CVAC®

Image Processor

Only to be used with the CVAC® Aspiration System

Calyxo®

USER MANUAL

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Foreword

This User Manual contains the recommended procedures for preparing and using the CVAC Image Processor. 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 Image Processor and CVAC Aspiration System. 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 Image Processor and CVAC Aspiration System, follow the provided product or equipment User Manual instructions to avoid any possible hazards due to device incompatibility.

NOTE: Definitions of **WARNING, CAUTION, NOTE, and PRECAUTIONS** 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, and damage to the system or to other properties.
3. **NOTE:** Highlights important information on the use of the system.
4. **PRECAUTION:** Description of the actions to be taken to prevent adverse events to the PATIENT and OPERATOR due to ELECTROMAGNETIC DISTURBANCES.

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.

Authorized Service Technician

Only an authorized service technician may perform repairs, adjustments, or alterations on the device or accessories and use the service menu. Any violation will void the manufacturer's warranty. Authorized service technicians are trained and certified only by the manufacturer.

1. INTENDED USE / INDICATIONS FOR USE

The CVAC Image Processor is only to be used with the CVAC Aspiration System to provide treatment and removal of urinary stones (kidney stones, fragments, and dust) and endoscopic examination of the urinary tract and the interior of the kidney.

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. WARNINGS

- The service and maintenance of the device and its accessories must be carried out per instructions to ensure the safe operation of the device. For the protection of the patient and the operation team, check the integrity and function of the device before each use.
- Only the physician can evaluate the clinical factors involved with each patient and determine if the use of this device is indicated. The physician must determine the specific technique and procedure that will accomplish the desired clinical effect.
- Factory settings are not mandatory settings for the physician. The physician is responsible for all settings affecting the surgical procedure.
- For your own safety and that of your patient, use only original accessories.
- Never install and operate the device in locations where:
  - the concentration of oxygen is high.
  - oxidizing agents (such as nitrous oxide (N2O) are present in the atmosphere.
  - flammable gases are present in the atmosphere.
  - flammable liquids are near.
- Otherwise, explosion or fire may result because this device is not explosion-proof.
- Do not modify this device. Doing so can cause electric shock to the operator and patient. The CVAC Image Processor does not contain any serviceable components or parts. All repair and servicing must be performed only by authorized Calyxo service personnel.
- Components and parts of the CVAC Image Processor have no radioactive source; there is no related safety risk during lifetime management of the CVAC Image Processor.
- This manual does not include descriptions or instructions for surgical procedures/techniques. It is also not suitable for training physicians in the use of surgical techniques. Medical peripherals and devices may be used only by physicians or medical assistants with the appropriate technical/medical qualification working under the direction and supervision of a physician.
- Always work exclusively with sterile substances and mediums, sterile fluids, and sterile accessories if indicated.
- In case the device or any of the accessories are damaged or stop functioning during a procedure, a replacement device and/or replacement accessories should be kept within easy reach to be able to finish the operation with the replacement components.
- Do not sterilize the device.
- Protect the device from moisture. Do not use it if moisture has penetrated the device.
- Do not insert a contaminated, wet, or compromised cable connector into the device receptacle. Doing so can cause poor video performance or damage to the CVAC Image Processor and CVAC Aspiration System.
- If a device defect is suspected or confirmed, do not use it. Make sure the device can no longer be used until a qualified service technician conducts the appropriate tests and repairs.
- The residual current flowing through the patient could increase when using the ureteroscope with electrically powered accessories.
- Never use the device if it has obvious defects, especially if these involve the power plugs or the mains power supply connection cables. In this case, have the device repaired by authorized service personnel.
- The device is only completely disconnected from the mains power supply if the power plug is unplugged from the shockproof safety socket. Always grasp the power plug when disconnecting the device from the power supply. Never pull on the cable itself.
- The electrical connections of the operating room where the equipment is used must comply with the corresponding national requirements.

- Always comply with national regulations concerning avoiding the danger of ignition caused by electrostatic charges.
- To prevent electric shock, ensure that there is no electrical short between the CVAC Aspiration System and the outer casing of the CVAC Image Processor.
- Do not use the CVAC Aspiration System unless a clear, live endoscopic image is confirmed prior to procedure. Do not insert or advance the ureteroscope and/or accessories if the live endoscopic view is lost. Stop the procedure immediately, and remove the ureteroscope and/or accessories from patient. Continuing the procedure without a live video image can cause patient injury.
- The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals only (CISPR 11 class A).
- Never pull on the video cable. Never squeeze, compress, bend, twist, or spindle the video cable. This can damage the wires inside of the cable and cause image loss or cable failure.
- Use of this equipment adjacent to or stacked with other equipment should be avoided, because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- 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 this equipment, including cables specified by Calyxo. Otherwise, degradation of the performance of the CVAC Image Processor could result.
- Components and parts of the CVAC Image Processor have no stored energy, but please collect and dispose of them separately according to local regulations for the disposal of electronic devices.

4. PRECAUTION

- Check to make sure the available mains voltage matches the values listed on the label on the bottom of the device. Incorrect voltage can cause errors and malfunctions and may destroy the device.
- The CVAC Image Processor may only be connected to the CVAC Aspiration System. Connection to any other ureteroscope can cause injury to patient, operator, and device and/or property damage.
- Electrical interference with other devices or instruments was practically eliminated when developing these devices, and none was detected during testing. Furthermore, the CVAC Image Processor has been designed to be immune to levels of external electromagnetic interference or energy sources (see Table 6). However, sources that emit levels of energy that exceed the immunity test levels of their reference to EMC Standards or have other emissions characteristics to which the CVAC Image Processor has not been tested for may lead to interference. If you still detect or suspect such interference, please follow these suggestions:
  - Move this, the other, or both devices to a different location.
  - Increase distance between the devices.
  - Consult a technician. If more power-consuming devices are connected simultaneously to one socket by means of distribution boxes, the sum of the individual leakage currents may exceed the tolerated limit values.
- If the CVAC Image Processor is operated within an enclosed device tower or rack system, the operating temperature within this tower may be higher than the ambient room temperature. Therefore, always install the equipment in an environment compatible with the manufacturer's rated ambient temperature.
- Additional peripheral equipment connected to interfaces of the medical monitor must meet the requirements of the following specifications: IEC 60601-2-18 for endoscopic devices and IEC 60601-1 for electrical medical devices. All configurations must comply with IEC 60601-1-1 specifications. Whoever connects additional equipment to signal input is obliged to meet the requirements of the standard IEC 60601-1-1.
- Keep fluids away from all electrical equipment. If fluids are spilled on or into the unit, stop operation of the CVAC Image Processor immediately, and contact the manufacturer.

- Do not prepare, inspect, or use the CVAC Image Processor with wet hands.
- Use accessories approved by the manufacturer only, or they will interfere with other medical electronic equipment used in combination.
- Do not use the device if the provided cables are damaged (bent, broken or exposed wires, cuts in insulation layer; etc.).
- Check to make sure the available mains voltage matches the data listed on the label on the bottom of the device. Incorrect voltage can cause errors and malfunctions and may destroy the device.

5. CAUTIONS

- Verify the cable connector on the CVAC Aspiration System is not damaged prior to use. The CVAC Aspiration System should connect to the CVAC Image Processor easily. Do not force the cable connector into the device receptacle, as it may damage the device.
- The CVAC Image Processor must not be sterilized (e.g. through autoclaving). The parts may be damaged.
- Do not use near heating sources or an opening or vent for air conditioning and ventilation. Do not expose the unit to direct sunlight, excessive dust, vibrations, or mechanical shocks.
- The CVAC Image Processor should be thoroughly cleaned and disinfected after each use (Section 11).
- Electromagnetic interference may cause unexpected system performance or failure such as loss or intermittency of the CVAC Aspiration System camera image.

6. NOTES

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). It is not for use in a residential environment.

7. PRODUCT DESCRIPTION

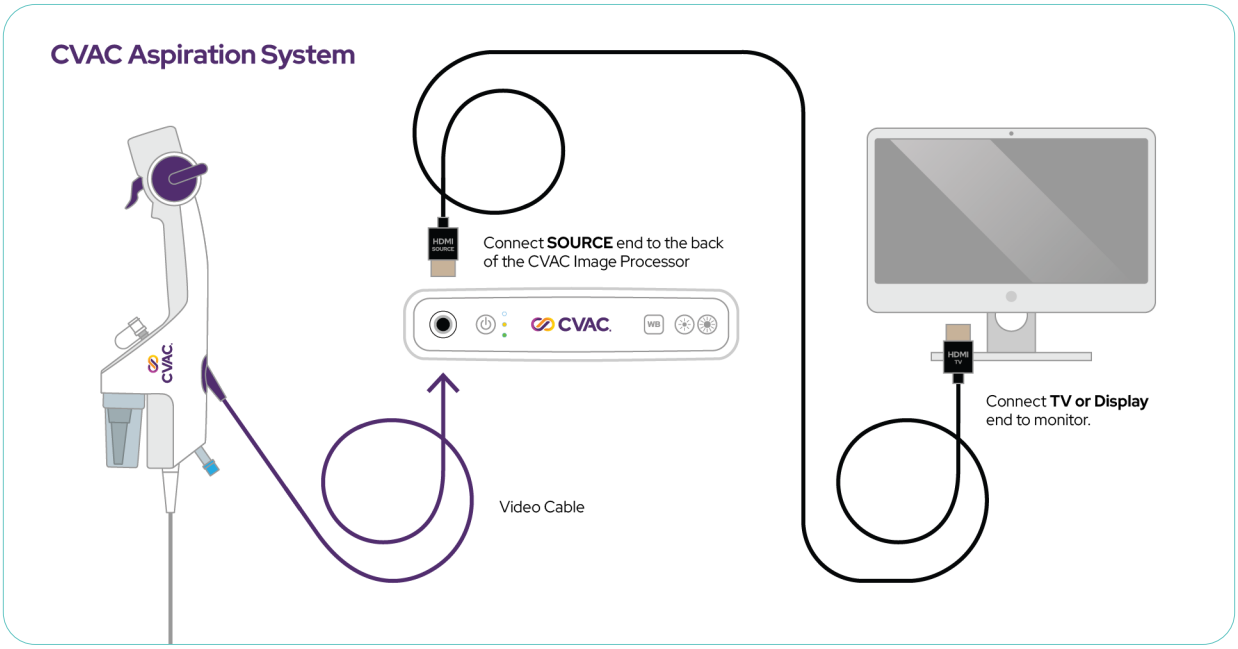
The CVAC Aspiration System and CVAC Image Processor are designed to work together. The CVAC Image Processor is connected to a standard external hospital monitor in the operating suite using the provided HDMI cable, as depicted in Figure 1. The devices are intended to be used in a hospital environment.

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.

7.1. 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 1. CVAC Aspiration System and CVAC Image Processor



7.2. CVAC Aspiration System

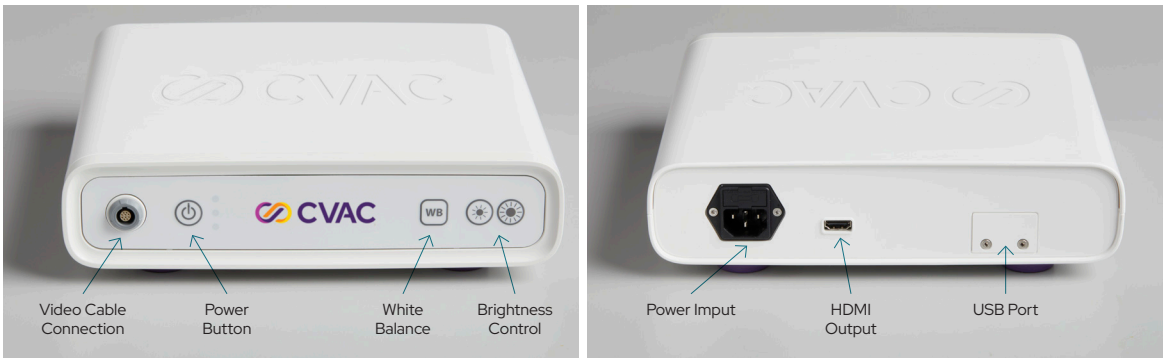
The CVAC Aspiration System is a sterile single-use steerable ureteral catheter employing ureteroscopy with built-in irrigation and vacuum functionality. The CVAC Aspiration System is designed to allow physicians to establish a conduit to the kidney and renal calyces using ureteroscopy, to visualize stone(s), 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. See the CVAC Aspiration System User Manual (electronically available) for detailed instructions.

7.3. 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 image processor that connects to any standard 110 V hospital electrical outlet via a provided power cord.

The CVAC Image Processor is also referred to as "device" or "equipment" in this document.

FIGURE 2. CVAC Image Processor Front (left) and Back (right)



The front of the CVAC Image Processor has a power button, white balance button, and brightness up/down buttons. The back of the CVAC Image Processor has connections for the HDMI output (an HDMI-to-DVI adapter is included, if needed) and power input.

On the right of the power button are three LED lights stacked: white (top), yellow (center), and green (bottom).

- The white LED will illuminate when the CVAC Image Processor is powered on.
- The yellow LED will be solid if the system does not detect that the CVAC Aspiration System is connected. The light will blink yellow if there is an error (see Troubleshooting section).
- The green LED will illuminate when the CVAC Aspiration System camera is on and the system is functioning.

FIGURE 3. **Front Panel With LED Lights**

7.4. Accessories Found in the Box

The CVAC Image Processor has three (3) accessories in the box.

TABLE 1. **Accessories to CVAC Image Processor**

NO.	ACCESSORIES	UNIT	QTY	REMARK
1	Power cable, 10 ft.	Each	1	Standard configuration
2	HDMI cable, length 10 ft.	Each	1	Standard configuration
3	HDMI-to-DVI adapter	Each	1	Standard configuration

7.5. Compatible Hospital Monitors

The CVAC Image Processor is compatible with hospital-grade high-definition monitors (e.g. Karl Storz Full HD Wideview or equivalent).

Minimum requirements:

- Supported input signals: HDMI or DVI
- Display resolution: high-definition 1920 X 1080p (full HD)
- Color depth: RGB, 8-bit colors (standard), 16.77 million colors
- Brightness (luminance): 400 cd/m^2
- Contrast Ratio: 1000:1
- Monitor size: 26 to 32 in. recommended.

4K Resolution Compatibility: While the device is capable of being displayed on a 4K resolution monitor, compatibility may vary based on the monitor's manufacturer, model, and specifications.

8. GENERAL DEVICE INFORMATION

8.1. Delivery Inspection

Always check all parts and accessories of the device immediately after receiving the shipment. The manufacturer considers only replacement claims that have been immediately submitted or reported to a sales representative or an authorized service company. DO NOT use a damaged device. DO NOT attempt to repair the device.

Check the delivered equipment for completeness. Compare delivered parts with the enclosed packaging list.

Inspect the CVAC Image Processor, power cable, HDMI cable, and connectors for cuts, cracks, bent pins, exposed wires, contamination, or other damage prior to use.

9. DEVICE STARTUP

9.1. Device Setup

Place the CVAC Image Processor on a level surface (such as an equipment tower) and in a dry environment. The ambient temperature and humidity must meet the requirements mentioned in Section 13 below.

The hospital monitor should be within reach of the 10-foot HDMI cable, usually on an equipment tower or other suitable location. An HDMI-to-DVI adapter is provided if needed.

The single-use CVAC Aspiration System should be prepared for use and accessible to plug into the video cable connection of the CVAC Image Processor.

9.2. Connect Cables and CVAC Aspiration System

Connect the accessories and the CVAC Aspiration System to the CVAC Image Processor.

- Prepare the **CVAC Aspiration System** for use, and connect the System **video cable** to the front port on the CVAC Image Processor.
- Connect the provided HDMI cable end marked "TV" (with or without a DVI adapter) directly to the back of the monitor and the other end marked "SOURCE" to the HDMI output port (on the back of the CVAC Image Processor).
- Connect the supplied **power cable** from the power input on the back of the CVAC Image Processor to a 110 V electrical outlet.

The order in which the cables are connected does not matter.

9.3. Power On the CVAC Image Processor

Power on the CVAC Image Processor using the power button on the front of the unit.

After powering on, the white (top) LED will illuminate.

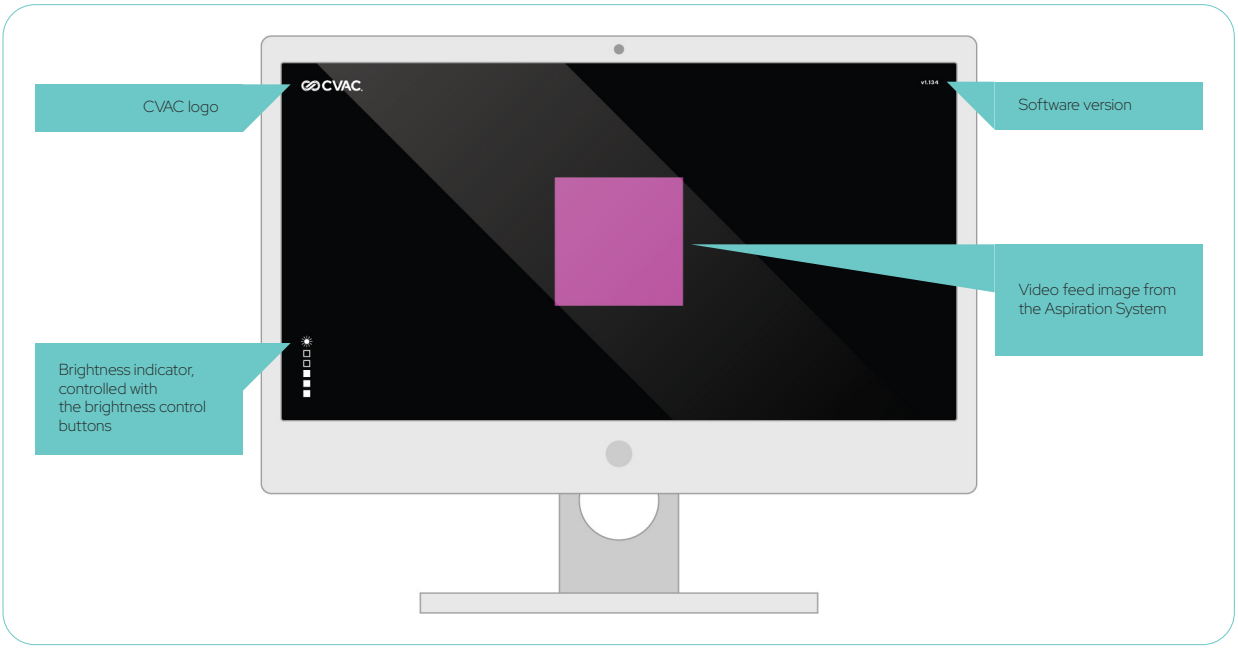
The yellow LED will be solid if the CVAC Aspiration System is not connected.

The green (bottom) LED will illuminate once the CVAC Aspiration System camera is on, the system is functioning, and the live endoscopic view is obtained.

If there is a problem or error, a blinking yellow LED light on the Image Processor will illuminate. See the Troubleshooting section.

The dashboard displayed on a monitor is shown in **Figure 4**. This screen shows the software version, brightness level indicators, and the video feed.

FIGURE 4. Dashboard information



9.4. Perform White Balance

White balance can be performed at the user's discretion by holding a white area (e.g. a white sheet of paper) in front of the tip of the CVAC Aspiration System to fill the screen completely with the white area and pressing the White Balance button on the device.

Press the White Balance button once to accomplish this. Multiple presses will not further change the image.

9.5. Adjust Brightness

Users can make adjustments to the brightness of the displayed image by pressing the positive (+) brightness control button or the negative (-) brightness control button.

9.6. Perform Clinical Procedure

The practicing physician performs the endoscopic urological kidney stone removal procedure.
See the CVAC Aspiration System User Manual (electronically available) for detailed instructions.

9.7. Disconnecting From Power Supply

Press the power button to power down the device and ensure the CVAC Image Processor has shut down completely. Disconnect the power cable from the facility's electrical outlet when the device is not in use.

10. SERVICE, MAINTENANCE, AND SOFTWARE UPDATES

Software updates can only be performed through the external USB port. This USB port is secured by tamper-proof screws and will only accept Calyxo's certified USB drives.

Service and/or software updates may be performed by an authorized service technician. See Troubleshooting section below for user actions that may be taken in the event of errors.

11. CLEANING AND DISINFECTING THE CVAC IMAGE PROCESSOR

The external surfaces of the CVAC Image Processor, provided HDMI cable, HDMI-to-DVI adapter and power cord surfaces as applicable should be thoroughly cleaned and low-level disinfected after use or whenever visibly soiled. The procedure consists of a manual cleaning step followed by a manual disinfection step, as described below.

STEP	INSTRUCTIONS
	Manual Cleaning
1	Use 70% Isopropyl Alcohol (IPA) pre-saturated wipes, or soft non-linting wipes dampened with 70% IPA, to thoroughly wipe the exterior surfaces of the device, using a minimum of one (1) wipe per side of the device. **Pay particular attention to seams, recessed areas, and buttons.** Replace wipes as they become visibly soiled.
2	Using a clean soft-bristled nylon brush wetted with 70% IPA, brush the exterior device seams, housing logo, screws, and other hard-to-clean areas for a minimum of 30 seconds in total. Re-wet the brush as necessary during brushing. Remove residual soil with wipe(s) dampened with 70% IPA.
3	Repeat Step 2 until all visible soil is removed.
4	Allow the device to air-dry.
5	Inspect the device in a well-lit area to ensure all device surfaces are clean. If visible soil is observed, do not proceed to disinfection; repeat the cleaning steps above until the device is visibly clean.
	Manual Disinfection
1	Using low-linting wipes dampened (wet but not dripping) with 70% IPA, thoroughly wipe all exterior surfaces of the device. All surfaces must remain visibly wet for a minimum of five (5) minutes. **Pay particular attention to seams, recessed areas, and buttons.** If needed, use additional wipes to ensure the surfaces remain wet for the full 5-minute dwell duration.
2	Allow the device to air-dry.

Inspection and Damage Check

Visually inspect all components before use and after reprocessing for soil, cuts, cracks, exposed conductors, deformation, discoloration, damaged connectors, or other deterioration. If damage is observed, discontinue use and replace the affected component.

The CVAC Image Processor should be thoroughly cleaned and disinfected immediately after soil is observed on the device. If visible soil remains after cleaning, repeat the cleaning process until clean.

12. TROUBLESHOOTING

TABLE 2. Errors and Troubleshooting Actions

ERROR	TROUBLESHOOTING
Solid yellow LED is on (front of CVAC Image Processor)	• Camera not detected; connect the CVAC Aspiration System to the CVAC Image Processor
Blinking yellow LED is on (front of CVAC Image Processor)	• System error detected. Power-cycle the unit, or contact Customer Service if the error persists
Device does not turn on	• Check the power outlet • Check the power cord • Contact Customer Service
No image on monitor	• Check HDMI and power input connections on the CVAC Image Processor • Check that the CVAC Image Processor is turned on (the top white LED should be illuminated on the front of the CVAC Image Processor) • Check to ensure that all connections have been established properly and cables are plugged in firmly • Check monitor power connection • Check monitor output channel • Check that the monitor has 1920 X 1080p resolution (4K displays should be checked for compatibility) • As a control measure, connect CVAC Image Processor to a different monitor • Connect the CVAC Image Processor to different CVAC Aspiration System • Contact Customer Service
Display color not satisfactory	• Check all cable connections • Perform white balance • Adjust color options from the monitor if available • Contact Customer Service
Distorted image	• Contact Customer Service
Loss of image	• Check device-on indicator (green light) on CVAC Image Processor • Check the monitor output channel • Check the HDMI or HDMI-to-DVI connection • Check the CVAC Aspiration System cable connection to the CVAC Image Processor • Unplug the CVAC Aspiration System from the CVAC Image Processor, and reconnect • Press the power button on the front of CVAC Image Processor to reboot the system • Power-cycle the device by unplugging the power cord from the power outlet. Wait a few seconds, and reconnect the power • Connect CVAC Image Processor to different CVAC Aspiration System • Do not operate the CVAC Aspiration System and CVAC Image Processor if there is no visualization available • Contact Customer Service
Error message persists and does not clear automatically	• Press the power button on the front of CVAC Image Processor to reboot the system • Power-cycle the device by unplugging the power cord from the power outlet. Wait a few seconds, and reconnect the power • Connect CVAC Image Processor to different CVAC Aspiration System • Contact Customer Service

TABLE 3. Error Messages

ERROR OR STATUS MESSAGE	TROUBLESHOOTING
White balance required	• Perform white balance per IFU instructions
White balance complete	• Information text will disappear after 5 seconds
Camera starting. Please wait.	• Informational text
Camera signal not detected. Please replace the CVAC Aspiration System.	• Replace the CVAC Aspiration System. Contact Calyxo Customer Service if the error message persists
CVAC Aspiration System not connected. Please connect a CVAC Aspiration System to continue.	• Connect a new CVAC Aspiration System. Contact Calyxo Customer Service if the error message persists
CVAC Aspiration System unplugged. 1. Power off the Image Processor. 2. Connect a CVAC Aspiration System. 3. Power on the Image Processor.	• Follow steps in the error message. Power-cycle the unit, or contact Customer Service if the error persists
LED signal not detected. Please replace the CVAC Aspiration System.	• Replace the CVAC Aspiration System. Power-cycle the unit, or contact Customer Service if the error persists
Video feed frozen. Please replace the CVAC Image Processor.	• Follow steps in the error message. Contact Calyxo Customer Service if the error message persists
Internal signal not detected. Please replace the CVAC Image Processor.	• Follow steps in the error message. Power-cycle the unit, or contact Customer Service if the error persists
Video delay detected. Please restart the CVAC Image Processor.	• Follow steps in the error message. Power-cycle the unit, or contact Customer Service if the error persists
Low system memory. Please restart the CVAC Image Processor.	• Follow steps in the error message. Power-cycle the unit, or contact Customer Service if the error persists
The CVAC Image Processor internal temperature is high. Please relocate it to a cooler area with better airflow that is away from other equipment.	• Follow steps in the error message. Power-cycle the unit, or contact Customer Service if the error persists

12.1. Return of Device

If it becomes necessary to return the device, contact Customer Service.

The manufacturer does not take responsibility for damage that has occurred during transportation if the damage was caused by inadequate transport packaging.

Please make sure that all required information has been supplied: Owner name, address, device name and serial number, description of problem or issue.

13. TECHNICAL SPECIFICATIONS

13.1. CVAC Aspiration System and CVAC Image Processor Technical Specifications

Refer to CVAC Aspiration System User Manual for CVAC Aspiration System Specifications.

TABLE 4. CVAC Image Processor Specifications

Function	White Balance	Adjust white balance manually
	Brightness	With 20%, 40%, 60%, 80%, 100% level
Operating Environment	Ambient Temperature	10°C to 40°C
	Humidity	15% to 90%
	Air Pressure	700 hPa to 1060 hPa (-1253 ft to 9878 ft)
	Power Supply	AC 100 V to 240 V
	Frequency	50 Hz to 60 Hz
	Environment Condition	Away from the interference of magnetic field
	Ambient Condition	The device should be far away from the interference of strong magnetic field environment
Storage and Transport Environment	Temperature	-18°C to 60°C
	Humidity	15% to 90%
	Air Pressure	500 hPA to 1060 hPa (-1253 ft to 18,281 ft)
Product Use Life	4000 hours over 4 years	
Electric Shock	Class I	
Protect Electric Shock	BF	

13.2. Cybersecurity

Calyxo will provide secure access for customers to access the SBOM, and all customers will be notified of updates to the SBOM through the coordinated vulnerability disclosure process. Please email cvac2sbom@calyxoinc.com to receive the SBOM details for any released software version.

14. 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.

14.1. Guidance and Manufacturer's Declaration – Electromagnetic Emissions

TABLE 5. EMC Emissions

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
Conducted Emissions	CISPR 11 Group 1 Class A	This instrument uses radio frequency (RF) 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.

14.2. 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 6. Electromagnetic Immunity

STANDARD	DESCRIPTION	SEVERITY LEVEL OR LIMIT (IEC 60601-1-2)	SEVERITY LEVEL OR LIMIT (IEC TR 60601-4-2)	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%.

STANDARD	DESCRIPTION	SEVERITY LEVEL OR LIMIT	SEVERITY LEVEL OR LIMIT	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
EN/IEC 61000-4-5:2014 Basic Test Standard	Surge Immunity	±0.5 kV, ±1 kV, ±2 kVCM Line-Gnd ±0.5 kV, ±1 kV, DM Line-Line NA on I/O Ports	±0.5 kV, ±1 kV, ±2 kVCM 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 cycle at 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.
EN 61000-4-8:2010, IEC 61000-4-8:2009 Basic Test Standard	Power Frequency Magnetic Field Immunity test	30 A/m at 60 Hz 3 orthogonal orientations	30 A/m at 60 Hz 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 farther 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	3 Vrms, 6 Vrms in ISM Bands, 0.15 – 80 MHz, AC Mains 3 Vrms, 6 Vrms in ISM Bands, 0.15 – 80 MHz, I/O Ports 80% 1 kHz AM Modulation	3 Vrms, 6 Vrms in ISM Bands, 0.15 – 80 MHz, AC Mains 3 Vrms, 6 Vrms in ISM Bands, 0.15 – 80 MHz, I/O Ports 80% 1 kHz AM Modulation	3 V 0.15 MHz to 80 MHz	Recommended separation distance: 30 cm
EN 61000-4-3:2006: +A1:2008 + A2:2010, IEC 61000-4- 3:2006 + A1:2007 + A2:2010 Basic Test Standard	Radiated Electro-magnetic Field Immunity	3 V/m, 80 – 1000 MHz 3 V/m, 1.4 GHz – 2 GHz 3 V/m, 2.0 GHz – 2.7 GHz 80% 1 kHz AM Modulation	3 V/m, 80 – 1000 MHz 3 V/m, 1.4 GHz – 2 GHz 3 V/m, 2.0 GHz – 2.7 GHz 80% 1 kHz 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 2.1 kHz pulse modulation 65 A/m field strength 13.56 MHz at 50 kHz pulse modulation 7.5 A/m field strength	134.4 kHz at 2.1 kHz pulse modulation 65 A/m field strength 13.56 MHz at 50 kHz pulse modulation 7.5 A/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 ±1 kV on I/O Ports	±2 kV on AC Mains ±1 kV 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	3 Vrms, 6 Vrms in ISM Bands, 0.15 – 80 MHz, AC Mains 3 Vrms, 0.15 – 80 MHz, I/O Ports 6 Vrms, ISM Frequencies, I/O Ports 80% 1 kHz AM Modulation	3 Vrms, 6 Vrms in ISM Bands, 0.15 – 80 MHz, AC Mains 3 Vrms, 6 Vrms in ISM Bands, 0.15 – 80 MHz, I/O Ports 80% 1 kHz 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).

15. WARRANTY

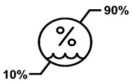
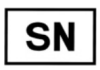
Calyxo, Inc. warrants that reasonable care has been used in the design and manufacture of this device. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied 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.**

Calyxo, Inc.
4473 Willow Road, Suite 100
Pleasanton, CA 94588

Customer Service: 833.214.3354

16. SYMBOLS GLOSSARY

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
REF	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
LOT	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
QTY	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
Rx ONLY	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 reuse	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 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 500 hPa – 1060 hPA	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)