ADDITIONAL INSTRUCTIONS FOR CVAC ASPIRATION SYSTEM

NOTE: Failure to follow these additional instructions can lead to elevated intrarenal pressure, which may result in patient injury or death.

WARNING: Do not continue to provide fluid inflow in the presence of unresolved slow or absent fluid outflow. Doing so can create an intrarenal pressure imbalance, which may result in serious injury or death.

REMINDER: Contraindications for the CVAC Aspiration System and CVAC Image Processor are the same as those specific to ureteroscopy. Diagnostic or therapeutic ureteroscopy is contraindicated in patients with untreated urinary tract infection. Patients with coagulation disorders, severe cardiopulmonary insufficiency or uncontrolled diabetes should be managed appropriately.

Additional Instructions

1. The CVAC Aspiration System is compatible with 12/14 Fr and larger Ureteral Access Sheaths. When used with a 12/14 Fr sheath, outflow occurs via the 7 Fr vacuum channel of the CVAC Aspiration System; limited outflow is provided through the sheath. Use caution to maintain outflow through the CVAC Aspiration System to avoid over-pressurization of the kidney. If drainage through the access sheath is desired, use a 13/15 Fr or larger Ureteral Access Sheath.
2. Use the following procedure (i) to confirm your equipment is set up properly for use with the CVAC Aspiration System, and (ii) when low outflow is suspected and proper outflow needs to be confirmed.
   a. Fill a sterile bowl with 50ml of sterile saline or sterile water
   b. Confirm that the irrigation and vacuum tubing are connected to the CVAC Aspiration System and that the irrigation and vacuum sources are set to 150 - 200 mmHg.
   c. Place the tip of the CVAC Aspiration System in the 50ml of fluid and pull the trigger fully. To confirm that the aspiration function is properly set-up, verify that the stone collector fills with fluid and the bowl is emptied in 8-15 seconds.
3. If a patient has cloudy, turbid, or suspected high-viscosity fluid observed in the kidney's collecting system, stop irrigation immediately using the three-way stopcock. If visibility within the collecting system is completely obscured by opaque fluid, do not use the CVAC Aspiration System in the procedure. If visibility is sufficient to proceed, follow the evacuation procedure below to clear the fluid in the kidney:
   a. Confirm that the three-way stopcock is in the OFF position. There should be no irrigant inflow.
   b. If the Laser Bridge is present in the vacuum lumen, remove it to allow for a higher outflow. Then, attach the working channel cap.
   c. Pull the trigger fully to activate aspiration and evacuate fluid from the collecting system. There will be no irrigant inflow since the stopcock is in the OFF position. The outflow rate may be slow if the fluid is highly viscous.
   d. Release the trigger fully and turn ON the stopcock to allow passive irrigation to slowly refill the collecting system.
   e. Repeat steps a-d until clear, free-flowing fluid is observed throughout the collecting system, CVAC Aspiration System and vacuum tubing.
4. If there is a suspected slowing or lack of fluid outflow from the CVAC Aspiration System, stop irrigation inflow using the three-way stopcock and proceed to diagnose per the Instructions for Use (IFU; item 3 above and section 11.3 in the IFU).

   Please contact your local Calyxo representative or Calyxo Customer Service at **qualitycontrol@calyxoinc.com or call 833-214-3354** for more information and training.

CVAC®

Aspiration System

Single-Use Steerable Ureteral Catheter with Ureteroscopy
Only to be used with the CVAC® Image Processor

Calyxo

Table of Contents

Foreword

This User Manual contains the recommended procedures for preparing and using the CVAC Aspiration System Single-Use Steerable Ureteral Catheter with Ureteroscopy. It is intended for physicians and other healthcare professionals who will use this device and contains pertinent information on the handling of the device. Please read and become familiar with this entire manual before using the CVAC Aspiration System and CVAC Image Processor. Failure to understand and follow all instructions, cautions and warnings provided in this User Manual may result in damage to the device and/or injury to the patient or user. For any product or equipment being used in conjunction with the CVAC Aspiration System and CVAC Image Processor, follow provided product or equipment User Manual instructions to avoid any possible hazards due to device incompatibility..

NOTE: Definitions of **WARNING, CAUTION,** and **NOTE** are as follows:

1. **WARNING:** Alerts to possible personal injury, death or other serious adverse reactions associated with the use or misuse of the system.
2. **CAUTION:** Alerts to potential system problems when being misused, such as system malfunction, system failure, damage to the system or to other properties.
3. **NOTE:** Highlights important information on the use of the system.

CAUTION: Rx Only. Federal Law (USA) restricts this device to sale by or on the order of a licensed physician.

NOTE: This User Manual is available as an electronic document. If you would like a hard copy of the document, please contact your local distributor or the Calyxo, Inc. customer service department.

1. INTENDED USE / INDICATIONS FOR USE

The CVAC® Aspiration System and CVAC® Image Processor consists of a sterile single use, steerable ureteral catheter and a reusable software-controlled image processor. It is intended to establish a conduit during endoscopic urological procedures for the treatment and removal of urinary stones (e.g. kidney stones, fragments, and dust). It employs flexible ureteroscopy within the urinary tract for endoscopic examination of the urinary tract and the interior of the kidney.

The steerable ureteral catheter is used for irrigation and aspiration of kidney stones and stone dust with dedicated irrigation and vacuum channels under ureteroscopy. The CVAC Aspiration System and CVAC Image Processor can be used with additional accessories to perform various diagnostic and therapeutic procedures.

2. CONTRAINDICATIONS

Contraindications for the CVAC Aspiration System and CVAC Image Processor are the same as those specific to ureteroscopy.

Diagnostic or therapeutic ureteroscopy is contraindicated in patients with untreated urinary tract infection. Patients with coagulation disorders, severe cardiopulmonary insufficiency or uncontrolled diabetes should be managed appropriately.

3. POTENTIAL ADVERSE EVENTS

Possible complications include, but may not be limited to:

- Perforation, puncture, bleeding, and/or hematuria
- Damage to ureter or kidney
- Discomfort, pain, inflammation, infection, and/or fever
- Ureteral avulsion

4. WARNINGS

- The CVAC Aspiration System is designed for single use only. Do not reuse, reprocess, or re-sterilize the device. Reuse, reprocessing, or re-sterilization may compromise the structural integrity of the device and/or lead to device failure, which in turn, may result in patient injury or illness. Reuse, reprocessing, or re-sterilization also create risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury or illness of the patient.
- The CVAC Aspiration System is a single-use device and there are no serviceable parts. DO NOT repair a damaged or non-operating CVAC Aspiration System. DO NOT use the CVAC Aspiration System if damage is discovered or suspected.
- If damage to the CVAC Aspiration System occurs or it stops functioning during a procedure, stop using the device immediately. See troubleshooting section for more information. Continue the procedure with a new device, as appropriate.
- Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged.
- Do not use if the package is open or damaged. DO NOT use if labeling is incomplete or illegible.
- Do not use a damaged or expired CVAC Aspiration System.
- Always wear appropriate protective equipment when using the CVAC Aspiration System, such as gowns, gloves, surgical masks, and goggles.
- Failure to perform inspection and operational checks may result in patient injury and/or damage to the device and accessories.
- DO NOT look directly into the light emitted from the CVAC Aspiration System.
- Do not use electromedical energy sources in the presence of flammable detergents, anesthetics, nitrous oxide (N2O), or oxygen.
- Advance into kidney with imaging (direct endoscopic visualization and/or fluoroscopic guidance) using standard ureteroscopic technique to avoid patient injury such as perforation, avulsion, hemorrhage, or urothelial damage.
- If resistance is felt during advancement or withdrawal of the CVAC Aspiration System, investigate the source of resistance and take remedial action (e.g., turn vacuum off, change the catheter actuation direction, remove the CVAC Aspiration System, use built in ureteroscope or fluoroscopy to identify the cause of the resistance).
- Do not use excessive force when advancing or withdrawing an accessory within the CVAC Aspiration System. Doing so can cause patient injury such as perforation, avulsion, hemorrhage, urothelial damage, or damage to the CVAC Aspiration System.
- If there is a slowing or lack of fluid outflow in the vacuum tubing, stop active irrigation, stop the procedure, and remove the straightened CVAC Aspiration System from the patient to check for clogging of the vacuum lumen.
- Test all accessory devices for fit and compatibility with the CVAC Aspiration System prior to inserting the CVAC Aspiration System in a patient.
- When inserting or using accessories, ensure the distal tip is in a straight configuration and maintain continuous visualization of the distal tip. Ensure that there is sufficient space beyond the distal tip of the CVAC Aspiration System to accommodate the tip of the accessory device. Failure to do so may result in the accessories causing patient injury.
- Do not use excessive force when removing stone fragments through the working channel, doing so may cause damage to the device or injury to the patient.
- If any accessory device becomes trapped inside the CVAC Aspiration System, straighten the CVAC Aspiration System tip and remove it together with the accessory device from the patient.

- Laser fiber under 660µm outer diameter should be used with the provided Laser Bridge. Do not use excessive force when inserting a laser fiber into the Laser Bridge. Use a smaller diameter fiber if necessary.
- Do not activate a laser with a laser fiber tip within the lumen of the CVAC Aspiration System. Doing so may cause patient injury and/or damage to the CVAC Aspiration System.
- Bring the CVAC Aspiration System to its straight, neutral position before withdrawing the catheter tip from the kidney. Removing the CVAC Aspiration System with the catheter tip deflected may damage the device and render it unusable, or cause injury to the patient. If the steering lever cannot be used to straighten the catheter tip, follow the "Loss of Steering Control" instructions in the Troubleshooting section.
- The CVAC Aspiration System is single-use only. After use, dispose of the product and packaging in accordance with hospital procedures and local laws.
- Use of the CVAC Image Processor adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the CVAC Image Processor and the other equipment should be observed to verify that they are operating normally.
- The emissions characteristics of the CVAC Image Processor make it suitable for use in industrial areas and hospitals only (CISPR 11 class A).
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the CVAC Image Processor, including cables specified by Calyxo. Otherwise, degradation of the performance of the CVAC Image Processor could result.

5. CAUTIONS

- Failure to thoroughly understand and follow all instructions, cautions and warnings provided in this CVAC Aspiration System User Manual may result in injury to the patient or user and may result in damage to or malfunction of this equipment. Follow all instructions, cautions and warnings provided with all products and equipment to be used in conjunction with the CVAC Aspiration System to avoid any possible hazards due to device incompatibility.
- The CVAC Aspiration System can only be used in conjunction with the CVAC Image Processor. Connection to other 3rd party devices may cause device damage or operator injury.
- Use the CVAC Aspiration System with caution on patients who have undergone previous urinary tract reconstructive surgery or with known strictures. These conditions may prevent passage of the flexible catheter shaft.
- Do not insert a wet, contaminated, or damaged video cable into the CVAC Image Processor as poor video performance or damage to the system may result.
- Do not articulate the catheter tip inside a ureteral access sheath.
- Use caution and monitor the vacuum tubing for outflow when using active irrigation. If no fluid outflow is observed, check that the vacuum tubing outflow line is not kinked, remove the CVAC Aspiration System and check the vacuum lumen for clogs.
- If a clog in the vacuum lumen cannot be cleared, do not use the device. Obtain a new CVAC Aspiration System to complete the procedure.
- Do not coil or bend the CVAC Aspiration System. Store the device in a straight condition when not in use. Do not use a bent or kinked device.

6. NOTES

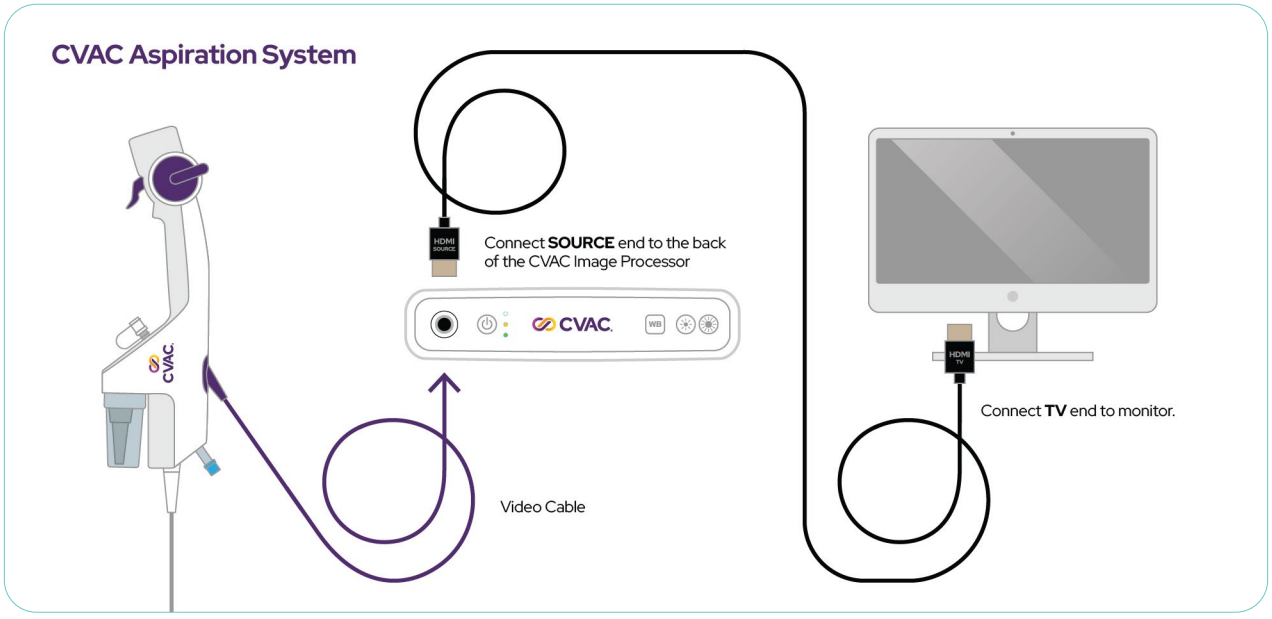
- The CVAC Image Processor should be placed away from the sterile field. The physician who is working in the sterile field should not handle the CVAC Image Processor. A professional healthcare assistant, who is not working in the sterile field, should handle the non-sterile CVAC Image Processor.
- The CVAC Aspiration System is compatible with the CVAC Image Processor. It is not compatible with any other image processors.

7. PRODUCT DESCRIPTION

The CVAC Aspiration System and the CVAC Image Processor are designed to work together. The CVAC Image Processor is connected to a standard external hospital monitor in the operating suite using a provided HDMI cable, as depicted in Figure 1.

The CVAC Aspiration System and CVAC Image Processor are specially designed to allow physicians to locate kidney stones, to establish a conduit to visualize kidney stones, and to irrigate and apply suction to remove stone and dust fragments in the renal pelvis and calyces during the endoscopic urological kidney stone removal procedure.

FIGURE 1. CVAC Aspiration System and CVAC Image Processor



7.1. CVAC Aspiration System

The CVAC Aspiration System is a sterile single-use steerable ureteral catheter employing ureteroscopy with built-in irrigation and vacuum functionality. The CVAC Aspiration System is designed to allow physicians to establish a conduit to the kidney and renal calyces using ureteroscopy, to visualize stone(s), to facilitate commercially available laser lithotripsy and stone basketing, and to initiate and control irrigation and vacuum to remove stones and stone dust from the urinary system. The CVAC Aspiration System is compatible with standard 12/14 French ureteral access sheaths.

The CVAC Aspiration System sterile package contents include the following:

- CVAC Aspiration System
- Accessories
  - Introducer
  - Laser bridge
  - Trigger tie
  - 3-way stopcock
  - Vacuum port cap

TABLE 1. CVAC Aspiration System Specifications

Working Length	70cm
Distal Hydrophilic Coated Length	43cm
Outer Diameter	11.9Fr (3.97mm)
Working Channel Inner Diameter	7Fr (2.33mm)
Articulation Range	Nominal 250° up/ 250° down
Laser Bridge Inner Diameter	660µm
Recommended Vacuum Settings	150mmHg – 200mmHg
Recommended Irrigation Pressure Settings	150mmHg – 200mmHg

7.2. CVAC Image Processor

The CVAC Image Processor is required for use of the CVAC Aspiration System. The CVAC Image Processor is a software-controlled, reusable, and electrical image processor that connects to any standard 110V hospital electrical outlet via a provided power cord. See the CVAC Image Processor User Manual (electronically available) for detailed instructions.

7.2.1 Essential performance

The CVAC Image Processor should continuously operate and display the image on the screen. The CVAC Image Processor can power cycle itself to return to normal operation without operator intervention. The image on the screen should not have permanent color changes or permanent partial displays.

FIGURE 2. CVAC Image Processor Front

7.3. Compatibility

The CVAC Aspiration System and CVAC Image Processor are compatible with the following hospital equipment and supplies. Collect the required supplies before starting the procedure:

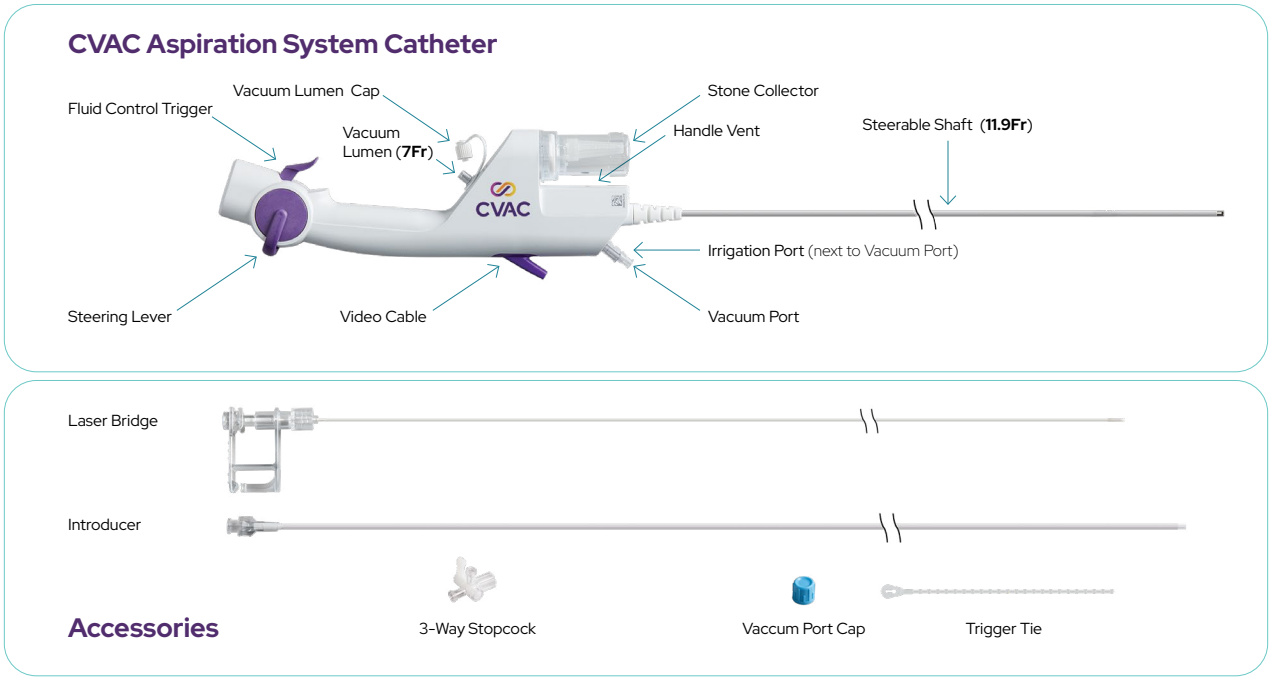
- Guidewire, .038" or smaller
- 12/14 Fr ureteral access sheath with tapered dilator
- Suction and irrigation tubing (required)
- Vacuum source set at 150-200 mmHg (required)
- Irrigation source with pressure set at 150-200 mmHg (required)
- Irrigation fluid (sterile saline) (required)
- HD Display monitor with HDMI or DVI Input (required).

The CVAC Aspiration System is compatible with commercially available medical devices that can fit inside the 2.3mm (7 Fr) working channel. Examples include:

- Stone removal baskets 1.9 Fr or smaller
- Laser fibers, < 660µm outer diameter (to fit in the Laser Bridge)

8. CVAC ASPIRATION SYSTEM COMPONENTS

FIGURE 3. CVAC Aspiration System Diagram



1. **Vacuum Port:** Barbed fitting connected by the user to hospital vacuum supply using standard vacuum tubing. Standard hospital vacuum settings of 150 to 200 mmHg should be used.
2. **Irrigation Port:** Luer fitting connected to a standard pressurized saline reservoir using standard irrigation tubing.
3. **Video Cable:** Permanently attached to the handle, disposed after use as hospital waste, connected to the CVAC Image Processor.
4. **Steering Lever:** Rotates catheter tip with up and down motion of the lever from the neutral position (see Figure 4).
5. **Fluid Control Trigger:** Three positions (neutral: passive irrigation, half pull: active irritation, and full pull: active irrigation and vacuum) (see Figure 5)
6. **Working Channel Cap:** Working Channel Cap is loosely attached to the device and is removed prior to inserting accessory device into working channel. The Working Channel Cap must be secured onto Working Channel Luer fitting to utilize vacuum function.

7. **Working Channel:** Functions as a working channel for accessories and vacuum function including:
   - **Introducer** (provided) during placement of the CVAC Aspiration System,
   - **Laser bridge** (provided) and commercially available laser fiber for laser lithotripsy,
   - Placement of compatible commercially available medical devices (e.g., laser fiber, stone basket; compatibility determined by accessory device size, Section 7.3)
   - Vacuum function for removal of fluid and urinary stones (kidney stones, fragments, and dust).
8. **Stone Collector:** Removable stone collector, used for collection of kidney stones for analysis.
9. **Steerable Shaft:** 70 cm-long steerable ureteral catheter with two lumens: irrigation lumen and vacuum lumen/working channel. Hydrophilic coating on distal 43 cm to the catheter tip.
10. **Distal Tip:** The distal tip includes the following 4 elements:
    a. The opening of the irrigation channels
    b. The opening of the working channel
    c. The digital image sensor
    d. The dual light source

FIGURE 4. Steering Lever Control

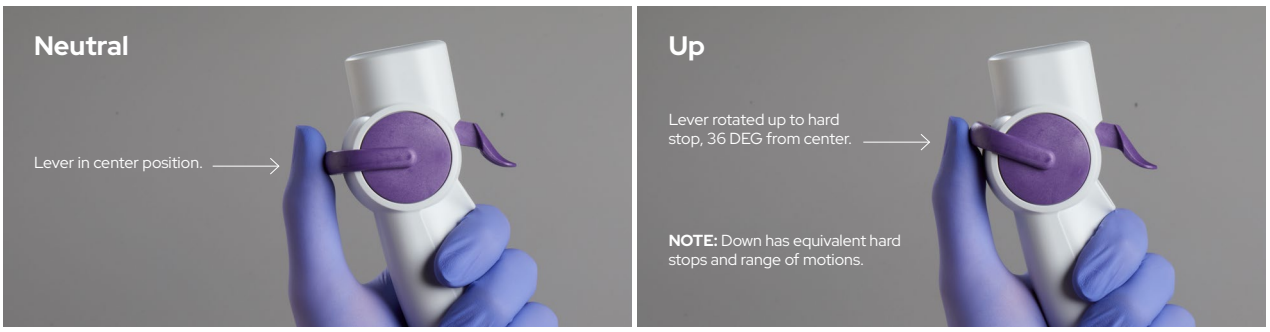
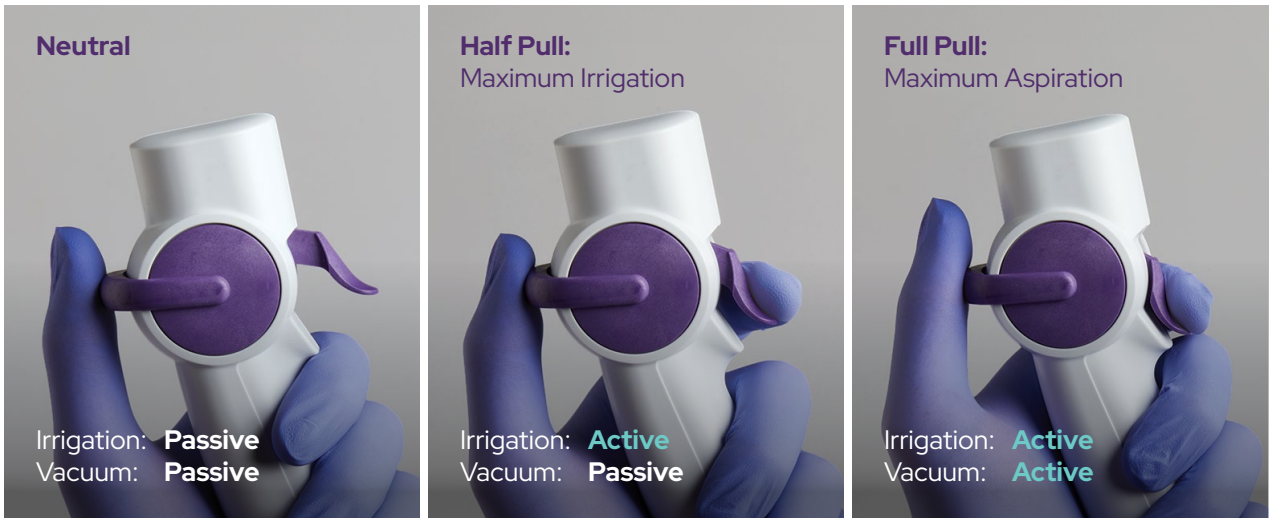


FIGURE 5. Flow and Vacuum Control



9. USER QUALIFICATIONS

The CVAC Aspiration System and CVAC Image Processor are only intended to be used by physicians who are trained and experienced with endoscopic operations.

Only physicians who are trained in flexible ureteroscopy should use the CVAC Aspiration System and CVAC Image Processor. Physicians should understand the techniques, clinical applications, and risks associated with ureteroscopy and be familiar with laser lithotripsy, the use of fluoroscopy, administration of irrigation/contrast and vacuum, as well as the safe use of commercial medical devices such as ureteral access sheaths, baskets, lasers and guidewires.

Calyxo strongly recommends a thorough review of all relevant medical literature relative to techniques, complications, and hazards prior to undertaking any ureteroscopic procedure.

For the preparation of the CVAC Aspiration System before use, users should be thoroughly trained. The CVAC Aspiration System should be disposed of as biological waste according to the hospital policy after use. Failure to completely understand these details may pose an infection risk and/or cause device damage and/or patient injury.

If training assistance is required from either the manufacturer or local distributor, please contact your distributor or Calyxo, Inc. customer service.

10. OPERATING INSTRUCTIONS

10.1. Unpacking the CVAC Aspiration System

Upon receipt, examine the shipping carton and its contents for signs of damage. Confirm that the sterile barrier is intact and check the expiration date. DO NOT use a damaged or expired device. DO NOT attempt to repair the device.

Inside the shipping carton, the device is packaged in a tray which is sealed by a sterile barrier. Remove the tray from the sterile barrier using aseptic technique and place in the sterile field. Remove the retainer lid on the tray. Remove the device from the tray into the sterile field. After removing the device from the packaging, perform the following operational checks.

Unpack and retain all box contents in the sterile field:

- CVAC Aspiration System
- Laser Bridge
- Introducer
- Trigger Tie
- Stopcock
- Vacuum Port Cap

10.2. CVAC Aspiration System Setup and Inspection

Inspect the entire surface of the CVAC Aspiration System. Ensure that no components of the device are loose, bent or broken. Inspect the distal tip for damage including dents, protrusions, breakages, or sharp edges. Inspect the catheter for damage including bends, tears, or holes. Examine the video cable and distal connector for damage. Do not use a damaged device.

Activate the hydrophilic coating on the distal 43 cm (17") of the catheter by wetting with sterile water or saline.

Inspect the CVAC Aspiration System by moving the steering lever up and down. This will articulate the tip up and down. Confirm the plane of articulation and that the tip articulates in both directions. Return the distal tip to a neutral position.

Connect the **Video Cable** from CVAC Aspiration System to the Video Cable Connection on the front of the CVAC Image Processor until the cable plug is fully inserted.

Ensure that all connections to the **CVAC Image Processor** are made (monitor, power, CVAC Aspiration System). See CVAC Image Processor User Manual (electronically available) for detailed instructions.

Turn on the CVAC Image Processor.

Connect the CVAC Aspiration System to **Vacuum:** Connect the wall suction or similar vacuum source tubing to the Vacuum Port of the device. Set the vacuum source pressure to 150-200 mmHg.

Connect the CVAC Aspiration System to the **Irrigation Source:** Connect a compatible irrigation source (pressure bag set to 150-200 mmHg) to the supplied three-way stopcock and then to the Irrigation Port of device using standard irrigation tubing. Irrigant flow will start. The flow level can be adjusted using the three-way stopcock.

Remove the Trigger Tie from the CVAC Aspiration System or slide it down the handle to release the Fluid Control Trigger.

Prime the device by pulling the Fluid Control Trigger halfway (to the detent). Irrigant will be observed coming out of the tip of the catheter. Place the catheter tip into a container with irrigant and pull the Fluid Control Trigger fully to test the vacuum. Irrigant will be observed filling up the Stone Collector.

Hold the distal tip of the CVAC Aspiration System close to an object (about the same distance as the width of the shaft) and ensure the video monitor displays a clear image. Adjust the brightness, as necessary (see the CVAC Image Processor User Manual).

10.3. CVAC Aspiration System Use

The CVAC Aspiration System is designed for use with or without a ureteral access sheath and is always placed over a guidewire.

If a ureteral access sheath is used, remove the Working Channel Cap and advance the CVAC Aspiration System over the guidewire. Once the CVAC Aspiration System is in the kidney, remove the guidewire and replace the Working Channel Cap on the Working Channel.

If no ureteral access sheath is used, remove the Working Channel Cap, insert the **Introducer** (provided accessory) into the Working Channel of the CVAC Aspiration System and then advance the CVAC Aspiration System and the Introducer over the guidewire. Remove the Introducer when the tip of the CVAC Aspiration System is in the kidney. Replace the Working Channel Cap on the Working Channel.

Navigate and inspect the upper urinary tract and collecting system using standard ureteroscopic techniques.

When using the Laser Bridge, laser lithotripsy can be performed using a laser fiber with outer diameter less than 660µm. Remove the Working Channel Cap. Insert a laser fiber into the Laser Bridge (provided accessory) such that the laser fiber tip is flush with the tip of the Laser Bridge. Insert the Laser Bridge with the laser fiber into the working channel and secure the Laser Bridge to the working channel. Adjust laser fiber position and perform laser lithotripsy using standard ureteroscopic techniques. Actuate (press) the Laser Bridge to clear stone debris at the tip as needed.

Passive outflow of fluid and stone dust will occur through the working channel during laser lithotripsy.

Prior to the initiation of stone fragment removal under full aspiration, remove the Laser Bridge with the laser fiber and re-install the Working Channel Cap on the working channel. Then, open the three-way stopcock to maximum flow and pull the Fluid Control Trigger past the detent to activate the vacuum with full irrigation. Move the tip of the CVAC Aspiration System close to the stone debris, pull the Trigger halfway to fill the kidney with irrigant and intermittently pull the trigger fully to activate the vacuum.

A retrograde pyelogram can be performed by injecting contrast/saline mixture into the Irrigation Port via the three-way stopcock.

Caution: Monitor the vacuum tubing and Stone Collector regularly to confirm outflow. If there is a slowing or lack of the fluid outflow in the vacuum tubing, stop active irrigation, inspect the vacuum tubing for any kinks, stop the procedure, and remove the straightened CVAC Aspiration System from the patient to check for clogging of the vacuum lumen.

Other accessory devices including stone baskets <1.9 French may be used in the working channel of the CVAC Aspiration System according to standard technique and at the discretion of the urologist.

Do not extract stones through the working channel of the CVAC Aspiration System using a basket. If a stone does not fit in the working channel perform additional laser lithotripsy to enable stone fragment removal.

The Stone Collector contains an integrated conic filter that captures fragments >270µm to preserve specimens for pathology. Twist ¼ turn to remove Stone Collector and empty stones if desired. Reconnect the Stone Collector and resume procedure.

10.4. Disposal of CVAC Aspiration System

Unplug the CVAC Aspiration System from the CVAC Image Processor. Dispose of the CVAC Aspiration System as biological waste according to the hospital policy.

11. TROUBLESHOOTING

11.1. Loss of Image

See the CVAC Image Processor User Manual (electronically available) Section 11 for detailed troubleshooting instructions.

11.2. Loss of Steering Control

In the event that the Steering Lever becomes unresponsive, discontinue use of the CVAC Aspiration System and remove the device from the patient by following steps:

1. Return the tip to its neutral (center) position using the steering lever.
2. Confirm that the distal tip is in a straight position using fluoroscopy.
3. If the steering lever fails to straighten the tip, the introducer and/or an 0.035" or 0.038" guidewire may be passed through the working channel to aid in straightening the distal tip. Make sure to advance the guidewire slowly and confirm with fluoroscopy to ensure that the distal tip has been straightened.
4. Slowly withdraw the CVAC Aspiration System from the patient.

11.3. Clog Clearance

Stone fragments can lead to clogging of the CVAC Aspiration System. Physicians must regularly monitor the vacuum tubing or Stone Collector to confirm fluid outflow during the procedure. Fluid outflow in the vacuum tubing indicates there is no clogging in the vacuum lumen of the CVAC Aspiration System. **If there is slow or no flow in the vacuum tubing or Stone Collector,** check the vacuum tubing connected to the CVAC Aspiration System for kinks. Inspect the CVAC Aspiration System for clogs and clear the clog using the following steps.

WARNING!: Clog clearance should NEVER be performed while the CVAC Aspiration System is inside the patient. Always remove the CVAC Aspiration System prior to clog clearance.

1. Stop irrigation and vacuum.
2. Bring the CVAC Aspiration System to straight position and carefully remove it from the patient.
3. Place the CVAC Aspiration System on the sterile table and disconnect the vacuum tubing.
4. Inspect the Stone Collector filter. Ensure the Stone Collector filter is not clogged.
5. Attach the Vacuum Port Cap (provided accessory) to seal the vacuum lumen of CVAC Aspiration System and use the Trigger Tie (provided accessory) to hold down the Irrigation-Vacuum trigger fully. See Figure 6.
6. Fill the Stone Collector with fluid using a syringe until there are no air bubbles. Refill the syringe as needed. See Figure 7.
7. Place the tip of the CVAC Aspiration System in a bowl filled with enough fluid to submerge the tip of the device. Perform a hydraulic cycle of the 20cc syringe with repeated push-pull action of the syringe plunger until the clog is removed. Collect released debris in the bowl.

FIGURE 6. **Vacuum Port Cap and Trigger Tie in Place for Clog Clearance**

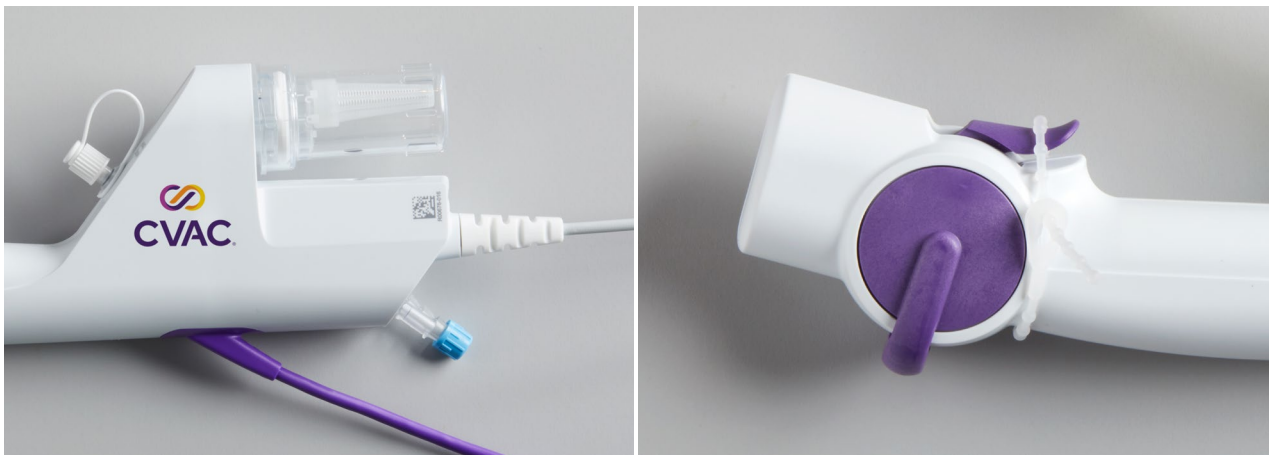


FIGURE 7. **Stone Collector with Adequate Fluid for Clog Clearance**

12. TECHNICAL SPECIFICATIONS

12.1. CVAC Aspiration System and CVAC Image Processor Specifications

Refer to CVAC Image Processor User Manual for CVAC Image Processor Specifications.

TABLE 2. CVAC Image Processor Specifications

Image System	The CVAC Image Processor is connected to the CVAC Aspiration System and provides power to the ureteroscope. The following are the specifications for the camera in the CVAC Aspiration System.	
Compatible Display	Standard Monitor with HDMI or DVI input	
Resolution (pixels)	200 x 200	
Digital Video Technology	Color CMOS	
Illumination	LED	
Field of View (°)	100°	
Direction of View (°)	0°	
Light (lux)	> 5000 lux	
Image/Video Capture	No image or video capture; live viewing only	
Operating Environment	Ambient Temperature	10°C to 40°C
	Humidity	15% to 90%
	Air Pressure	700 hPa to 1060 hPa (-1253 to 9878ft);
Storage and Transport Environment	Temperature	-18°C to 60°C
	Humidity	15% to 90%
	Air Pressure	500hPa to 1060hPa (-1253 to 18281ft)
Storage Environment	The CVAC Aspiration System must be stored in the original product box. Store the device in the product carton in a cool, dry place away from direct sunlight.	

13. EMC INFORMATION

This model should be used in the electromagnetic environment specified. The customer or user shall ensure that it is installed and used in such environments.

13.1. Guidance and Manufacturer's Declaration – Electromagnetic Emissions

TABLE 3. EMC Emissions

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Conducted Emissions	CISPR 11 Group 1 Class A	This instrument uses RF (Radio Frequency) energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radiated Emissions	CISPR 11 Group 1 Class A	This instrument is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	This instrument is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

13.2. Guidance and Manufacturer's Declaration – Electromagnetic Immunity

This model is intended for use in the electromagnetic environment specified below. The customer or the user of this equipment should ensure that it is used in such an environment.

TABLE 4. Electromagnetic Immunity

STANDARD	DESCRIPTION	SEVERITY LEVEL OR LIMIT	SEVERITY LEVEL OR LIMIT	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
EC/EN 60601-1-2:2020, IEC 60601-2-18 Section 202.6.2.1.10 Product Family Standard Immunity	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	See Basic Standards Below	N/A	N/A	N/A
EC/CISPR 11:2019, FCC Part 15 Subpart B, ICES-003 Issue 7 Product Family Standard Emissions	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement	See Basic Standards Below	N/A	N/A	N/A
IEC TR 60601-4-2:2016 Product Family Standard Immunity	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems	N/A	See Basic Standards Below	N/A	N/A
EN 61000-4-2:2009, IEC 61000-4-2:2008 Basic test standard	Electrostatic Discharge Immunity	±15 kV Air Discharge ±8 kV Contact Discharge,VCP, HCP	±2, 4, 8, 15 kV Air Discharge ±8 kV Contact Discharge, VCP, HCP	Same as left	Floors should be made of wood, concrete or ceramic tile. If floors are covered with synthetic material that tends to produce static, the relative humidity should be at least 30%.
EN/IEC 61000-4-5:2014 Basic test standard	Surge Immunity	±0.5 kV, ±1 kV, ±2kVCM Line-Gnd ±0.5 kV, ±1 kV, DM Line-Line NA on I/O Ports	±0.5 kV, ±1 kV, ±2kVCM Line-Gnd ±0.5 kV, ±1 kV, DM Line-Line NA on I/O Ports	Same as left	Mains power quality should be that of a typical commercial or hospital environment.
EN/IEC 61000-4-11:2004 Basic test standard	Voltage Dips Voltage Interruptions	0 %, 0.5 cycleAt 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°, 0%, 1 cycle 70%, 25/30 cycles 0%, 250/300 cycle	0 %, 0.5 cycle 0%, 1 cycle 70%, 25/30 cycles 0%, 250/300 cycles	Same as left	Mains power quality should be that of a typical commercial or hospital environment. If the user of instrument requires continued operation during power mains interruptions, it is recommended that the instrument be powered from an uninterruptible power supply or a battery.

STANDARD	DESCRIPTION	SEVERITY LEVEL OR LIMIT	SEVERITY LEVEL OR LIMIT	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
EN 61000-4-8:2010, IEC 61000-4-8:2009 Basic test standard	Power Frequency Magnetic Field Immunity test	30A/m @ 60Hz 3 orthogonal orientations	30A/m @ 60Hz 3 orthogonal orientations	Same as left	It is recommended to use this instrument by maintaining enough distance from any equipment that operates with high current. If image distortion occurs, it may be necessary- to position the model further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
EN 61000-4-6:2014, IEC 61000-4-6:2013 Basic test standard	Conducted Immunity	3Vrms, 6Vrms in ISM Bands, 0.15 - 80 MHz , AC Mains 3Vrms, 6Vrms in ISM Bands, 0.15 - 80 MHz ,, I/O Ports 80% 1kHz AM Modulation	3Vrms, 6Vrms in ISM Bands, 0.15 - 80 MHz , AC Mains 3Vrms, 6Vrms in ISM Bands, 0.15 - 80 MHz ,, I/O Ports 80% 1kHz AM Modulation	3V 0.15MHz to 80MHz	Recommended separation distance·30cm
EN 61000-4-3:2006: +A1:2008 + A2:2010, IEC 61000-4- 3:2006 + A1:2007 + A2:2010 Basic test standard	Radiated Electromag-netic Field Immunity	3V/m, 80 - 1000 MHz 3V/m, 1.4 GHz to 2 GHz 3V/m, 2.0 GHz to 2.7 GHz 80% 1kHz AM Modulation	3V/m, 80 - 1000 MHz 3V/m, 1.4 GHz to 2 GHz 3V/m, 2.0 GHz to 2.7 GHz 80% 1kHz AM Modulation	Same as left	For hospital environment
EC 61000-4-39:2017 Basic test standard	Proximity Magnetic Field Immunity test	134.4 kHz at 2.1kHz pulse modulation 65A/m field strength 13.56 Mhz at 50Khz pulse modulation 7.5A/m field strength	134.4 kHz at 2.1kHz pulse modulation 65A/m field strength 13.56 Mhz at 50Khz pulse modulation 7.5A/m field strength	Same as left	For hospital environment
EN/IEC 61000-4-4:2012 Basic test standard	EN/IEC 61000-4-4:2012 Basic test standard	±2 kV on AC Mains ±1kV on I/O Ports	±2 kV on AC Mains ±1kV on I/O Ports	Same as left	For hospital environment
EN 61000-4-6:2014, IEC 61000-4-6:2013 Basic test standard	Conducted Immunity	3Vrms 6Vrms in ISM Bands, 0.15 - 80 MHz, AC Mains 3Vrms,, 0.15 - 80 MHz, I/O Ports 6Vrms, ISM Frequencies,, I/O Ports 80% 1kHz AM Modulation	3Vrms, 6Vrms in ISM Bands, 0.15 - 80 MHz , AC Mains 3Vrms, 6Vrms in ISM Bands, 0.15 - 80 MHz ,, I/O Ports 80% 1kHz AM Modulation	Same as left	For hospital environment

NOTE 1 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NOTE 2 Portable and mobile RF communications equipment should be used no closer to any part of the CVAC Image Processor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance

$d = 1.2\sqrt{P}$

$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz

$d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

14. WARRANTY

Calyxo, Inc. warrants that reasonable care has been used in the design and manufacture of this device. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties or merchantability or fitness for a particular purpose.** Handling and storage of this device as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Calyxo's control directly affect the device and the results obtained from its use. Calyxo's obligation under this warranty is limited to the repair or replacement of this device and Calyxo shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from its use. Calyxo neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. **Calyxo assumes no liability with respect to devices repaired, adjusted, or altered by persons not authorized by Calyxo or used, stored, prepared, or maintained contrary to prescribed instructions or schedules and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such devices.**

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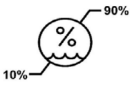
15. SYMBOLS GLOSSARY

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified	ISO 15223-1:2021 Reference no. 5.1.6 (ISO 7000-2493 2004-01-15)	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1:2021 Reference no. 5.1.5. (ISO 7000-2492 2004-01-15)	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	Quantity	Indicates the number of units per package	N/A	N/A
	Use by date	Indicates the date after which the medical device is not to be used	ISO 15223-1:2021 Reference no. 5.1.4. (ISO 7000-2607 2004-01-15)	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	Prescription Use Only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner	N/A	N/A
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1:2021 Reference no. 5.1.1. (ISO 7000-3082 2011-10-02)	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use	ISO 15223-1:2021 Reference no. 5.4.3 (ISO 7000-1641 2004-01-15)	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide	ISO 15223-1:2021 Reference no. 5.2.3. (ISO 7000-2501 2004-01-15)	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	Do not resterilize	Indicates a medical device that is not to be resterilized	ISO 15223-1:2021 Reference no. 5.2.6. (ISO 7000- 2608 2004-01-15)	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	Do not re-use	Indicates a medical device that is intended for one single use only	ISO 15223-1:2021 Reference no. 5.4.2. (ISO 7000- 1051 2004-01-15)	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information	ISO 15223-1:2021 Reference no. 5.2.8. (ISO 7000-2606 2004-01-15)	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	ISO 15223-1:2021 Reference no. 5.4.4. (ISO 7000-0434A 2004-01-15)	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	Refer to instruction manual/ booklet NOTE On ME equipment "Follow instructions for use"	Refer to instruction manual/ booklet	ISO 7010-M002	Graphical symbols - Safety colours and safety signs - Registered safety signs
	Keep away from sunlight	Indicates a medical device that needs protection from light sources	ISO 15223-1:2021 Reference no. 5.3.2. (ISO 7000-0624 2014-06-04)	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	Humidity limitation 15% - 90%	Indicates the range of humidity to which the medical device can be safely exposed	ISO 15223-1:2021 Reference no. 5.3.8. (ISO 7000-2620 2014-01-15)	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	Type BF Applied Part	To identify a type BF applied part complying with IEC 60601-1	IEC 60417-5333	Graphical symbols for use on equipment, Database Snapshot
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified	ISO 15223-1:2021 Reference no. 5.1.7. (ISO 7000-2498 2004-01-15)	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	Date of manufacture	Indicates the date when the medical device was manufactured	ISO 15223-1:2021 Reference no. 5.1.3. (ISO 7000-2497 2004-01-15)	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	Temperature limit -18∞ to 60∞	Indicates the temperature limits to which the medical device can be safely exposed	ISO 15223-1:2021 Reference no. 5.3.7. (ISO 7000-0632 2014-06-04)	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	Atmospheric pressure limitation 500hPa – 1060hPa	Indicates the range of atmospheric pressure to which the medical device can be safely exposed	ISO 15223-1:2021 Reference no. 5.3.9. (ISO 7000-2621 2004-01-15)	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	Waste Management	Waste electrical and electronic equipment	EN 50419	Marking of electrical and electronic equipment (EEE) in respect to separate collection of waste EEE (WEEE)