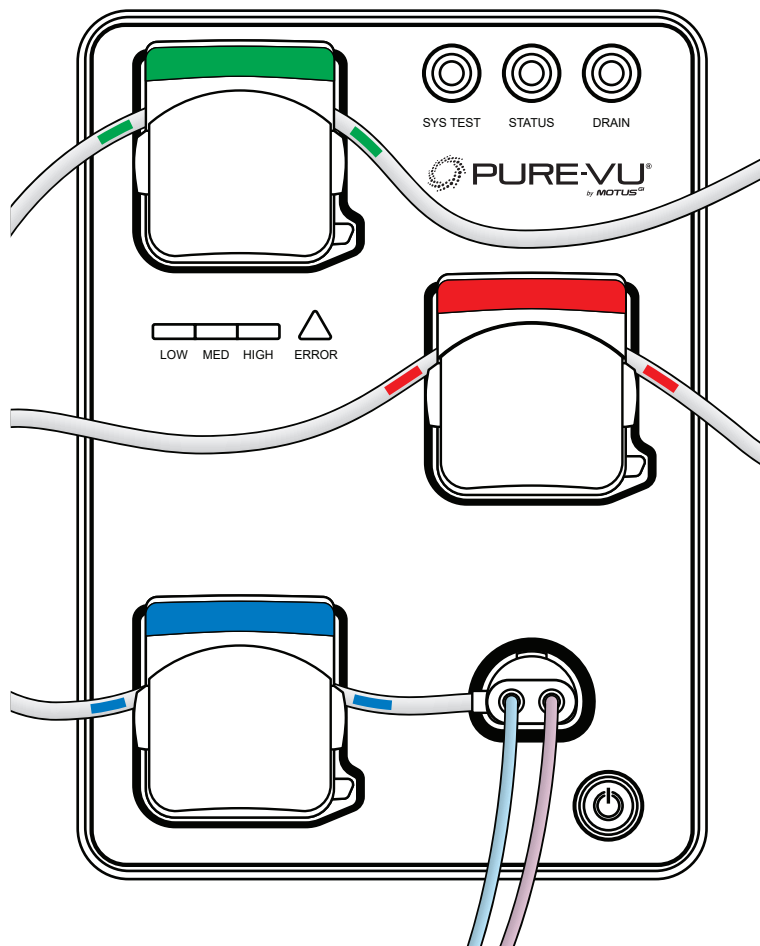




Motus Pure-Vu® System Instructions For Use



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1. 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 instruction and operating conditions described in this manual. Failure to do so could result in compromised safety, equipment malfunction or instrument damage.
- The Pure-Vu System shall only be used under the supervision of a licensed physician. Do not use for any purpose other than the intended application.
- 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 both 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 meets the compatibility 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 only be connected to a supply main with protective earth.
- 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 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, 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.
- Electrical safety inspections shall be performed annually (or as required by institutional procedures). The inspection shall be performed only by Motus GI authorized technical personnel.
- The Oversleeve, Umbilical Section, Loading Fixture, 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.
- A New, single use irrigation bag (IB) shall be used for each patient.

Precautions:

- Advance cautiously when performing anal retroflex and/or entering the ileocecal valve.
- Care shall be taken to avoid pinching the tubing during advancement through the colon and/or when applying torque to the colonoscope.
- Only Motus GI personnel or a trained designee should service the Pure-Vu System.

1.1. Symbols Used

The Pure-Vu System has a safety warning and compliance label located on the Workstation, Loading Fixture, 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
	Authorized representative in the European Community
	CE compliance symbol

2.0 INTENDED USE

The Pure-Vu® System is intended to connect to standard or slim colonoscopes to help facilitate intraprocedural cleaning of a poorly prepared colon by irrigating or cleaning the colon and evacuating the 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, ambulatory surgery centers, ambulatory endoscopy centers, clinics and doctor offices.

3.0 PRODUCT DESCRIPTION

The Pure-Vu System enables colon cleansing during colonoscopy using a standard or slim colonoscope with a length of 1630mm - 1710mm and an outer diameter range of 11.7mm - 13.3mm (slim) and 12.8mm - 13.7mm (standard). The Oversleeve, which fits over the colonoscope and is connected to an external Workstation, generates fluid and gas to break up feces. The fecal matter & fluids are removed through the suction channels of the Oversleeve into an external waste container.

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

- Disposable device which includes an Oversleeve and an Umbilical Section. The Oversleeve fits over the colonoscope and the Umbilical section is connected to the external Workstation.
- Workstation that is reusable and supplies an irrigation mixture of water or saline and gas, and evacuates fecal material & fluids.
- Loading Fixture that is reusable and aids in assembling the Oversleeve onto the colonoscope.
- Additional components include 60cc luer lock syringe/3-way stopcock assembly, sealing plug, and air line tubing.

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

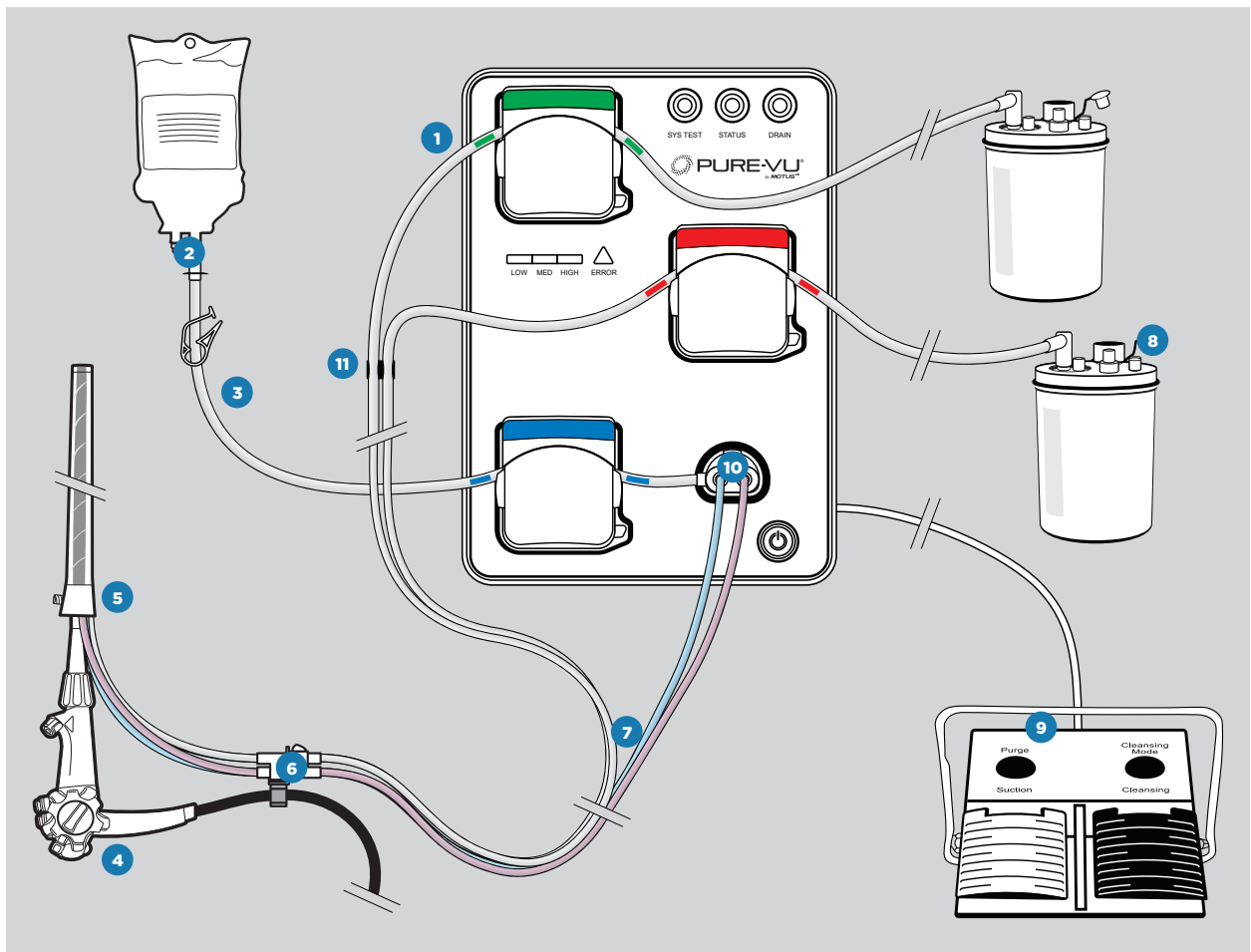


FIGURE 1: Pure-Vu Workstation - General Design & Components

- | | | | |
|-------------------------|---------------------|---------------------|-------------------------|
| 1 Workstation | 4 Colonoscope | 7 Umbilical Section | 10 Main Connector |
| 2 Irrigation Bag | 5 Oversleeve | 8 Waste Container | 11 Suction Tubing Clamp |
| 3 Irrigation Line Clamp | 6 In-Line Connector | 9 Foot Pedal | |

3.1. Pure-Vu® Workstation

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

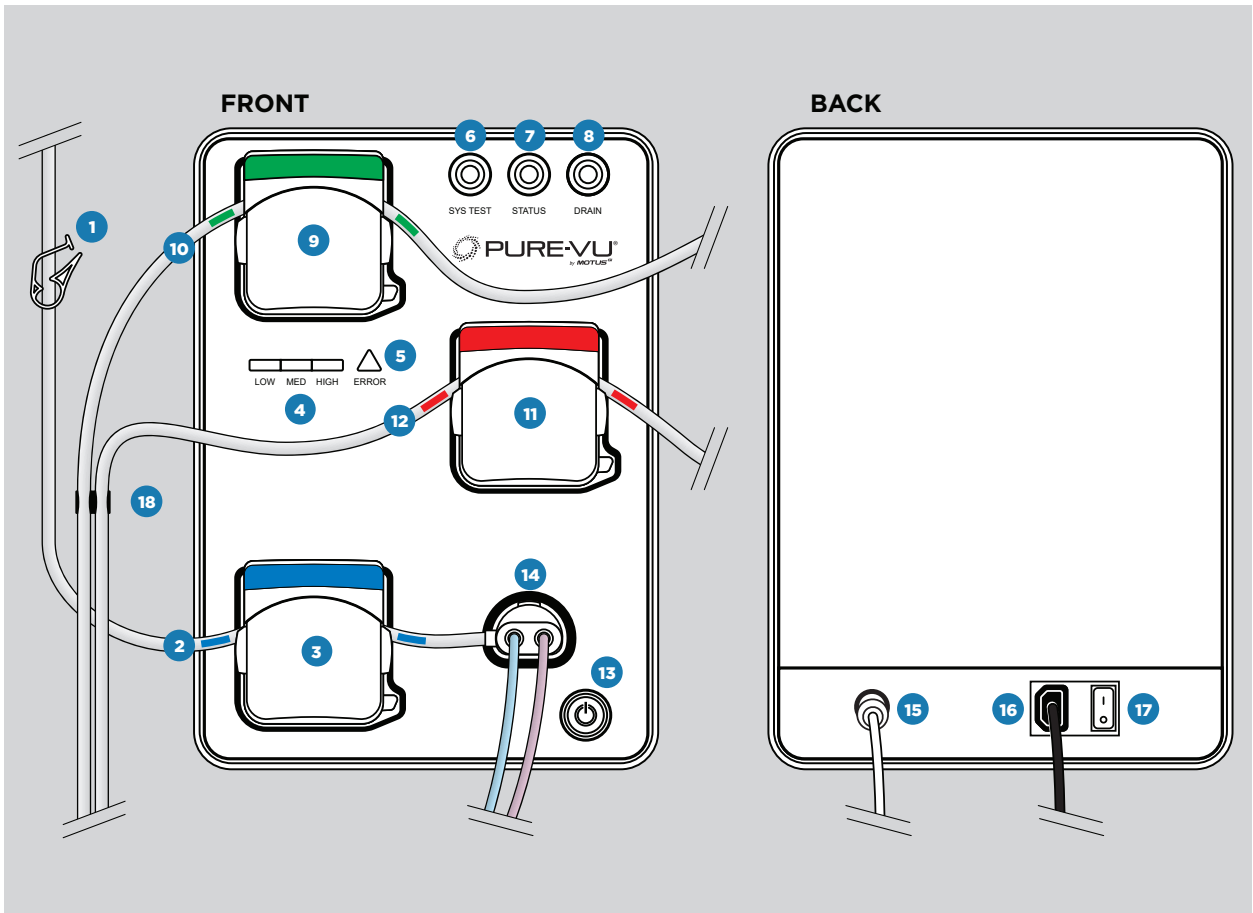


FIGURE 2: Pure-Vu Workstation

- | | |
|--|---------------------------------|
| 1 Irrigation Line Clamp | 10 Suction Tube (Green markers) |
| 2 Irrigation Line (Blue markers) | 11 Suction Pump (Red) |
| 3 Irrigation Pump (Blue) | 12 Suction Tube (Red markers) |
| 4 Cleansing Mode Indicators (Low / Med / High) | 13 Power Button |
| 5 Error Light | 14 Main Connector |
| 6 System Test Button | 15 Foot Pedal Connector |
| 7 Status Light | 16 Power Cord |
| 8 Drain Button | 17 Main Power Switch |
| 9 Suction Pump (Green) | 18 Suction Tubing Clamp |

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 feces from the colon.
- Irrigation Bag (saline or water) which is connected to the irrigation line.
- Waste Containers for collecting the fecal material & fluids that are suctioned from the colon 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 3). The system can be operated in three cleansing modes; low, medium (default mode) and high
- Two Suction Pumps - remove the fecal material, gas & fluids from the colon into the waste containers
- Main Connector - connects the Umbilical Section to the Workstation and supplies gas to the irrigation and sensing line
- System Test Button- turns on system test when depressed for 3 seconds and ensures that the Pure-Vu System is functioning properly prior to the start of the procedure
- 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 orange light indicates recoverable error with the setup, the irrigation bag is empty or the end of drain routine
- Error Light (Triangle)- turns red when there is non-recoverable system error

3.1.3. Foot Pedal Unit

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):

- Cleansing - simultaneous irrigation and suction, activated by the right foot pedal
- 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

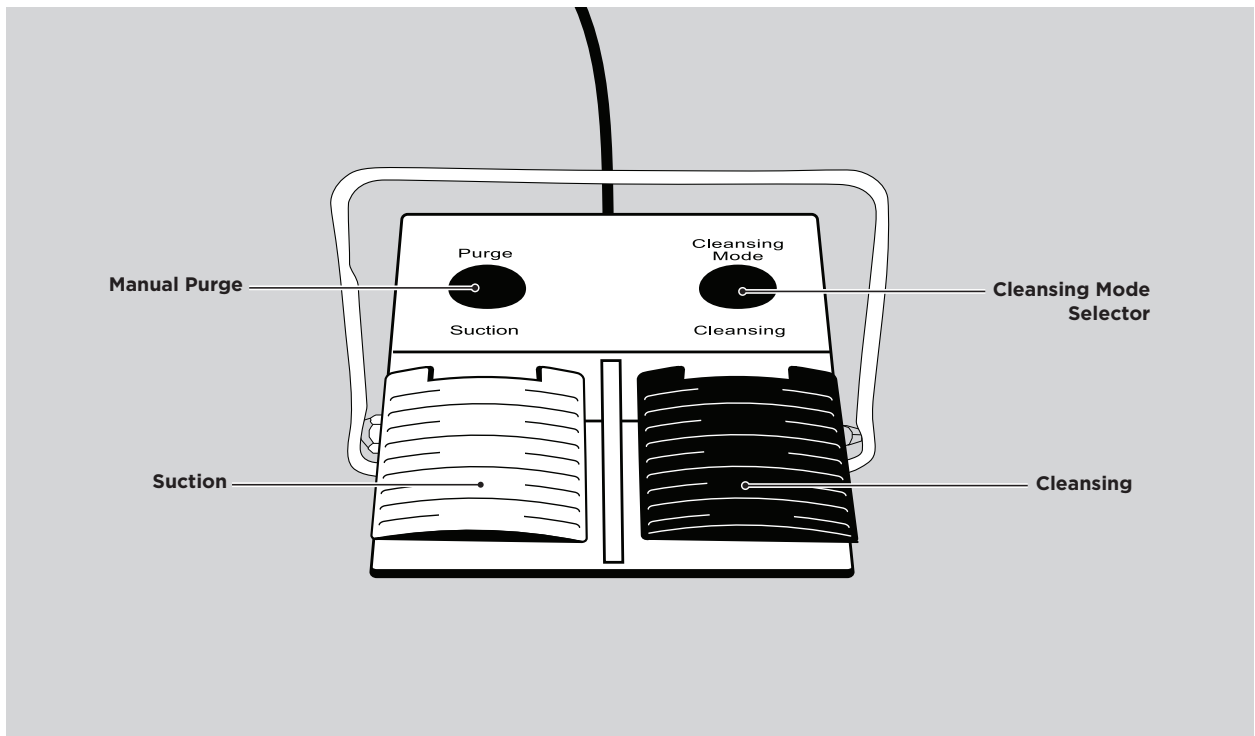


FIGURE 3: Pure-Vu Foot Pedal Unit

3.2. Pure-Vu® Disposable Kit

The Pure-Vu® Disposable Kit is comprised of the Oversleeve, Umbilical Section, and the Loading/Unloading Kit (includes sealing plug and syringe/3-way stopcock assembly). The Pure-Vu Oversleeve is a single use device, which fits over a standard or slim colonoscope. Once attached to the colonoscope the maximum outer diameter is 21 mm.

The Pure-Vu Oversleeve consists of multiple irrigation and suction channels as well as a channel for sensing blockages in the suction ports of the system. The Oversleeve allows for proper connection to the colonoscope. The inflation hub, located at the proximal end of the Oversleeve, allows for advancement of the colonoscope. The luer connector on the top of the inflation hub allows for the connection to the loading fixture control box via the disposable tubing to supply air to facilitate inflation of the inner sleeve during loading. Proximal to the inflation hub is the in-line connector that enables attachment to the Umbilical Section.

The Umbilical Section connects the Pure-Vu Oversleeve to the Workstation via the main connector.

3.3. Accessories for Use with Pure-Vu® System

The following 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

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 the date of expiry on the label.

Verify that the disposable label specifications are compatible with the selected colonoscope.

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 and Loading Fixture

Prior to unpacking the Workstation and the Loading Fixture, 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 Oversleeve to the Workstation

4.2.1. Cleaning the Loading Fixture

The Loading Fixture should be cleaned prior to loading the Pure-Vu Oversleeve onto the colonoscope. Thoroughly wipe down the Loading Fixture with a viricidal cloth (Opti-cide, Cavicide or similar surface disinfectant of choice) that has an active ingredient of isopropyl alcohol (17% - 21%).

4.2.2. Oversleeve Assembly

Remove the Oversleeve from the tray (item #1 in tray) and sealing plug (item #3 in tray). To load the Oversleeve onto the colonoscope complete the following steps:

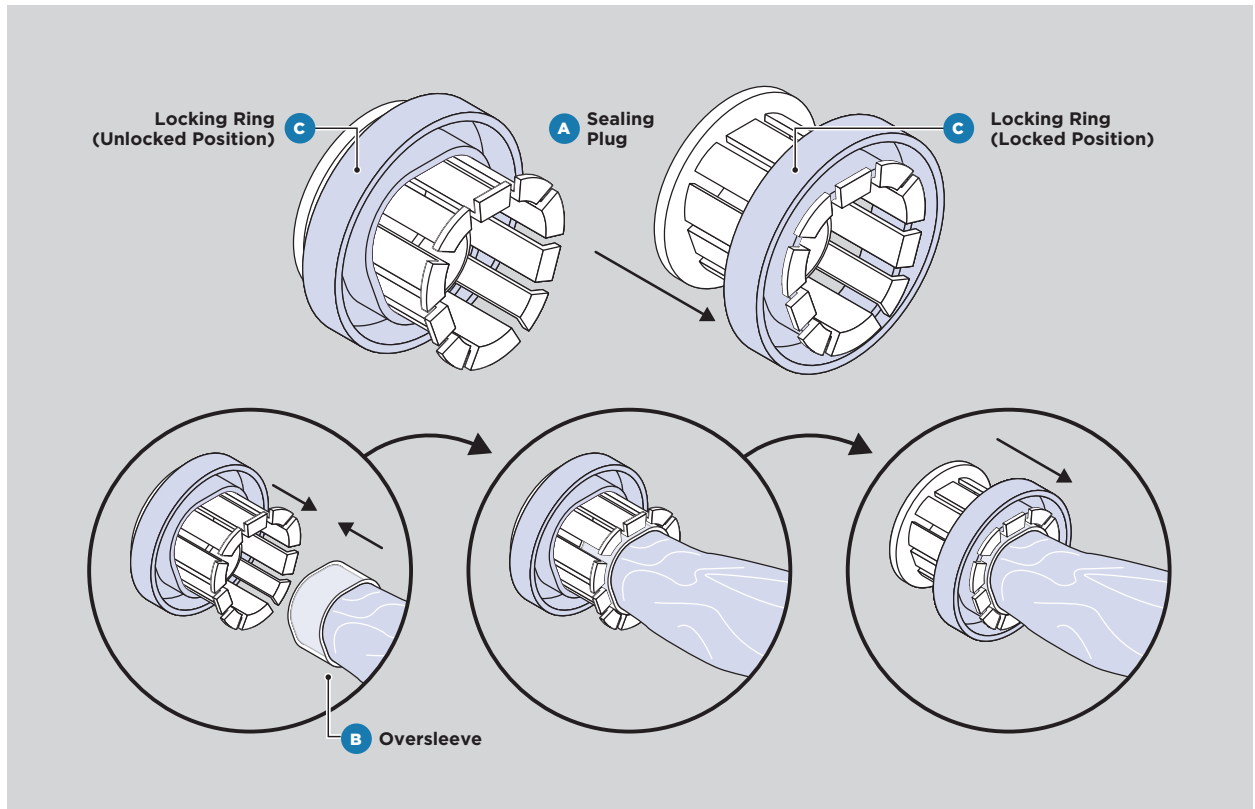


FIGURE 4: Align the sealing plug (A) with the distal tip of the Oversleeve (B). Advance the sealing plug onto the distal tip of Oversleeve, then slide the locking ring (C) to the proximal end of the plug (locked position).

4.2.2. Oversleeve Assembly (cont...)

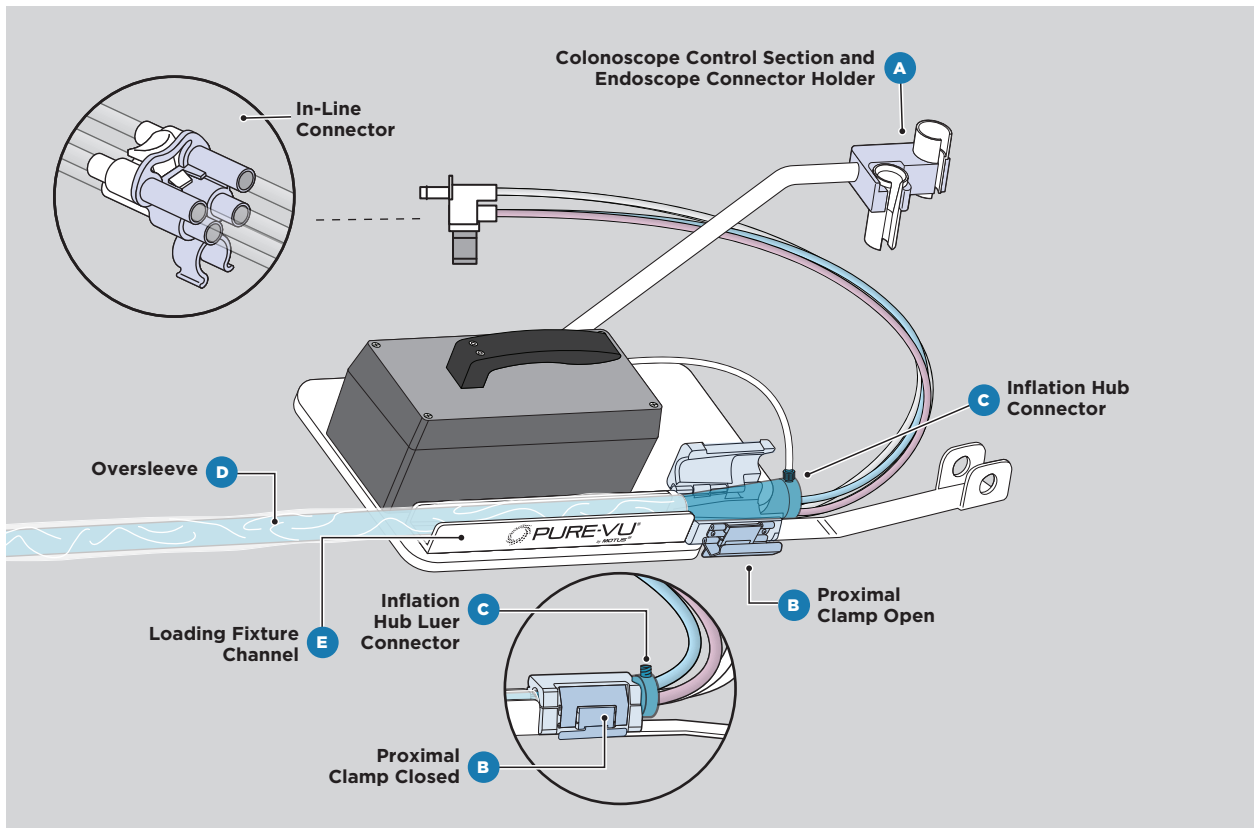


FIGURE 5: Place the Loading Fixture on a flat surface. Ensure that the colonoscope control section and endoscope connector holders are in the open position. Open the proximal clamp (B). Place the Oversleeve inflation hub connector facing up (C), ensure that the inflation hub luer connector is properly aligned and secured in the clamp, close and lock the proximal clamp (B). Place the Oversleeve (D) into the Loading Fixture channel (E).

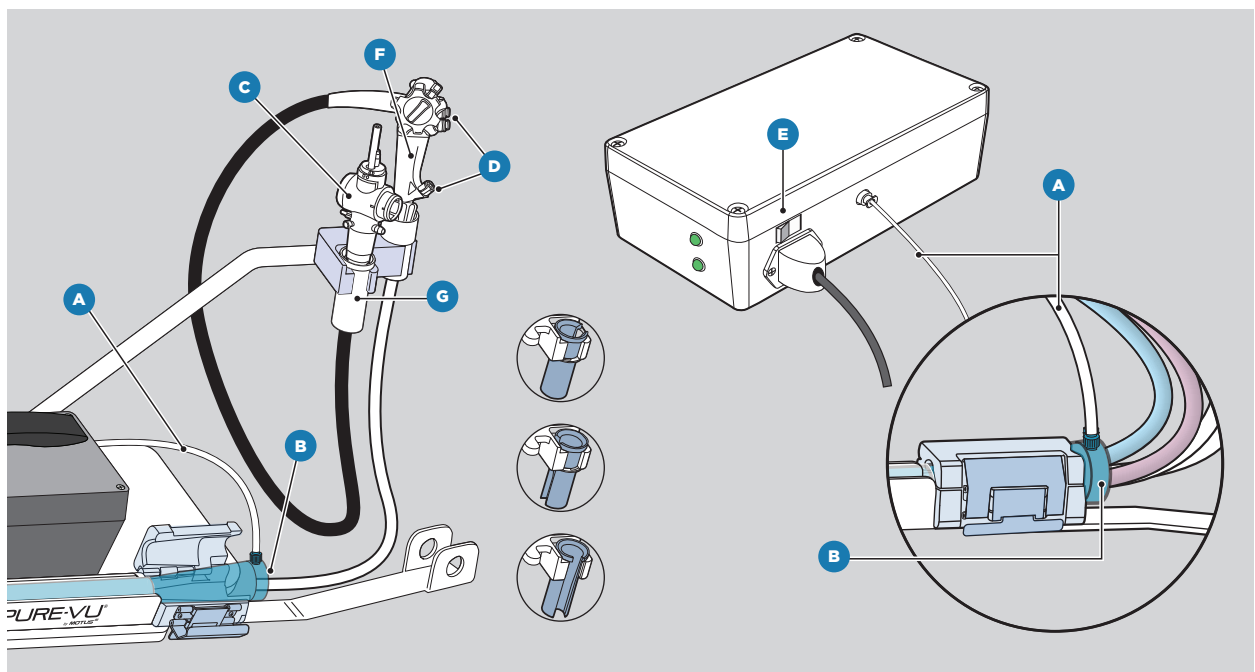


FIGURE 6: Connect the control box air line tubing (A) to the inflation hub (B) and turn ON the inflation control box power (E). Then place the colonoscope connector (C) and control section (F) on the Loading Fixture. Rotate the colonoscope holders (G) to lock. Ensure the colonoscope air/water, auxiliary water port, suction and biopsy valves (D) are in place and secure.

4.2.2. Oversleeve Assembly (cont...)

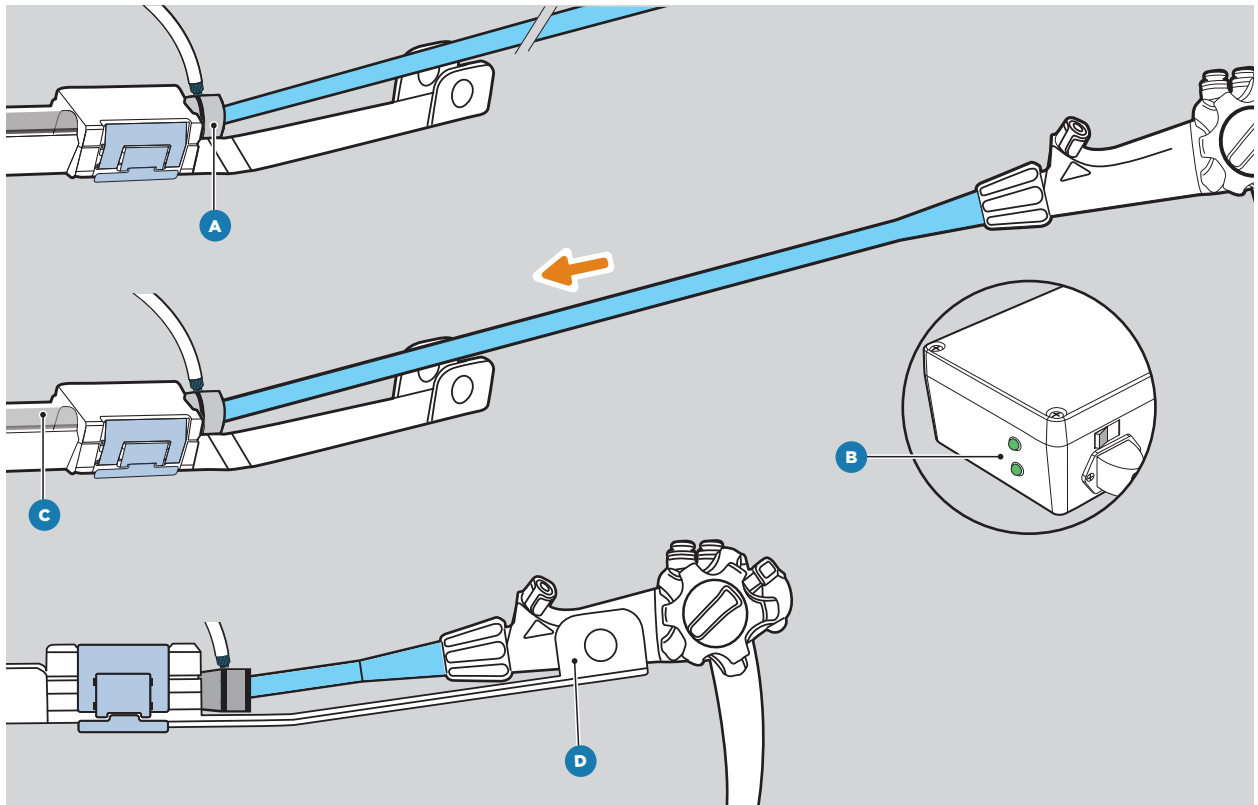


FIGURE 7: Prepare colonoscope by wetting its distal end with water or water-based lubricant (as used in standard colonoscopy procedures) and then insert the colonoscope tip into the proximal end of the inflation hub (A); wait until the bottom green LED light (B) illuminates. Begin to gently push the colonoscope into the Pure-Vu Oversleeve (C). Continue inserting the colonoscope until it reaches the distal end and will not advance with a gentle push. Place the colonoscope control section onto the scope support bracket (D).

4.2.2. Oversleeve Assembly (cont...)

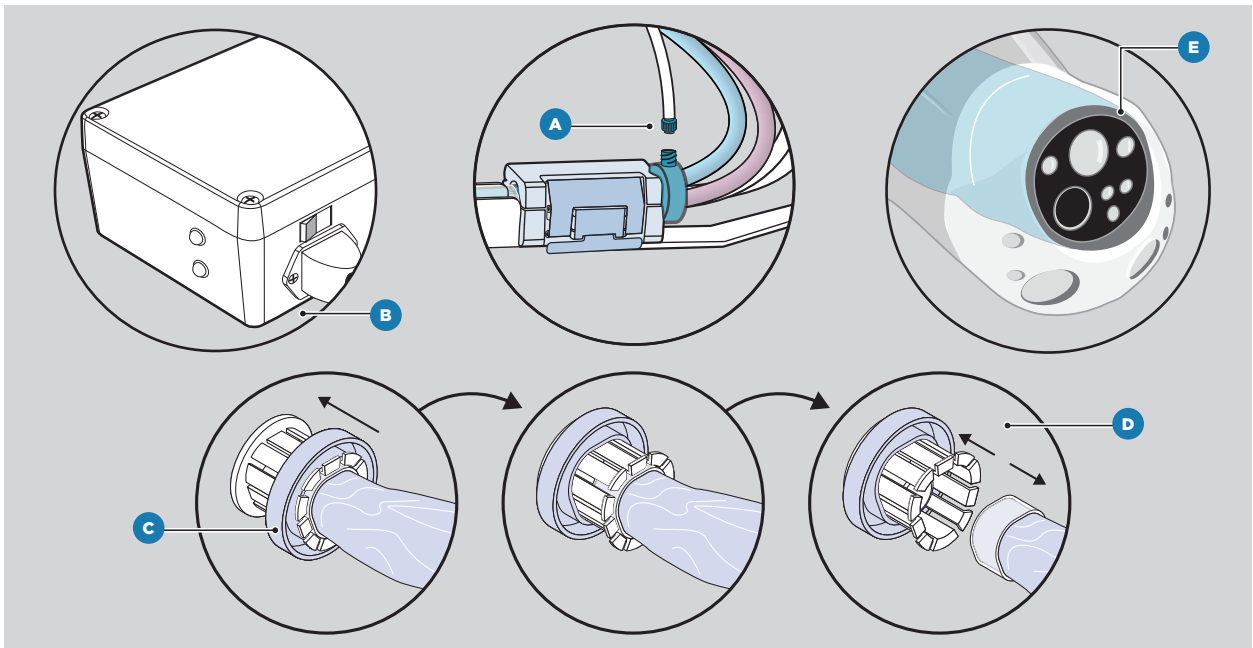


FIGURE 8: Disconnect the air line from the inflation hub (A). Turn OFF the inflation control box power (B). Move the locking ring (C) to the distal end (unlocked position) and remove the sealing plug (D). Do not dispose of the sealing plug, as it will be used in the unloading process. Inspect the distal end of the Pure-Vu Oversleeve/colonoscope interface, making sure the colonoscope is flush with the upper lip of the Pure-Vu Oversleeve as shown (E). Remove the Pure-Vu Oversleeve with colonoscope from the Loading Fixture. The Pure-Vu Oversleeve and colonoscope are now ready for assembly to the Pure-Vu Umbilical Section, Workstation controller, colonoscope light source and video processor.

4.2.3. 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 (item #2 in the tray). To attach the Umbilical Section to the Workstation complete the following steps:

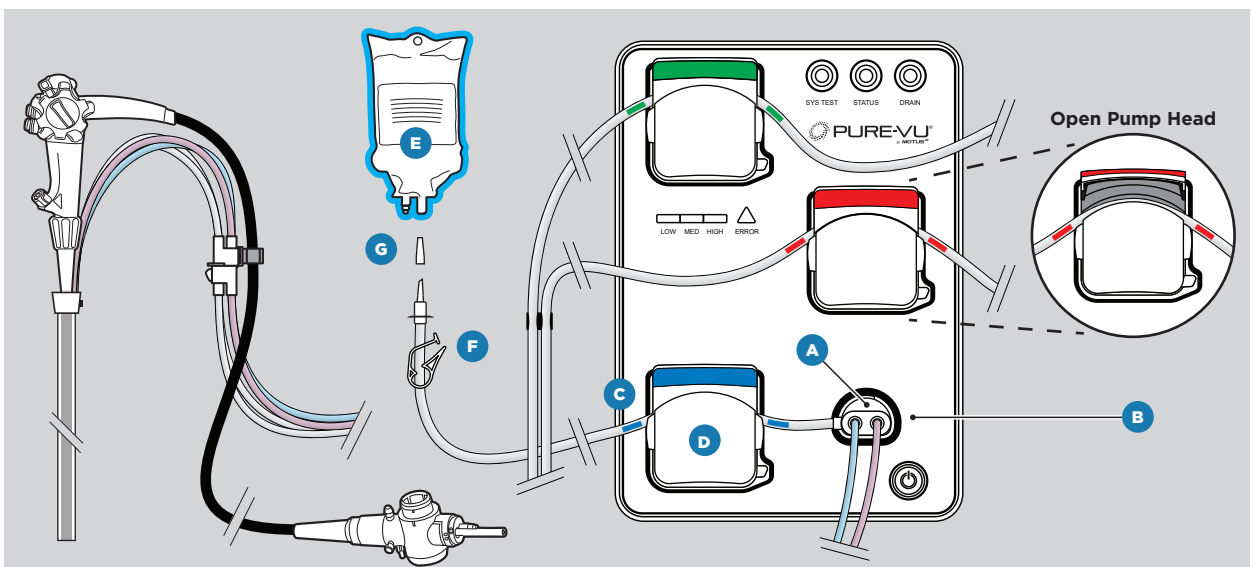


FIGURE 9: Connect the main connector (A) to the main connector socket in the Workstation (B). Place the irrigation tubing (C) into the irrigation pump marked in blue (D) between marked blue lines, then close the irrigation pump head. Remove the irrigation tube spike's cap (G), then connect the irrigation tubing to the irrigation bag (E) and ensure that the irrigation line clamp (F) is open.

4.2.3. Attaching the Umbilical Section to the Workstation (cont...)

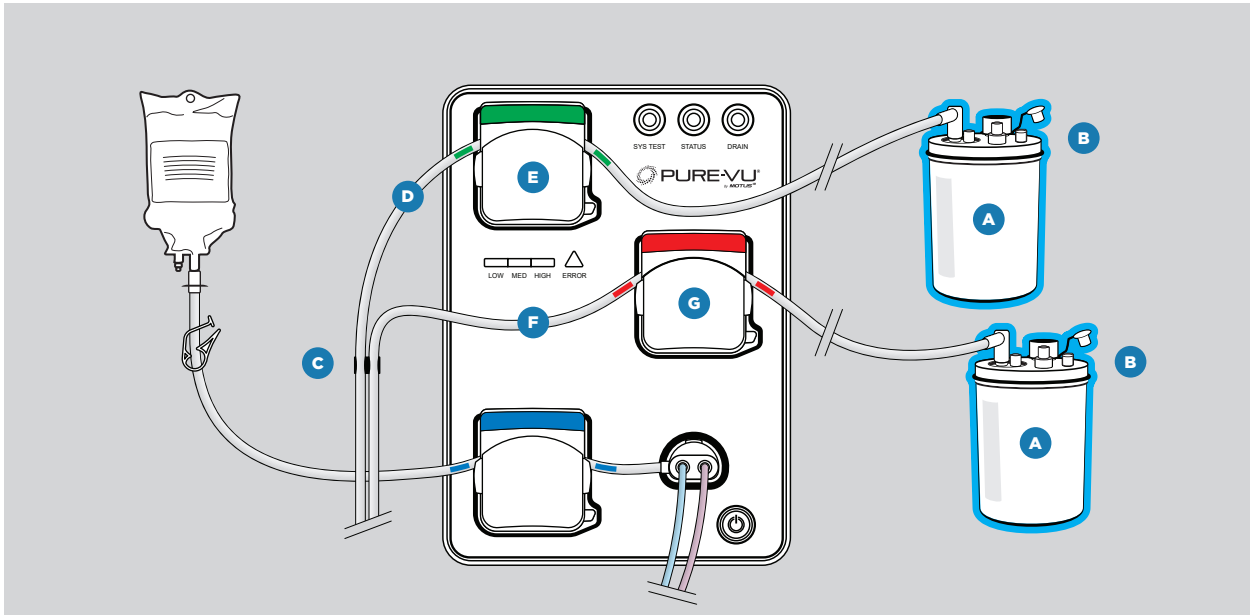


FIGURE 10: Connect the two suction lines to the two waste containers (A) and ensure that at least one port, in addition to the vacuum port (B), is open on each container. Ensure that the suction tubing clamp (C) is on the left of the Workstation and then place the suction tubing (D) into the suction pump marked in green (E) between marked green lines, then place the suction tubing (F) into the suction pump marked in red (G) between marked red lines, then close both suction pump heads.

4.2.4. Attaching the Oversleeve to the Umbilical Section

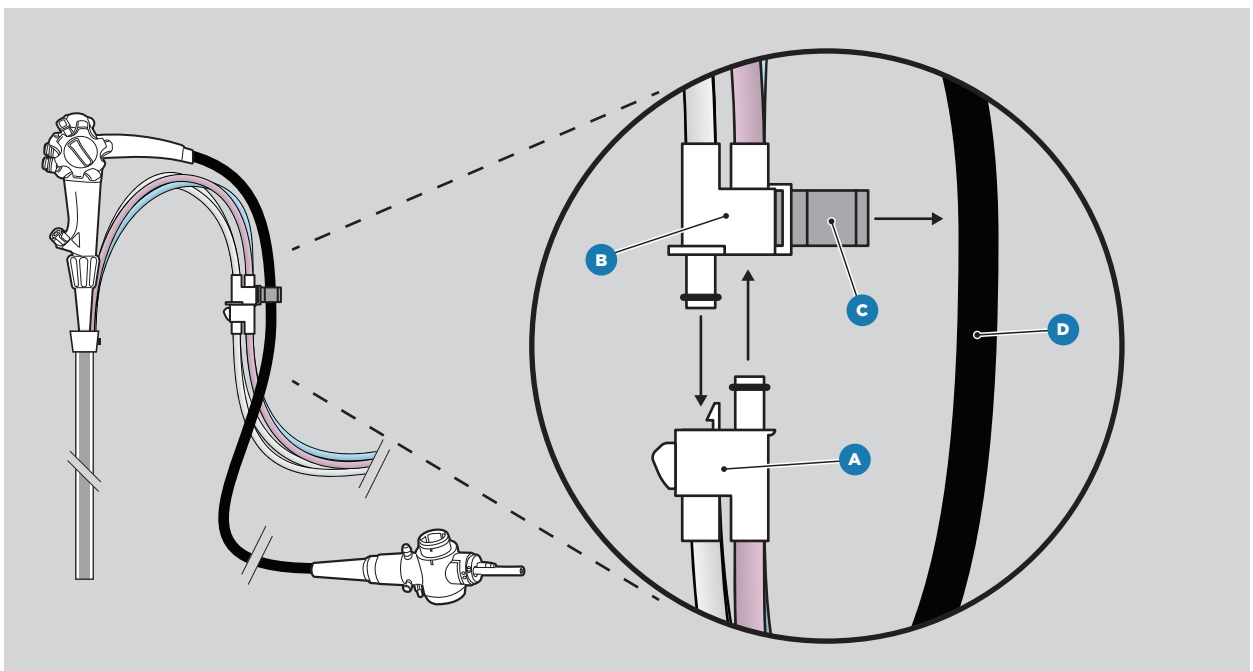


FIGURE 11: Connect the Oversleeve to the Umbilical Section by the inline connector (A to B). Attach the inline connector clip to the colonoscope Umbilical section (C to D).

4.2.5. Operation and System Test

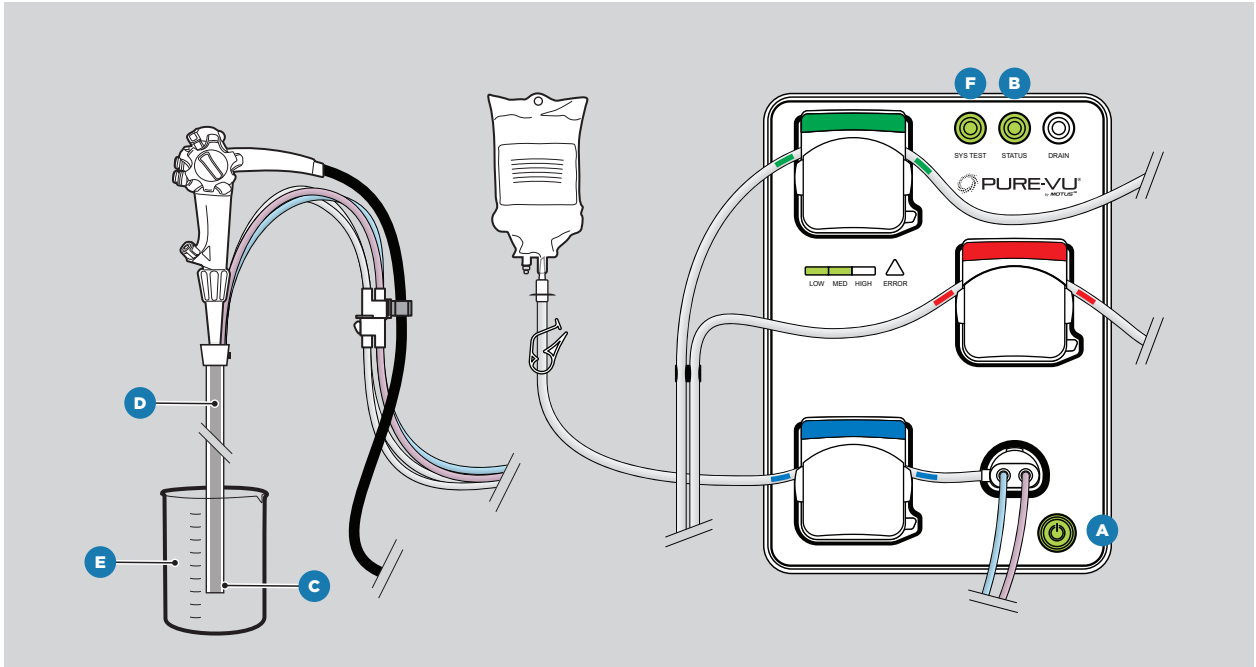


FIGURE 12: Turn ON the Workstation by pressing the Power On/Off button (A). Confirm status indicator (B) is green. Point the tip of the colonoscope (C) and the Pure-Vu Oversleeve (D) toward a container (E). Ensure that the Oversleeve's distal tip is not submerged in water, then press the system test button (F) for 3 seconds to verify irrigation. The Pure-Vu System is now ready for use.

5.0 SYSTEM OPERATION

5.1. Pre-procedure Operations

1. Use a new, single-use irrigation bag and new, single-use waste containers.
2. Verify that all cords and cables, including Workstation and Foot Pedal, are assembled correctly.
3. Confirm that the waste containers and irrigation bag are replaced at the same time at the beginning of the procedure.
4. Verify that the disposable is assembled correctly and that the irrigation line clamp is open.

5.2. Operating the Pure-Vu® Workstation

1. Turn on the Pure-Vu Workstation power button.
2. Turn on the colonoscope processor and light source.
3. Verify visually and functionally that the colonoscope functions properly (i.e. clear image, irrigation, insufflation and suction). Refer to colonoscope manufacturer Instructions for Use.
4. Check the Pure-Vu System visually and functionally by pressing and holding for 3 seconds the System Test button and verify irrigation. *Note:* Ensure that the disposable's distal tip is not submerged in water during the test. If no irrigation, refer to Section 8.0 TROUBLESHOOTING
5. After determining the Pure-Vu System is ready for use, wet at least 30cm of the distal section of the Oversleeve and then apply a water-based lubricant (as used in standard colonoscopy procedures) to at least 30cm of the distal section of the Oversleeve just before the procedure begins.
6. Place and prepare the patient for the procedure as per standard colonoscopy procedure. It is recommended that an absorbent pad be placed around/underneath the patient.
7. Begin to perform the colonoscopy. Activate the Pure-Vu System when cleansing is required per physician's discretion.
8. Activate the cleansing mode by stepping on the right foot pedal. The cleansing mode button is located on the foot pedal and the cleansing mode indicator on the workstation display. If a different cleansing mode is desired, depress the foot mode button to change the cleansing mode. The switching between the modes is performed in a cyclic manner - Medium - High - Low - Medium.
9. If only suction is desired, depress the left foot pedal to activate the suction function.
10. To ensure effective suctioning, position the suction ports below the fluid line.
11. If the suction channels are blocked, depress the manual purge pedal to remove the blockage.
12. Upon completion of the colonoscopy procedure, disassemble the disposables as per section 5.3.

5.3. Disassembling the Umbilical Section and Oversleeve

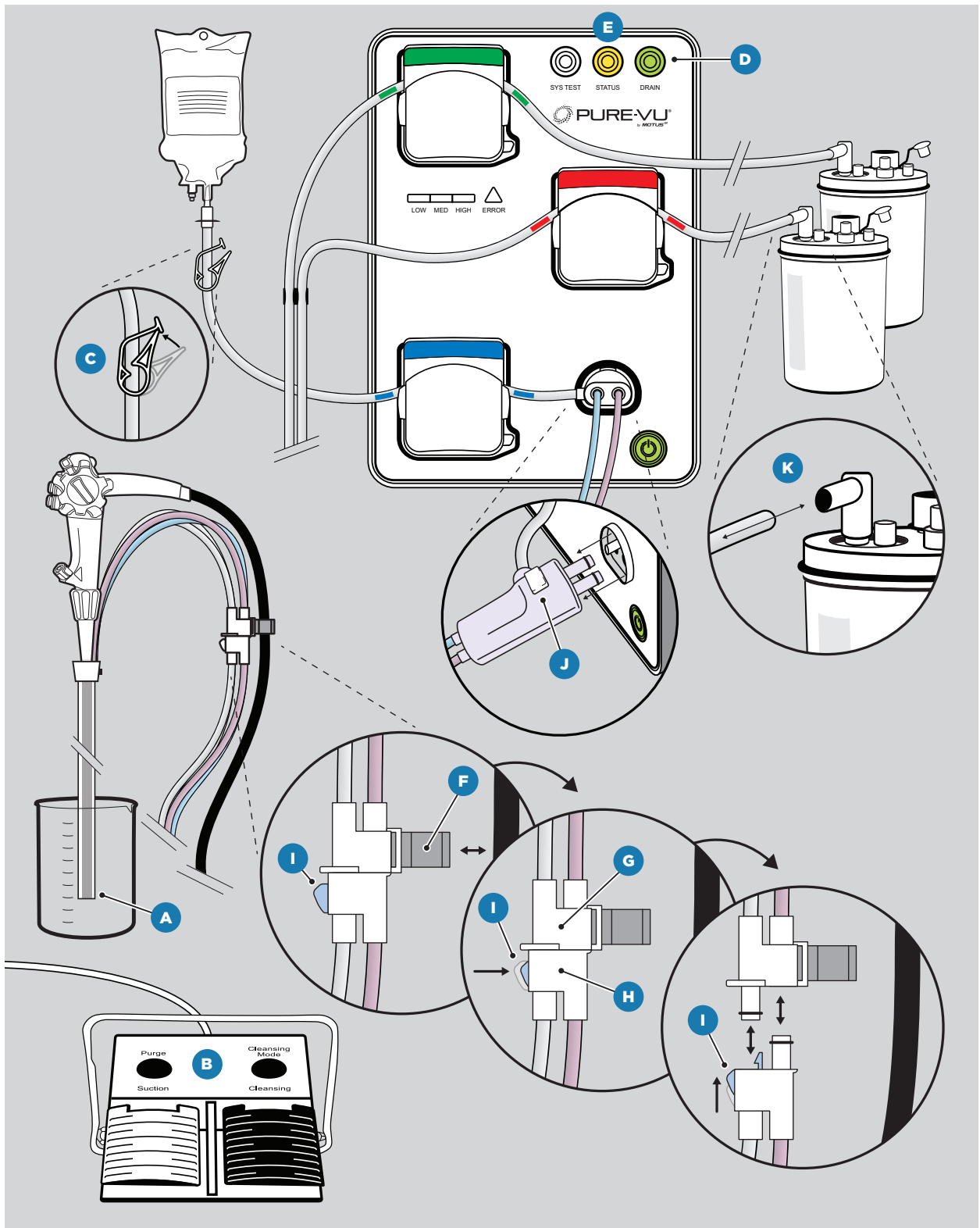


FIGURE 13: Upon completion of the colonoscopy, fill a container with 200cc of tap water (A). Point the tip of the colonoscope down in the container and suction the 200cc of tap water by depressing the suction pedal on the Foot Pedal unit (B). Close the irrigation line clamp (C), press the drain button (D) for 3 seconds and wait for drain cycle to complete. The status indication (E) will switch from green to orange. Disconnect the In-Line Connector Clip (F) from the Colonoscope. Disconnect the Oversleeve (G) from the Umbilical Section (H) by pressing the in-line connector button (I) down and forward, then separate the Oversleeve from the Umbilical Section by pulling apart the connectors. Open the pump heads and pull the tubes out. Then disconnect the Umbilical Section from the Workstation by depressing the main connector button (J). Disconnect the suction tubing from the waste containers (K). Discard irrigation bag, waste containers and tubing per facility protocol.

5.4. Removing the Oversleeve from the Colonoscope

Remove the unloading components (the sealing plug and the syringe/3-way stopcock assembly) from the disposable tray (item #3 in tray) and follow the unloading procedure instructions below.

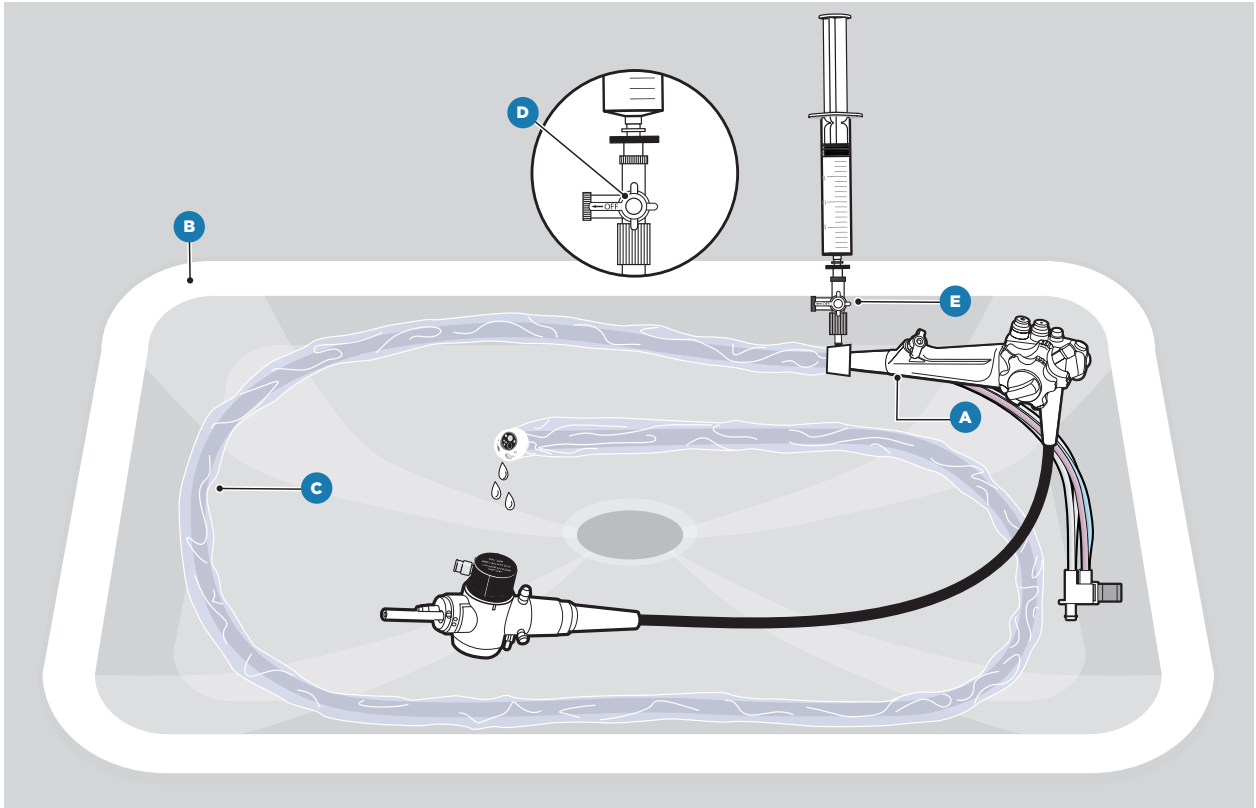


FIGURE 14: Place the colonoscope (A and C) in the bottom of a basin (B) or sink in large circle (s). Open the stopcock (D) by turning the off valve facing towards the side port of the stopcock and draw up 60 cc of a 4-part water, 2 part detergent solution (40 cc water, 20 cc detergent). Connect the stopcock and syringe assembly (E) to the Oversleeve luer hub. Flush the 60 cc volume of diluted detergent through the Oversleeve and look for the solution to exit the distal end.

5.4. Removing the Oversleeve from the Colonoscope (cont...)

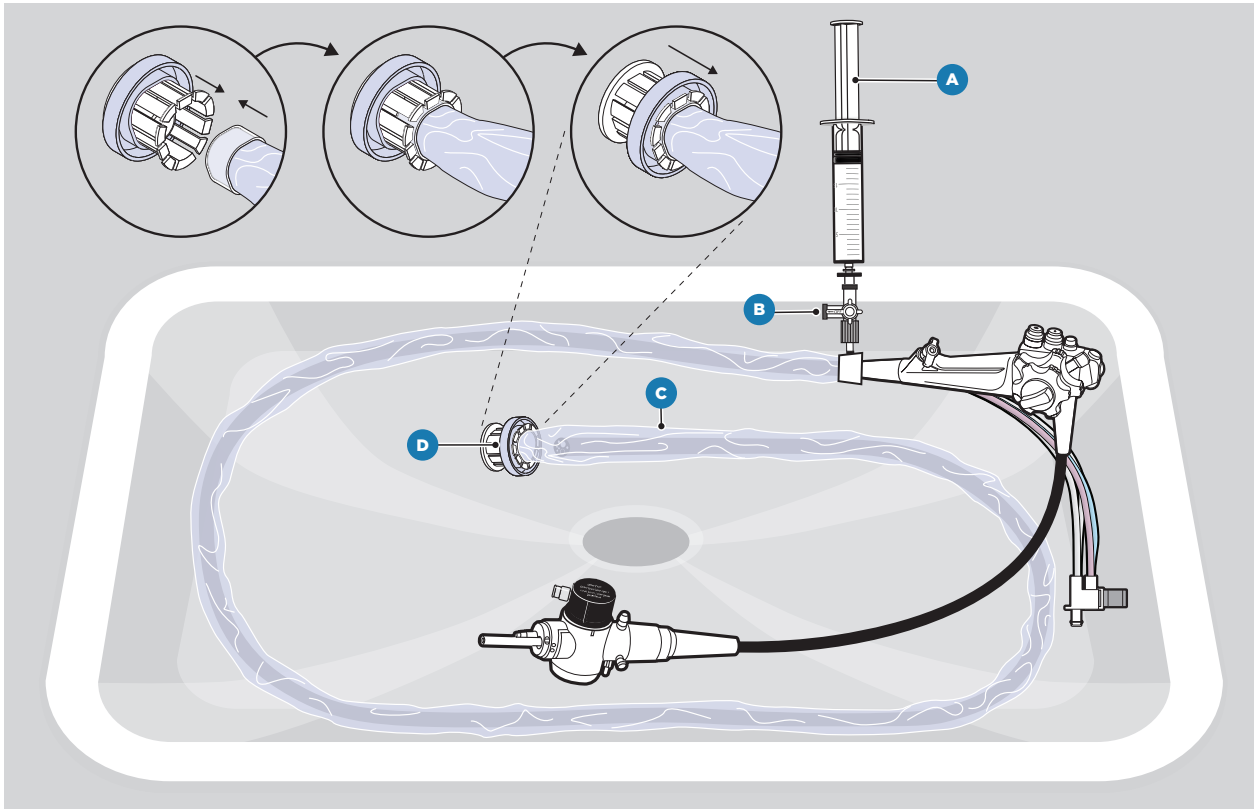


FIGURE 15: Maintain pressure on the syringe plunger (A) and close the stopcock valve (B) by turning the off valve towards the Oversleeve (C) to maintain pressure. Note: If fluid does not exit the Oversleeve, remove the syringe from the stopcock, draw up an additional 60 cc of diluted detergent solution into the syringe, attach the syringe to the stopcock and turn the off valve toward the side port of the stopcock and repeat step 5.

Push the tip of the colonoscope back approximately 2 cm into the Oversleeve. Advance the Sealing Plug (D) into the distal tip of the Oversleeve. Ensure that the sealing plug locking ring is in the locked position. Turn the stopcock off valve toward the Oversleeve, and draw up 60 cc of air. Turn the off valve to the side port position and infuse the air. Close by turning the off valve towards the Oversleeve.

5.4. Removing the Oversleeve from the Colonoscope (cont...)

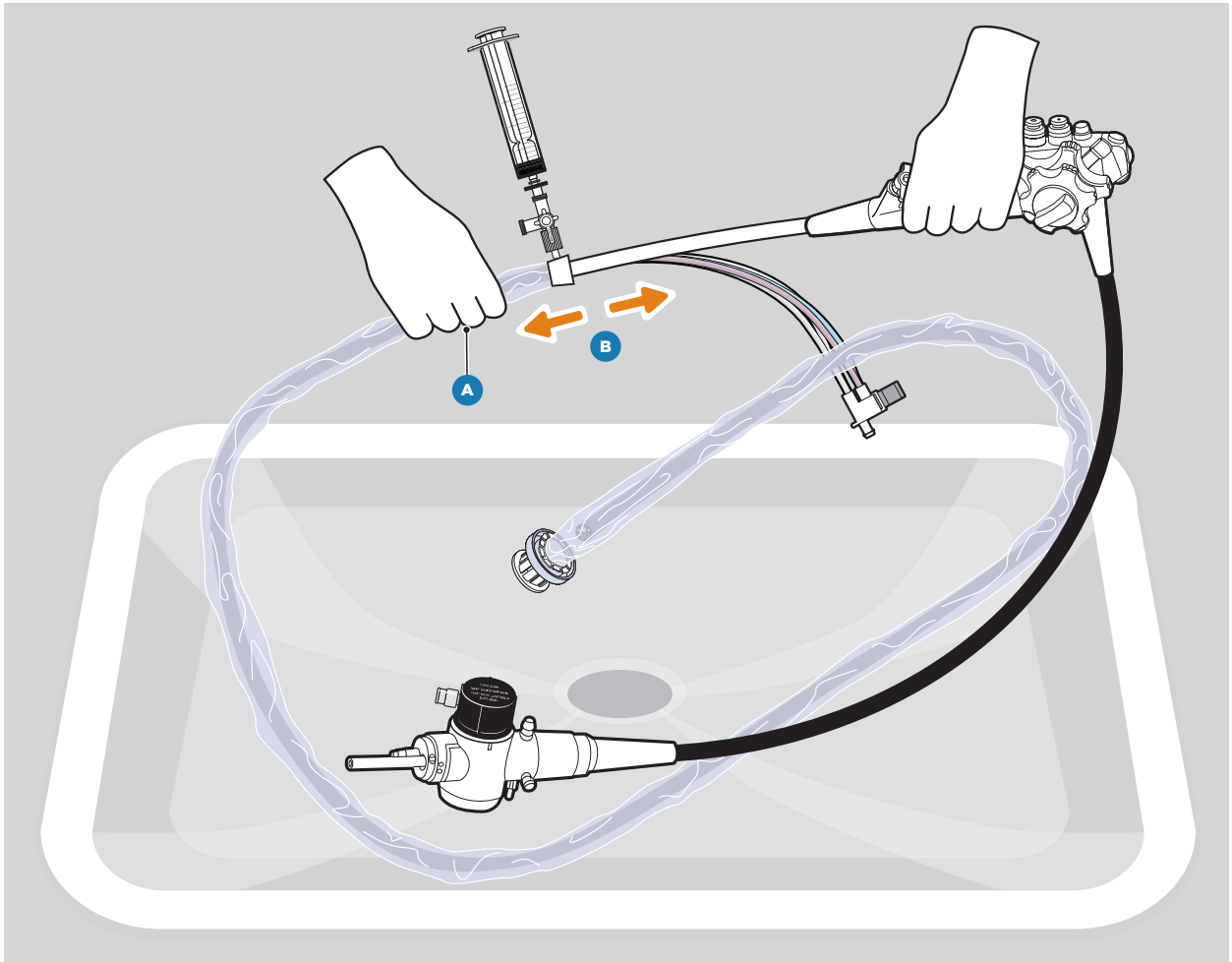


FIGURE 16: Proceed to separate the colonoscope by grasping the Oversleeve approximately 2" distal of the hub (A), pulling the Oversleeve and colonoscope away from each other (B). (Note: If at any point, you see the Oversleeve bunch up creating pinch points, simply grasp the Oversleeve on either side of the pinch point and pull apart from each other, then proceed to remove the Oversleeve by pulling the Oversleeve and colonoscope away.

Point the colonoscope tip and Oversleeve Inflation Hub downward just before the colonoscope exits the Oversleeve. Discard per facility protocol.

5.5. Discarding the Disposables

Following disassembly, discard the Pure-Vu Oversleeve, Umbilical section, irrigation bags, waste containers, 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, cords and loading fixtures 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
Incomplete loading of the Oversleeve	<p>If the Oversleeve inflates and the Loading fixture does not indicate two green lights:</p> <ul style="list-style-type: none"> • Verify the sealing plug is fully inserted into the Oversleeve distal tip. Refer to Figure 4 • Verify that all the valve and ports are properly installed/sealed and there are no air leaks. Refer to Figure 6 • Verify the sealing plug locking ring is in locked position. Refer to Figure 4 <p>If the scope does not reach the end of the Oversleeve, manually slide the Oversleeve to align the distal tip of the colonoscope. This procedure can be performed while the loading fixture is powered on.</p>
Incorrectly connecting the suction tubes to the waste containers	<ul style="list-style-type: none"> • Verify at least one port is open on each waste container (not the vacuum port) • Verify the suction tubing has been properly connected. Refer to Figure 10
Workstation does not power-up	<p>If you press the WS front panel Power On/Off button and power does not engage:</p> <ul style="list-style-type: none"> • Verify the fuse/power switch, located in the back of the workstation, is on. Refer to Figure 2 • Verify the power cord is fully inserted and secured to the back of the Workstation. Refer to Figure 2
Status light turns orange (Warning Indication)	<ul style="list-style-type: none"> • Verify liquid supply (e.g. Irrigation bag) is set up properly and not empty. If empty, replace irrigation bag and press Status button. Refer to Figure 9 • Verify the main connector is fully inserted and locked (indicated by an audible click). Refer to Figure 9 • Verify the pump heads are closed properly. Refer to Figure 9 • Verify the Foot Pedal is securely attached to the back of the Workstation. Refer to Figure 2 • Verify the pedals and buttons on the Foot Pedal are not depressed. Refer to Figure 3 <p>If status light is still orange, 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 13</p>
System test failure	<ul style="list-style-type: none"> • Verify Inline connector is fully inserted and locked (indicated by an audible click). Refer to Figure 11 • Verify that the irrigation line clamp is open • Check all tubes are patent • Ensure Oversleeve distal tip remains above the fluid level during the test. Refer to Figure 12 • After performing steps above, reboot system and repeat system test.
Foot Pedal is Not Responding	<ul style="list-style-type: none"> • Verify the Foot Pedal is securely attached to the back of the Workstation. Refer to Figure 2 • Verify that there is no object under any of the pedals of the Foot Pedal that prevents it from being depressed. Refer to Figure 3
No Irrigation	<ul style="list-style-type: none"> • Verify irrigation bag has liquid and set-up properly. Refer to Figure 9 • Verify irrigation tubing is properly loaded onto the pump head. Refer to Figure 9 • Verify the Foot Pedal is securely attached to the back of the Workstation. Refer to Figure 2 • Verify there is no torn/blocked/kinked tubing • Verify that the irrigation clamp is open. Refer to Figure 9
No Suction / Excessive Purging	<ul style="list-style-type: none"> • Verify the Foot Pedal is securely attached to the back of the Workstation. Refer to Figure 2 • Verify there is no torn/blocked/kinked evacuation tubing • Apply manual purge operation to remove any potential suction blockage. Refer to Section 5.2.11 • Make sure colonoscope advancement and/or torque application is not pinching tubing (because of manual gripping). Refer to Section 1 PRECAUTIONS • Verify that the Oversleeve suction ports are positioned below the fluid line to allow effective suctioning. Refer to Section 5.2.10 • Verify that the Oversleeve suction ports tip are not positioned against the colon wall. If so, direct the scope tip away from the wall
Difficulties during removal of Oversleeve	<ul style="list-style-type: none"> • Verify the sealing plug locking ring is in locked position. Refer to Figure 15 • Verify the sealing plug is fully inserted onto the Oversleeve distal tip. Refer to Figure 15 • Infuse additional detergent solution <p>If sealing plug has been inadvertently lost, use a Kelly clamp (Forceps) to clamp the Oversleeve distal to the colonoscope (do not clamp the colonoscope). If a leak in the Oversleeve is observed, contact a Motus GI representative.</p>
The Status Light is Orange	<p>Make sure that the system is set-up properly (check the pump heads are closed properly, all cables are attached securely, all tubing is attached properly and is kink-free)</p>

Internal sensor is outside optimal operating range. (System beeps twice and “Status” light blinks orange.)	<ul style="list-style-type: none"> • Verify system is outside optimal operating range by listening for audible indicators and confirming visual indicator. (System beeps twice and “Status” light blinks orange.) • Be aware that the auto-purge function may not be available while system is outside of optimal operating range. Manual purge should be used until system returns to optimal operating range. • Check tubing for obstructions or bending and mitigate as needed. • Verify system returns to optimal operating range by visually confirming “Status” light has returned to solid green. • No other action is required of the operator.
If irrigation is outside optimal operating range. (System beeps twice and “Status” light blinks orange and “Low” light blinks green.)	<ul style="list-style-type: none"> • Verify system is outside optimal operating range by listening for audible indicators and confirming visual indicators. (System beeps twice and “Status” light blinks orange and “Low” light blinks green.) • Check tubing for obstructions or bending and mitigate as needed. • Be aware that while the system is outside of optimal operating range system will automatically shift to or continue to run only in Low mode. Medium and High cleansing modes are deactivated until the system is restarted or drain operation is completed. • No other action is required of the operator.

*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 10° to 30° C
Humidity	10% to 80% (Non-condensing)
Altitude	Up to 81 Kpa

9.2. Shipping and Storage

Recommended Shipping and Storage Temperature

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

9.3. Performance Limitations

	MEDIA	MAX PRESSURE	FLOW
Cleansing	Air	1.55 Bar [23PSI]	Up to 1350 cc/min
	Water	3.5 Bar [52PSI]	Up to 645 cc/min
Pressure	Vacuum	Up to (-) 0.5 Bar	NA

9.4. Mechanical Properties and Sizes

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

	Workstation	Loading Fixture
Workstation Outer Dimensions	250mm x 476mm x 358mm [10in x 19in x 14in]	584mm x 267mm x 241mm [23in x 10.5in x 9.5in]
Workstation Weight	18kg (40lbs)	7.5kg (15.5lbs)
Power Supply	100 - 240 VAC / 50 - 60 Hz	100 - 240 VAC / 50 - 60 Hz

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