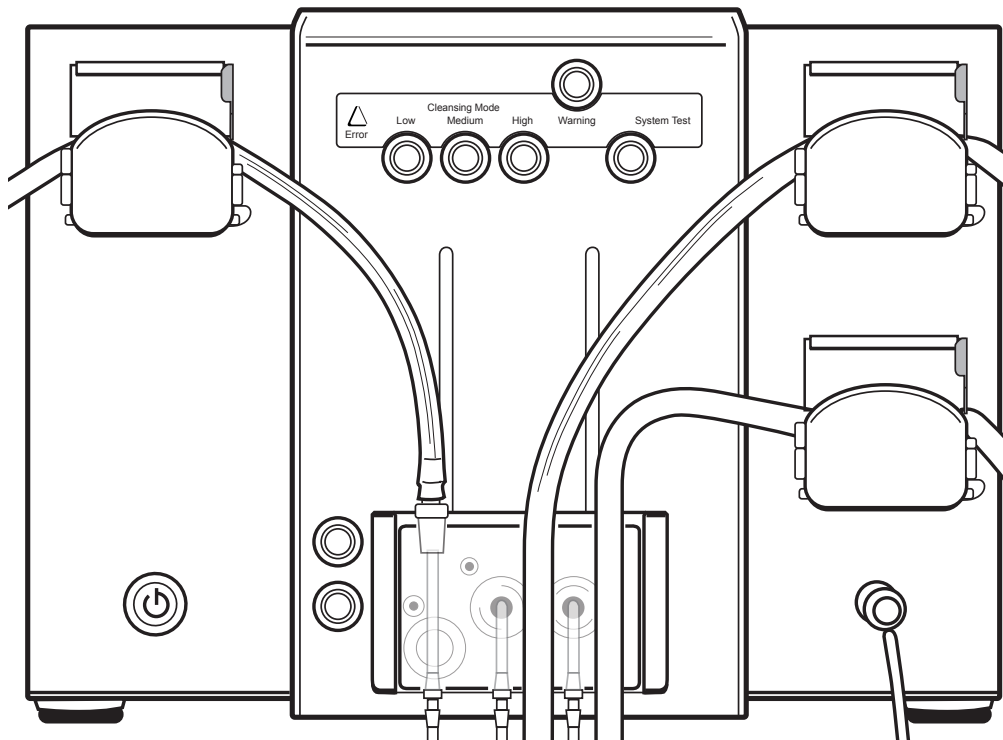


Motus Pure-Vu System Instructions For Use

IU00002 Rev. 7.0



**NAME/TRADE NAME OF
THE MEDICAL DEVICE:**

Motus Pure-Vu System

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Table Of Contents

1. WARNINGS AND PRECAUTIONS.....	3
1.1. Symbols Used.....	5
2. INTENDED USE.....	5
3. PRODUCT DESCRIPTION	6
3.1. System Workstation.....	7
3.1.1. Workstation Components:.....	8
3.1.2. Workstation Front Panel.....	8
3.1.3. The Foot Pedal	9
3.2. Pure-Vu Oversleeve	10
3.2.1. The Oversleeve	10
3.3. Accessories for Use with Pure-Vu	10
4. SETUP AND INTERCONNECTIONS.....	10
4.1. Unpacking the Oversleeve Package.....	10
4.2. Assembly of the Oversleeve on the Workstation.....	11
4.2.1. Cleaning the Loading Fixture	11
4.2.2. Oversleeve Assembly	11
4.2.3. Attaching the Oversleeve to the Workstation.....	14
5. SYSTEM OPERATION	16
5.1. Pre-procedure Operations	16
5.2. Operating the Pure-Vu Workstation	16
5.3. Disassembling the WS Connector and Oversleeve	17
5.4. Removing the Oversleeve from the Colonoscope.....	18
5.5. Discarding the Oversleeve and WS Connector.....	20
6. CLEANING UNLOADING FIXTURE	20
7. CLEANSING WORKSTATION AND FOOT PEDAL	20
8. STORAGE AND TRANSPORTATION.....	20
9. TROUBLESHOOTING	21
10. TECHNICAL SPECIFICATIONS	22
10.1. Environmental Standards.....	22
10.2. Shipping and Storage Standards.....	22
10.3. Performance Limitations	22
10.4. Mechanical Properties and Sizes	22

1. WARNINGS AND PRECAUTIONS

Please read this manual and follow its instructions carefully.

Warnings:

- FDA (USA) law restricts this device to sale by or on order of a physician.
- The Pure-Vu system should 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 should 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 is to be used only by trained medical personnel.
- The Pure-Vu Oversleeve and WS Connector are provided clean and intended for single patient use. Do not sterilize, clean or re-use the Oversleeve or WS Connector. Discard both devices properly after use.
- Confirm that the other devices used with the Pure-Vu System function properly and that these other devices will not adversely affect the operation or safety of this equipment. 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 must 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 should 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 should never be installed, used or transported in an inclined position nor should it be subjected to impact.
- A minimum of 2 people are required to transport the Pure-Vu workstation.
- The Pure-Vu workstation should be maintained in a clean condition during storage and be ready for subsequent use.
- Electrical safety checks shall be performed annually (or as required by institutional procedures). The check must be performed only by MOTUS GI authorized technical personnel.
- The Oversleeve, WS Connector, Loading and Unloading fixtures, as well as the Workstation (WS), are intended to be used only with MOTUS Pure-Vu System and its accessories.
- Avoid using the cleansing mode on the same area of tissue for an extended period of time.
- A new, single use waste receptacle should be used for each patient.
- A new, single use irrigation bag (IB) must be used for each patient.

Precautions:

- Use only new irrigation bag (IB).
- Advance cautiously when performing anal retroflex or/and entering the ileocecal valve.
- For optimal operation of the system, refrain from using the colonoscope suction and insufflation when the Pure-Vu System is activated.
- Care should 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 at the rear of the WS. For a definition of individual symbols, see table below:

	FDA (USA) law restricts this device to sale by or on order of a physician
	Product non-sterilized
	Do not use if package is damaged
	Caution! Consult accompanying documents for safety instructions
	Do not re-use
	Batch code (adjacent to the lot symbol)
	Date of manufacture
	Consult Instructions For Use, symbols are meant to support, not replace, operating instructions
	Must not be treated as unsorted municipal waste
	Type BF equipment
	CE Representative
	CE compliance symbol

2. INTENDED USE

The Pure-Vu System is intended to connect to standard 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, clinics and doctor offices.

3. PRODUCT DESCRIPTION

The Pure-Vu System enables colon cleansing during standard colonoscopy using a standard colonoscope with a length of 1630mm – 1710mm and a diameter between 12.8mm – 13.7mm. The Oversleeve, which fits over the colonoscope and is connected to an external workstation, generates fluid jets to breakup the feces. The fecal matter & fluids are removed through the evacuation channels of the Oversleeve into an external waste receptacle.

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

- The Oversleeve [O] is a disposable device that slips over the colonoscope and is connected to the external workstation, using the WS Connector [WSC].
- The Workstation [WS] is reusable and supplies irrigation mixture of saline and gas, and evacuates fecal material & fluids.
- WS Connector [WSC] is disposable and serves as an interface between the Oversleeve and the Workstation.
- The loading fixture is reusable and aids in assembling the Oversleeve onto the colonoscope.
- The unloading fixture is reusable and aids in disassembling the Oversleeve from the colonoscope.

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

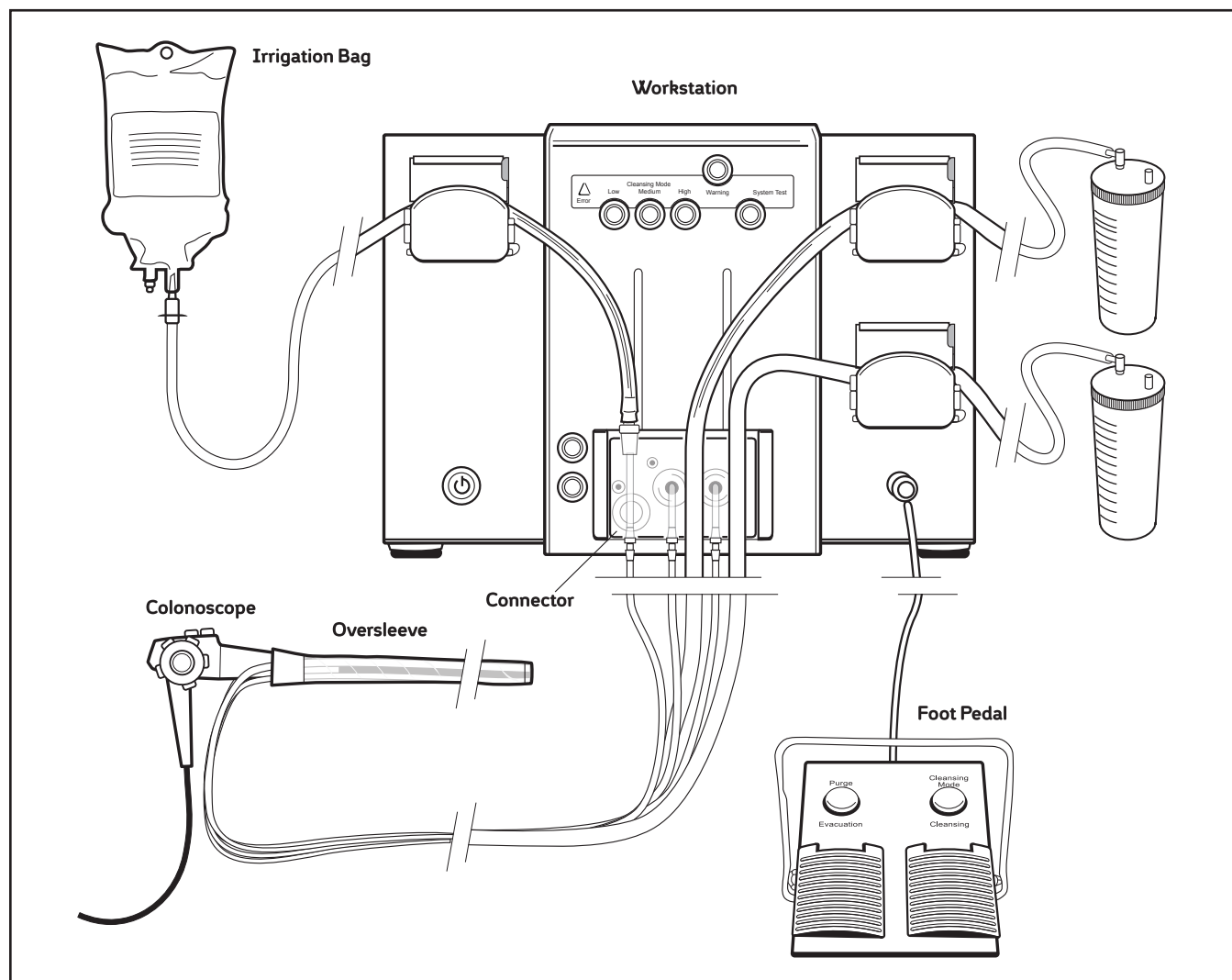


FIGURE 1: Pure-Vu Workstation – General Design & Components

3.1. System Workstation

The workstation is intended to provide irrigating water or saline & gas, and to drain fecal matter & fluids out of the body during the colonoscopy procedure.



FIGURE 2: Workstation

- | | |
|----------------------------------|-------------------------------------|
| 1 [IT] ___ Irrigation Tube | 10 [ET1] ___ Evacuation Tube 1 |
| 2 [IP] ___ Irrigation Pump | 11 [EP2] ___ Evacuation Pump 2 |
| 3 [EL] ___ Error Light | 12 [PW] ___ Power |
| 4 [LM] ___ Cleansing Mode (LOW) | 13 [CLU] ___ Lock and Unlock |
| 5 [MM] ___ Cleansing Mode (MED) | 14 [D] ___ Drain |
| 6 [HM] ___ Cleansing Mode (HIGH) | 15 [WSC] ___ Work Station Connector |
| 7 [WL] ___ Warning Light | 16 [ET2] ___ Evacuation Tube 2 |
| 8 [ST] ___ System Test | 17 [PC] ___ Foot Pedal Connector |
| 9 [EP1] ___ Evacuation Pump 1 | |

3.1.1. Workstation Components:

The workstation [WS] includes the following components:

- Monitoring & Control Unit that controls the delivery of irrigation fluids and gas into the colon, and evacuation of fluids and feces out of the colon.
- External receptacle containing irrigation liquid (saline or water) which is connected to the irrigation line (please note this is a consumable not supplied by MOTUS GI).
- External waste receptacle for collecting the fecal material & fluids that are evacuated out of the colon through the evacuation line (please note this is a consumable not supplied by MOTUS GI).
- External foot pedals that activate the cleansing, evacuation and purging functions, and switch between cleansing modes used by the physician.

3.1.2. The Workstation Front Panel:

The WS contains the following main components: On/Off power button [PW] that turns on and off the power. Irrigation pump (IP) that pumps room temperature saline (not shown in this figure) and gas into the Pure-Vu Oversleeve (not shown in this figure) via the irrigation tubing [IT]. The fecal material & fluids are removed from the colon, using the evacuation pumps [EP1, EP2] via the evacuation tubing [ET1, ET2], into the waste receptacle (not shown in this figure). The WS Connector [WSC] connects the Oversleeve to the Workstation. The WS Connector slides into place in the front of the workstation and has a lock/unlock button [CLU] to lock and unlock connector and a drain button [D] to drain the Oversleeve and WSC lines. The cleansing/evacuation mode is controlled by the foot pedal (not shown in this figure) which connects to the pedal connector [PC]. The Pure-Vu System undergoes a system test when the System Test button [ST] is activated. The system test ensures the Pure-Vu System is functioning properly prior to procedure commencement. The system can be operated in three cleansing modes; low, medium (default mode) and high. The mode selection is activated by using the cleansing mode selector button [CMS] on the foot pedal. The selected mode is indicated by the cleansing mode lights [LM, MM, HM] on the WS. The warning indication light [WL] will indicate an assembly related issue or when a system malfunction occurs. This warning indication is both visual and audible. For warning indication instructions see troubleshooting section. The error light (EL) will indicate when a non-recoverable error occurs.

3.1.3. The Foot Pedal Unit

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

- Cleansing – simultaneous irrigation and evacuation, activated by the right foot pedal [CP].
- Evacuation only mode – activated by the left pedal [EP].
- Manual Purge – activated by the left button [MP].
- Cleansing Mode Selector – activated by the right button [CMS]. User can switch between three cleansing modes; low, medium (default mode) and high.

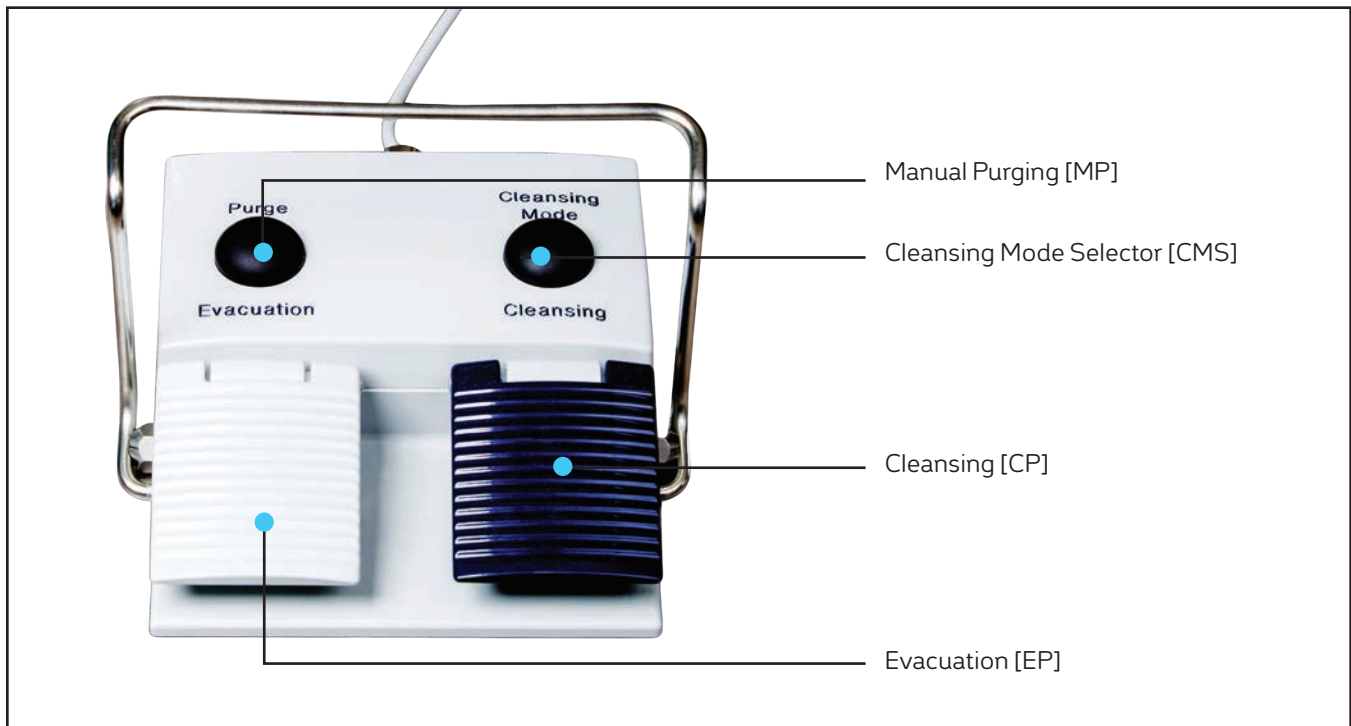


FIGURE 3: Pure-Vu Foot Pedal Unit

3.2. Pure-Vu Oversleeve

3.2.1. The Oversleeve

The Pure-Vu Oversleeve is a single use disposable, which fits over a standard colonoscope. Once attached to the colonoscope the maximum outer diameter is 21 mm. The device consists of multiple irrigation and evacuation conduits as well as channels for the sensing capabilities of the system. The Oversleeve has an outer sleeve to provide a smooth surface while inside the colon and an inner sleeve to provide the proper connection to the colonoscope. At the proximal end of the Oversleeve is the insertion port for the colonoscope, which also includes an inflation connector that is attached to an air compressor. The insertion port is loaded into the loading fixture which aids insertion of the colonoscope into the Oversleeve. Proximal to the insertion port are all of the Oversleeve's conduits which branch off and attach to the WS Connector [WSC]. The WS Connector [WSC] connects the Pure-Vu Oversleeve to the Workstation.

3.3 Accessories for Use with Pure-Vu

The following waste receptacle accessories should be used 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
Cardinal Health	65652-586	30 in. roll stand. 30 in. from floor to canister top. 4 side mounting locations for canister placements
Cardinal Health	65652-500	20 in. roll stand. 20 in. from floor to canister top. 4 side mounting locations for canister placements)
Cardinal Health	65652-570	Single canister roll stand. Mounted on four casters for stability and mobility

4. SETUP AND INTERCONNECTIONS

4.1. Unpacking the Oversleeve Package

Prior to unpacking the Oversleeve unit, verify that the packaging is not compromised. If the packaging is open or damaged, do not use the Oversleeve. During set-up ensure that no packaging material remains on the device and that the device does not touch the floor or other undesired surfaces.

4.2. Assembly of the Oversleeve on the Workstation

4.2.1. Cleaning the Loading Fixture

The loading fixture including the compressor and associated tubing should be cleaned prior to attaching the Pure-Vu Oversleeve to the colonoscope by thoroughly wiping down the device with a viricidal cloth (Opti-cide, Cavicide or similar surface disinfectant of choice) that has an active ingredient of isopropanol alcohol (17% - 21%).

4.2.2. Oversleeve Assembly

To load the Oversleeve onto the colonoscope complete the following steps:

Place the loading fixture on a flat surface and pull up on black levers to lock the suction cups in place. Open loading fixture channel, rack and colonoscope handle holders. Hang the umbilical tubing on the rack and open inflation hub clamp, distal channel cover and distal end clamp.

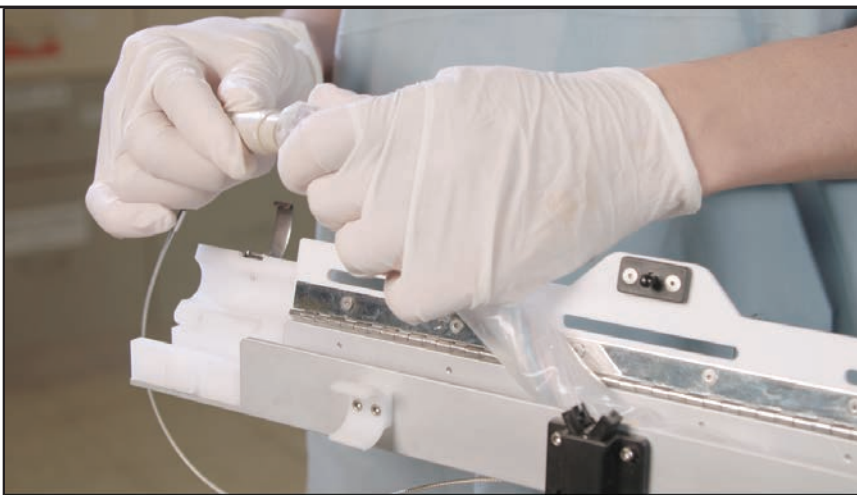


Place the Oversleeve into the loading fixture channel with the Oversleeve's inflation hub luer connector facing up. Close and lock the inflation clamp.

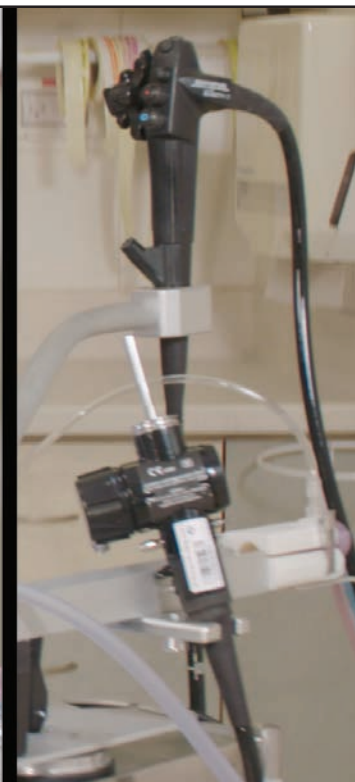


4.2.2. Oversleeve Assembly (cont...)

Prepare the distal sealing plug by first wetting it with water and then insert it into the distal end of Oversleeve. Place distal end of Oversleeve with sealing plug into the clamp making sure the evacuation ports are facing down and the interface between flexible distal head and the sealing plug is aligned directly with the outer clamp. Close and lock the clamp. Close the distal channel cover.



Connect the control box air-line tubing to the inflation hub and turn ON the inflation control box power. Then place the colonoscope connector and control section on loading fixture as shown and ensure all of the colonoscope caps are in place and secure.



4.2.2. Oversleeve Assembly (cont...)

Prepare colonoscope by wetting its distal end with water and then insert the colonoscope tip into the proximal end of the inflation hub; wait 2 seconds until the bottom green LED light illuminates.



Begin to gently push the colonoscope into the Pure-Vu Oversleeve. Continue inserting the colonoscope until it reaches the distal end and will not advance with a gentle push. Place the colonoscope steering handle onto the scope support bracket.



4.2.2. Oversleeve Assembly (cont...)

Turn OFF the inflation control box power and disconnect the air-line from the inflation hub. Unlock the inflation and sealing clamps and distal channel cover and then remove the sealing plug and inspect the distal end of the Pure-Vu/colonoscope interface, making sure the colonoscope is flush with the upper lip of the Pure-Vu Oversleeve as shown. Remove the Pure-Vu Oversleeve with colonoscope and umbilical tubing from the loading fixture. The Pure-Vu Oversleeve and colonoscope are now ready for assembly to the Pure-Vu workstation controller and colonoscope light source and video processor.



4.2.3. Attaching the Oversleeve to the Workstation

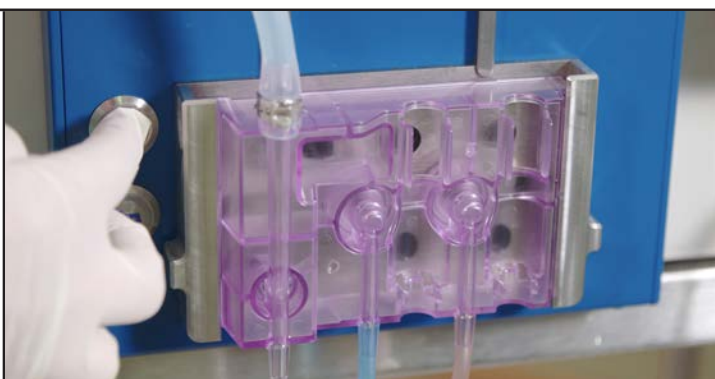
Connect the colonoscope to the light source and video processor according to manufacturer's recommended procedure.



Turn on the workstation by pressing the power button.

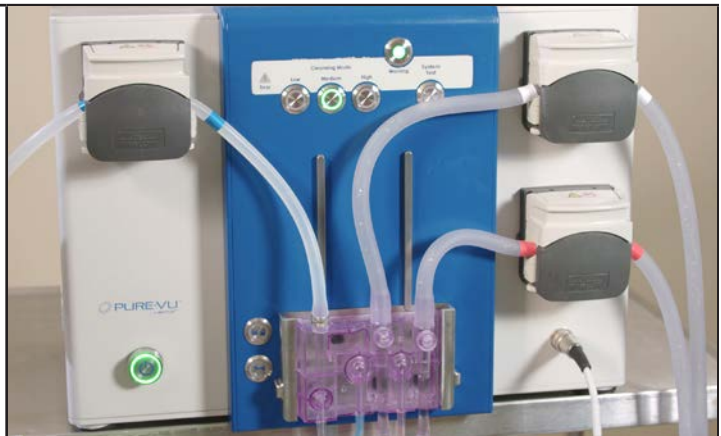


Place the workstation connector on front of the workstation and slide down into place. Push the workstation connector lock button.



4.2.3. Attaching the Oversleeve to the Workstation (cont...)

Open all three pump heads then place the irrigation tubing into the pump between marked blue lines as shown. Place evacuation tubing with white markings on top pump and evacuation tubing with red markings on lower pump. Close pump heads. Snap evacuation funnels into connector.



Connect the luer fittings on the umbilical tubing to the luer fittings on the workstation connector by matching the corresponding colors (Clear, Blue and Red).



Connect the irrigation tubing to the irrigation bag. Then connect evacuation tubes to the waste receptacles.



Point the tip of the colonoscope and Pure-Vu Oversleeve toward a container and press the system test button for 2 seconds to verify irrigation. The Pure-Vu system is now ready to use.



5. SYSTEM OPERATION

5.1. Pre-procedure Operations

1. Use a new, single use irrigation bag (IB) and a new, single use waste receptacle.
2. Confirm that the irrigation bag (IB) is filled with at least 3 liters of room temperature saline or water.
3. Confirm that the waste receptacle and IB are replaced at the same time at the beginning of the procedure, in order to avoid waste overflow.
4. Verify that the device is assembled correctly.
5. Check and confirm that all cords or cables are connected correctly and securely.

5.2. Operating the Pure-Vu Workstation

1. Turn on the Pure-Vu Workstation power button [PW].
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).
4. Check the Pure-Vu System visually and functionally:
 - a. Place the tip of the colonoscope in a container that can receive irrigation jet for approximately 2 seconds.
 - b. Press the System Test button [ST] and verify irrigation.
5. In case of an unrecoverable failure, take WSC out, turn the system off [PW], disconnect and discard the Oversleeve. Assemble new Pure-Vu Oversleeve and repeat steps outlined in sections 4 & 5.
6. After determining the Pure-Vu System is ready for use apply a water based gel (as used in standard colonoscopy procedures) to distal 30cm of the Oversleeve.
7. Place and prepare the patient for the procedure as per standard colonoscopy procedures. It is recommended an absorbing pad be placed around/underneath the patient.
8. Begin to perform the colonoscopy as per facility guidelines. Use Pure-Vu System when cleansing is required as per physician discretion.
9. Once the tip of the colonoscope is inserted, the Pure-Vu System can be operated as needed.
10. Activate the cleansing mode step by pressing on the right foot pedal. The cleansing mode selector switch is located on the foot button. The default cleansing mode is medium (denoted by Medium mode light), if a higher cleansing level is needed, press the foot button switch to the high mode (denoted by High mode light and an audible signal). If a lower cleansing level is needed depress the foot button switch to the low cleansing mode (denoted by Low mode light). The switching between the modes is performed in a cyclic manner – Medium – High – Low - Medium.

11. If only evacuation is desired, press the left foot pedal to activate the evacuation function.
12. If the evacuation channels are blocked the purging pedal button can be pushed.
13. Upon completion of the colonoscopy remove the colonoscope, remove the WS Connector and the Oversleeve from the workstation (section 5.3), remove the Oversleeve from the colonoscope (section 5.4) and discard Oversleeve and WS Connector per facility protocol (Sections 5.5).

5.3. Disassembling the WS Connector and Oversleeve

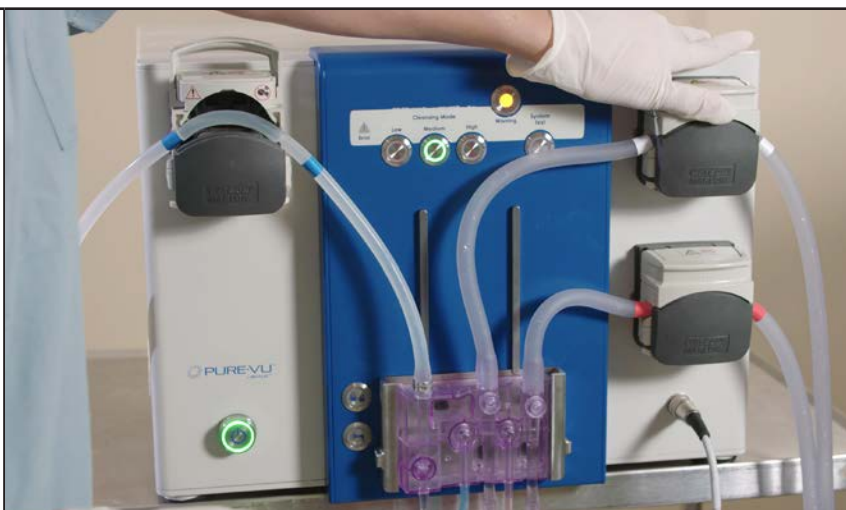
After the colonoscopy procedure, disconnect the irrigation bag then purge the evacuation lines by pressing the drainage button for 2 seconds and pointing the distal end of the colonoscope into a small container. Wait 8 seconds until the drainage stops.



Cut the umbilical tubing approximately 15cm from the proximal end of the Oversleeve.



Open workstation pumps and remove all tubing then discard the workstation connector and umbilical tubing as per facility protocol.



5.4. Removing the Oversleeve from the Colonoscope

Attach luer syringe with 50 cc of a 2% soapy water solution to the inflation hub and flush device; ensure solution exits distal end of device. If it doesn't exit distal end prepare another syringe and repeat. Remove syringe.



Unlock and open unloading fixture clamp. Insert the distal end of the Oversleeve through the tube past the sealing clamp.



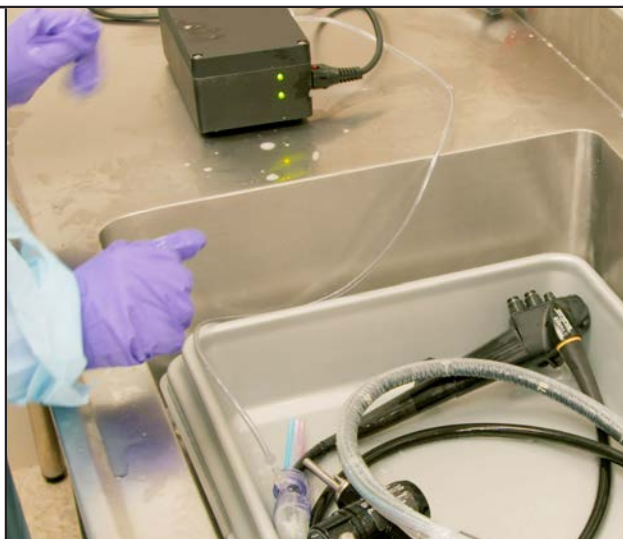
Insert plug into distal end of Oversleeve then place the Oversleeve with attached plug onto the unloading fixture clamp making sure the evacuation holes are next to clamp's flat surface and the section of flexible head that sits over plug is aligned with the outer clamp. Close and lock fixture clamp.



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

Attach the disposable air-line to the luer fittings on the control box and inflation hub (disposable air-line tubing can be found in the Oversleeve packaging tray).

Turn control box ON and wait a few seconds for the bottom GREEN LED light to illuminate.



Place one hand on inflation hub while placing other hand on the colonoscope and begin pulling colonoscope out of the Oversleeve. Prior to removing the last 10cm of the colonoscope, point the proximal end of inflation hub downward toward sink or bin to avoid spray of soapy water as colonoscope exits Oversleeve.



Once colonoscope is removed, turn OFF control box, remove air-line tubing, open unloading fixture clamp, and remove plug from Pure-Vu Oversleeve. Discard Pure-Vu Oversleeve and air-line tubing per facility protocol.

5.5. Discarding the Oversleeve and WS Connector

Following disassembling, discard the Pure-Vu Oversleeve, WS Connector, Irrigation Bags and Waste receptacles according to facility protocol.

6. CLEANING UNLOADING FIXTURE

The unloading fixture should be thoroughly cleaned using a 3 step process:

1. First remove any residual bioburden by wiping unloading fixture with a viricidal cloth (Opti-cide, Cavicide or similar surface disinfectant of choice) that has an active ingredient of isopropanol alcohol (17% - 21%).
2. Manually wash unloading fixture using soap and water or commercially available disinfectant.
3. Disinfect unloading fixture with a high level disinfectant such as peracetic acid, ortho-phthalaldehyde or glutaraldehyde by immersion in a FDA cleared automated endoscope reprocessor. All surfaces of the unloading fixture should be in contact for a specified period of time and at a temperature recommended by the disinfectant manufacturer.

7. 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 isopropanol alcohol (17% - 21%).

8. 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 accessories should be neatly stored and maintained in a clean condition during storage. This equipment should never be stored in areas exposed to high temperature, humidity, direct sunlight, dust, salt, which could adversely affect the equipment. This equipment should never be installed or used in the presence of flammable or explosive gases or chemicals. The Pure-Vu workstation and Oversleeve should never be installed, used or transported in an inclined position nor should it be subjected to impact or vibrations.

9. TROUBLESHOOTING

TROUBLESHOOTING*	ACTION
Warning Indication	<ul style="list-style-type: none"> • Verify liquid supply (e.g. Irrigation bag) is set up properly • Verify WS Connector position and in locked mode • Verify the pump heads are closed properly • Verify the foot pedal(s) are not in depressed state • If warning is still On restart workstation • If the above does not remedy the warning indication, contact Motus GI representative
Foot Pedal is Not Responding	<ul style="list-style-type: none"> • Verify foot pedal is connected properly to workstation
No Irrigation	<ul style="list-style-type: none"> • Verify irrigation bag has liquid and set up properly • Verify irrigation tubing is properly loaded onto the pump • Verify foot pedal is connected properly to workstation • Verify there is no loose irrigation tubing or connections • Verify there is no torn/blocked/kinked tubing • If all of the above is verified, remove the colonoscope from the colon, remove the Oversleeve and WS Connector and insert new Oversleeve, attach to new WS Connector and then restart the system.
No Evacuation / Excessive Purging	<ul style="list-style-type: none"> • Verify foot pedal is connected properly to workstation • Verify waste reservoir (e.g. bag) is not full • Verify there is no loose evacuation tubing or connections • Verify there is no torn/blocked/kinked evacuation tubing • Apply manual purge operation to open potential evacuation blockage • Make sure colonoscope advancement and/or torque application is not pinching tubing (as a result of manual grip). You may try to reposition the Oversleeve and colonoscope. • If all of the above is verified, remove the colonoscope from the colon and re-operate the system (see section "Operating the Pure-Vu workstation")
Turbulence Interfering with Colon Visualization	<ul style="list-style-type: none"> • Suction excessive water using the evacuation channels or use standard colonoscope suction

10. TECHNICAL SPECIFICATIONS

10.1. 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

10.2. Shipping and Storage Standards

Recommended Shipping and Storage Temperature

SPECIFICATIONS	
Shipping and Storage	14° to 140° F
Temperature	-10° to 60° C

10.3. Performance Limitations

	MEDIA	MAX PRESSURE	FLOW
Cleansing	Air	1.6 Bar [23PSI]	Up to 1300cc/min
	Water	3.5 Bar [52 PSI]	Up to 600cc/min
Pressure	Vacuum	Up to (-) 0.5 Bar	NA

*Note: These are the performance characteristics of the system's pumps.

10.4. Mechanical Properties and Sizes

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

Workstation Outer Dimensions	W460 \ D480 (520 with pump head) \ H340 mm
Workstation Weight	25kg
Power Supply	100 - 240 VAC / 50 - 60 Hz

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