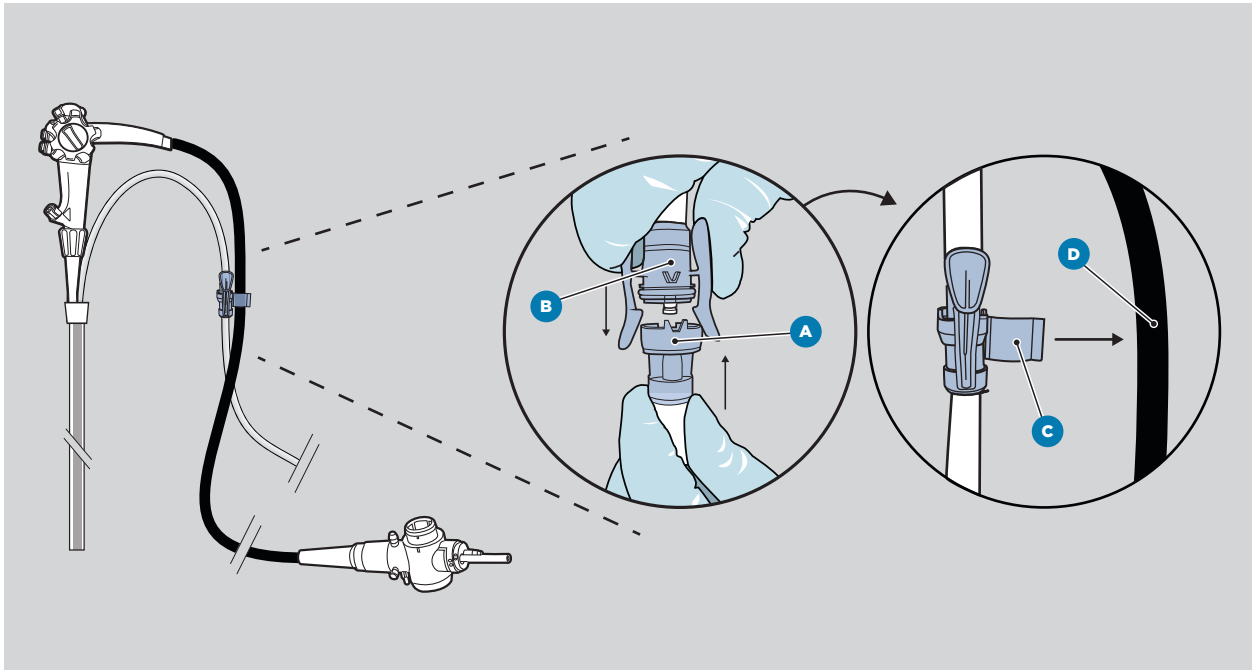


**FIGURE 4:** Connect the main connector (A) to the main connector socket in the Workstation (B). Place the irrigation tubing (C) into the irrigation pump marked with blue markers (D) between the marked blue lines of the tubing, then close the irrigation pump head. Remove the irrigation tube spike's cap (E), then either connect the irrigation tubing to the irrigation bag (F) or place the spike in a bottle (G) and screw the provided water bottle cap (H) onto the bottle securely. Ensure that the irrigation line clamp (I) is open. Ensure all tubing is free of any kinks.



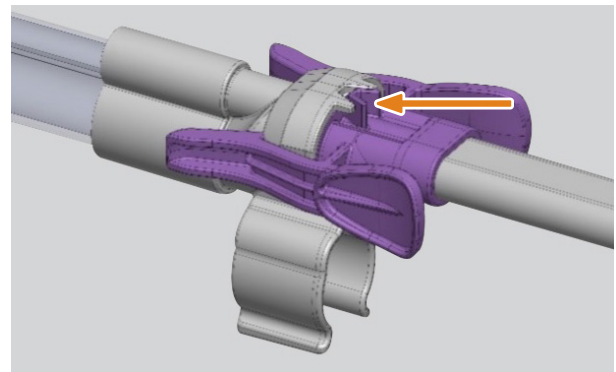
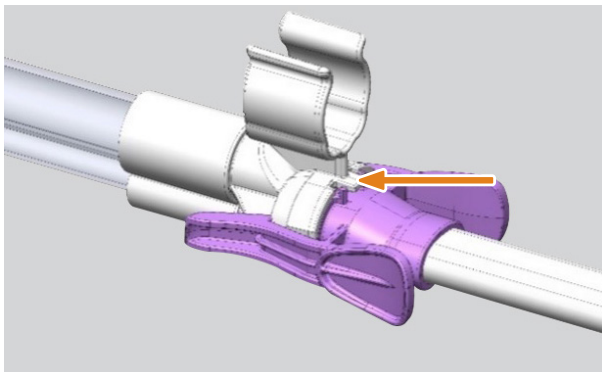
**FIGURE 5:** Connect the suction line to the waste container (A) and ensure that at least one port, in addition to the vacuum port (B), is open on the container or attach the suction line to a waste bag (C). Place the suction tubing (D) into the suction pump (E) marked with a single black and double blue lines aligning the black line of tubing with black line on pump head and blue lines on pump head to blue lines on tubing. Then close the suction pump head.

### 4.2.3. Attaching the EVS Flex Channel to the Umbilical Section



**FIGURE 6:** Connect the EVS Flex Channel to the Umbilical Section by the inline connector (A to B). Attach the inline connector clip to the endoscope Umbilical Section (C to D).

**Attention:** Make sure the in-line connector is attached correctly between the Flex Channel and the umbilical section as shown in the below image.



Verify the clips are well seated.

## 5.0 SYSTEM OPERATION

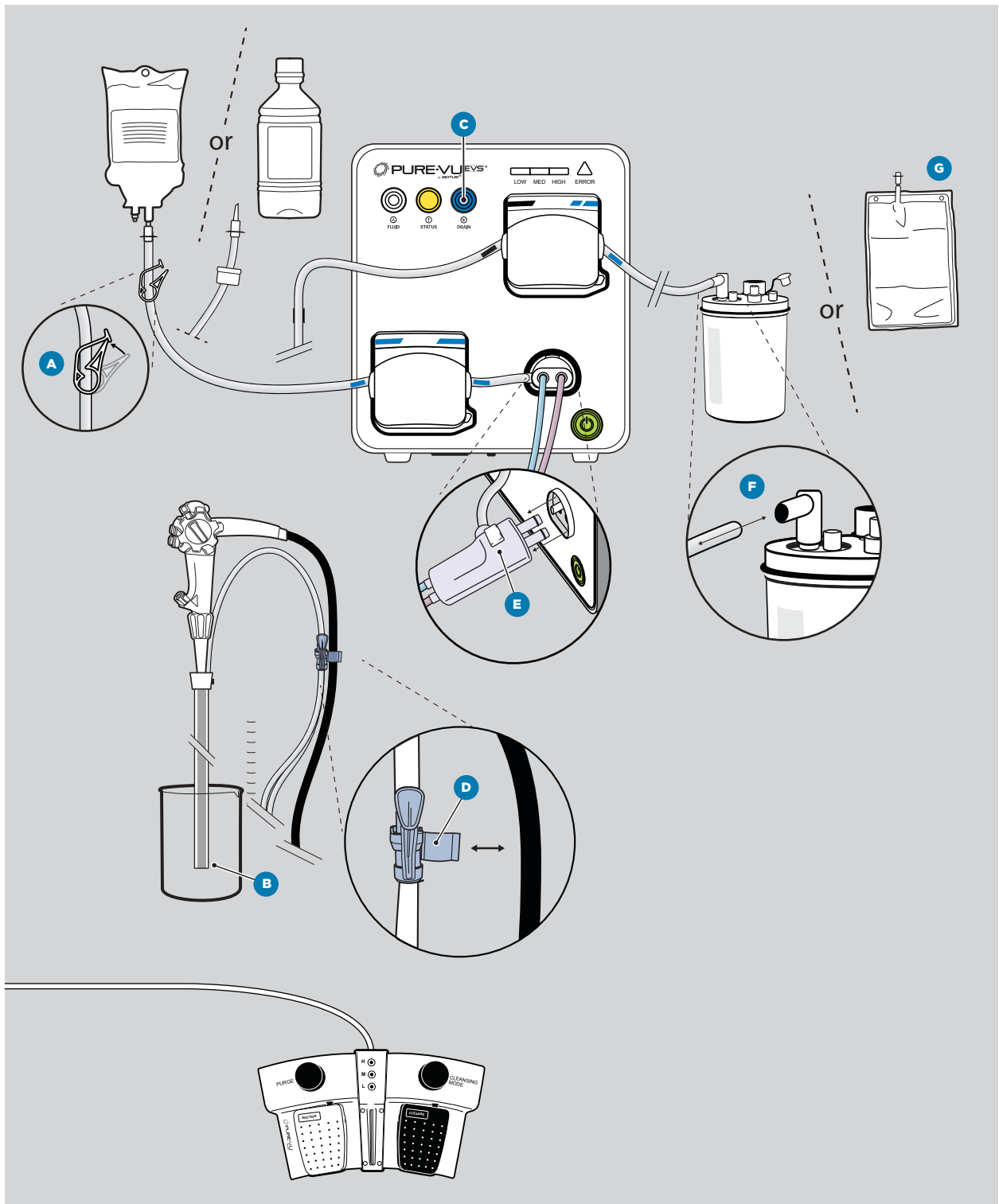
### 5.1. Pre-procedure Operations

1. Use a new single-use irrigation bag/water bottle and new single-use waste containers/bags.
2. Verify that all cords and cables, including Workstation and Foot Pedal, are assembled correctly.
3. Confirm that the waste containers and irrigation bag/bottle are replaced at the same time at the beginning of or during the procedure. **Be careful not to overfill the waste container/bag.**
4. Verify that the Disposable kit is assembled correctly, the irrigation line clamp is open, the pump heads are closed tight, and that the tubing is clear of any kinks.

### 5.2. Operating the Pure-Vu® Workstation

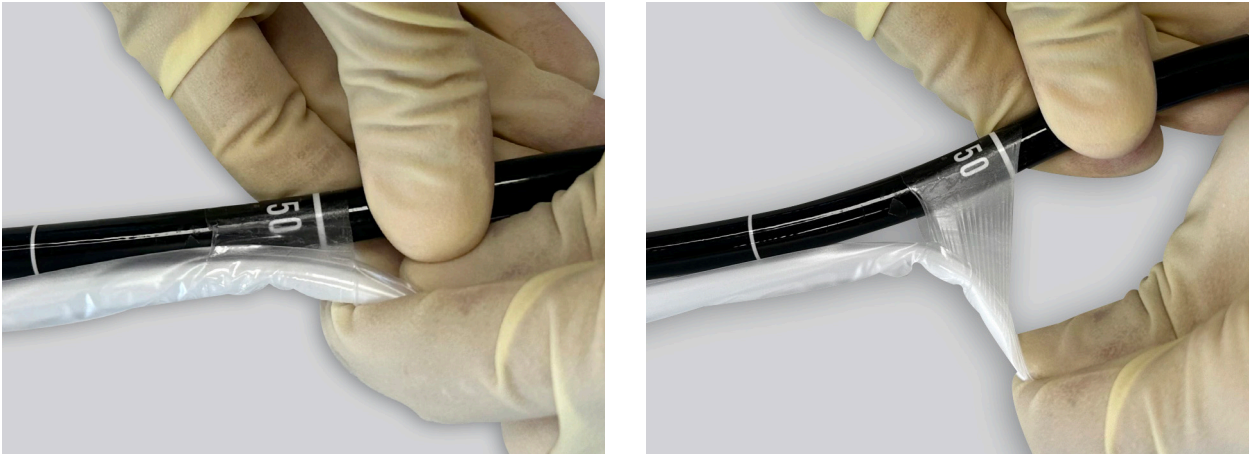
1. Turn on the Pure-Vu Workstation power button and wait for the STATUS light to be GREEN, indicating ready for procedure.
2. Turn on the endoscope processor and light source.
3. Verify visually and functionally that the endoscope functions properly (i.e. clear image, irrigation, insufflation and suction). Refer to endoscope manufacturer Instructions for Use.
4. Apply a water-based lubricant (as used in standard endoscopy procedures) to the distal section of the EVS Flexible Channel just before the procedure begins.
5. Place and prepare the patient for the procedure as per standard endoscopy procedure. It is recommended that an absorbent pad be placed around/underneath the patient when performing a colonoscopy.
6. Begin to perform the endoscopy procedure. Activate the Pure-Vu System when cleansing is required per physician's discretion.
7. Activate the cleansing mode by stepping on the right foot pedal. The cleansing selection mode button is located on the foot pedal (above the cleansing pedal) and the cleansing mode indicator on the workstation display. If a different cleansing mode is desired, depress the mode button to change the cleansing mode. The switching between the modes is performed in a cyclic manner – Medium – High – Low – Medium. This is reflected on the front of the system, as well as, on the foot pedal. If only irrigation is required, press the FLUID button until it turns to blue, then depress the right foot pedal to activate the cleanse function.
8. If only suction is desired, depress the left foot pedal to activate the suction function.
9. To ensure effective suctioning, position the suction ports below the fluid line.
10. If the suction channels are blocked, depress the manual purge pedal to remove the blockage.
11. To activate "Fluid Only" mode (no suction during cleansing only irrigation) press the "Fluid" button on the workstation (#6 in Figure 2). The light at the button will turn blue to show this mode is activated. To deactivate the Fluid Only mode press the button again.
12. Upon completion of the endoscopy procedure, disassemble the Disposable as per Section 5.3.

### 5.3. Disassembling the Umbilical Section and EVS Flex Channel



**FIGURE 7:** Upon completion of the endoscopy procedure, close the irrigation line clamp (A), point the tip of the endoscope into an empty container or a sponge (B), press the drain button (C) and wait for the drain cycle to complete. The drain button light will blink in blue until complete. Disconnect the in-line connector clip (D) remove the EVS Flex Channel (Figure 8 and 9). Open the pump heads and pull the tubes out. Then disconnect the umbilical from the Workstation by depressing the main connector button (E). If waste container was used disconnect the suction tubing from the waste container (F). If waste bag (G) is used it can remain connected to suction tubing. Discard irrigation bag or bottle, waste container or bag and tubing per facility protocol.

#### 5.4. Removing the EVS Flexible Channel from the Endoscope



**FIGURE 8:** Carefully remove the strips from the endoscope by pulling the strips.



**FIGURE 9:** While securing the end of the endoscope and pointing downward, gently pull back the EVS Flex Channel from the end of the distal tip of the endoscope. Discard per facility protocol.

## **5.5. Discarding the Disposables**

Following disassembly, discard the Pure-Vu EVS Flex Channel, Umbilical section, irrigation bags/bottles, waste containers/bags, unloading components and all other disposables according to facility protocol.

## **6.0 CLEANING WORKSTATION AND FOOT PEDAL**

The Workstation and foot pedal should be cleaned after the procedure by thoroughly wiping down their surfaces with a viricidal cloth (Opti-cide, Cavicide or similar surface disinfectant of choice) that has an active ingredient of isopropyl alcohol (17% - 21%).

## **7.0 STORAGE AND TRANSPORTATION**

Disconnect the Workstation electrical cord either from the inlet in the Workstation or from the socket in the wall.

The Workstation and cords should be stored in a clean condition. This equipment should never be stored in areas exposed to high temperature, humidity, direct sunlight, dust, salt, which could adversely affect the equipment (refer to Section 9.0 TECHNICAL SPECIFICATIONS). This equipment should never be installed or used in the presence of flammable or explosive gases or chemicals. The Pure-Vu Workstation should never be installed, used or transported in an inclined position nor should it be subjected to impact or vibrations.

## 8.0 TROUBLESHOOTING

| TROUBLESHOOTING*  | ACTION   |
|---|--|
| <b>Incorrectly connecting the suction tube to the waste container</b> | <ul style="list-style-type: none"> <li>• Verify at least one port is open on each waste container (not the vacuum port)</li> <li>• Verify the suction tubing has been properly connected. Refer to Figure 5</li> </ul>   |
| <b>Workstation does not power-up</b>                                  | <p>If you press the WS front panel Power On/Off button and power does not engage:</p> <ul style="list-style-type: none"> <li>• Verify the main power switch, located in the back of the workstation, is on. Refer to Figure 2</li> <li>• Verify the power cord is fully inserted and secured to the back of the Workstation. Refer to Figure 2</li> </ul>  |
| <b>Status light turns yellow</b>                                      | <ul style="list-style-type: none"> <li>• Verify the main connector is fully inserted and locked (indicated by an audible click).</li> <li>• Verify the pump heads are closed properly.</li> <li>• Verify the Foot Pedal is securely attached to the back of the Workstation. Refer to Figure 2</li> </ul> <p>If status light is still yellow, restart Workstation by pressing the front panel power button until OFF and then pressing the same power button to turn ON again. Refer to Figure 2</p>   |
| <b>Error light turns red</b>  | <ul style="list-style-type: none"> <li>• Restart Workstation by pressing the front panel power button until OFF and then pressing the same power button to turn ON again.</li> </ul>   |
| <b>Fluid light turns Orange (including 1 audio beep)</b>              | <ul style="list-style-type: none"> <li>• System has automatically switched to a Water Only mode and no gas is being introduced to the irrigation system. All irrigation modes will continue to operate without air.</li> </ul>   |
| <b>Status light turns Blue (including 1 audio beep)</b>               | <ul style="list-style-type: none"> <li>• The Auto Purge function is no longer active and has been disabled. Manual Purge can still be utilized.</li> </ul>   |
| <b>Foot Pedal is Not Responding</b>                                   | <ul style="list-style-type: none"> <li>• Verify the Foot Pedal is securely attached to the back of the Workstation. Refer to Figure 2</li> <li>• Verify that there is no object under any of the pedals of the Foot Pedal that prevents it from being depressed.</li> </ul>  |
| <b>No Irrigation</b>  | <ul style="list-style-type: none"> <li>• Verify irrigation bag has liquid and set-up properly.</li> <li>• Verify irrigation tubing is properly loaded onto the pump head.</li> <li>• Verify the Foot Pedal is securely attached to the back of the Workstation. Refer to Figure 2</li> <li>• Verify there is no torn/blocked/kinked tubing</li> <li>• Verify that the irrigation clamp is open. Refer to Figure 7</li> </ul>   |
| <b>No Suction / Excessive Purging</b>                                 | <ul style="list-style-type: none"> <li>• Verify the Foot Pedal is securely attached to the back of the Workstation. Refer to Figure 2</li> <li>• Verify there is no torn/blocked/kinked evacuation tubing</li> <li>• Apply manual purge operation to remove any potential suction blockage.</li> <li>• Make sure endoscope advancement and/or torque application is not pinching tubing (because of manual gripping). Refer to Section 1 PRECAUTIONS</li> <li>• Verify that the EVS Flex Channel suction ports are positioned below the fluid line to allow effective suctioning.</li> <li>• Verify that the EVS Flex Channel suction port tip is not positioned against the GI tract wall. If so, direct the scope tip away from the wall.</li> </ul> |

\*If the above does not remedy the warning indication, contact a Motus GI representative.

## 9.0 TECHNICAL SPECIFICATIONS

### 9.1 Environmental Standards

The table below describes the recommended environmental standards required for correct operation of Motus Pure-Vu System.

| SPECIFICATIONS        |                                |
|-----------------------|--------------------------------|
| Operating Temperature | 50° to 86° F<br>10° to 30° C   |
| Humidity              | 10% to 80%<br>(Non-condensing) |
| Altitude              | Up to 81 Kpa                   |

### 9.2. Shipping and Storage

Recommended Shipping and Storage Temperature:

| SPECIFICATIONS |                               |
|----------------|-------------------------------|
| Shipping       | 14° to 140° F / -10° to 60° C |
| Storage        | 59° to 86° F / 15° to 30° C   |

### 9.3. Performance Specifications

|           | MEDIA  | PRESSURE   | FLOW              |
|-----------|--------|--|-------------------|
| Cleansing | Air    | 1.65 Bar [24 PSI] - Colon<br>2.1 Bar [30.4 PSI] - Gastro | Up to 1000 cc/min |
|           | Water  | 3.5 Bar [52 PSI]   | Up to 645 cc/min  |
| Suction   | Vacuum | Up to (-) 0.5 Bar  | NA                |

### 9.4. Endoscope Compatibility

| TYPE        | OD (mm)     | LENGTH (mm) |
|-------------|-------------|-------------|
| Colonoscope | 11.7 - 13.2 | 1630 - 1710 |
| Gastroscope | 9.2 - 10    | 950 - 1030  |

### 9.5. Workstation Mechanical Properties and Sizes

Following are the mechanical properties and size for the Pure-Vu Workstation:

|                        | Workstation                                     |
|------------------------|---|
| Dimensions [W x D x H] | 250mm x 400mm x 280mm<br>[10in x 15.7in x 11in] |
| Weight                 | 12kg (26.5lbs)                                  |
| Power Supply           | 100 - 240 VAC / 50 - 60 Hz                      |





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