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HTx Disposable Hysteroscope System

Instructions for Use with HTx1000 Image Processing System



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1 Safety and Normal Use

1.1 Warning

- To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.
- The HTx disposable hysteroscope system can be damaged if powered by a voltage higher than the rated one given in the electrical specifications of the system.
- Use of HTx disposable hysteroscope system 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.
- Using incompatible devices in conjugation with the HTx hysteroscope system could result in patient or operator injury and/or equipment damage. It will be the user's sole responsibility for using any devices or components that are not part of the HTx disposable hysteroscope system.
- Unless approved by AcuVu, do not make any change to the system. Do not breach the intended use of the product.
- Use of accessories, transducers and cables other than those specified in the Appendix or provided by AcuVu could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and consequently a void of basic safety or essential performance.
- 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 HTx disposable hysteroscope system, otherwise degradation of the specified performance could occur.
- Note that the electromagnetic emission characteristics of this equipment makes it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- When Surges, Electrical Fast Transient, voltage dip or magnetic field impacts the system, black screen, flashes or image artifacts might appear on the live image. The user should wait till these phenomena disappear to perform diagnosis.
- When Electrical Fast Transient passes the system, it might temporarily cause disfunction of the USB connected devices (keyboard, barcode reader and USB stick). The user might need to unplug and re-plug the impacted device to restore the function.
- Certain frequencies of the conducted disturbances and radiated RF might interfere with the system. Black screen, flashes or image artifacts might appear on the live image. The user should wait till these phenomena disappear to perform diagnosis.
- The HTx disposable hysteroscope system is intended to be used with the tip immersed in water. Do not touch the cannula tip before fluid test to prevent damage by ESD.

- Do not use the hysteroscope in case the cannula tip appears to be unbearable hot. There might be tissue damage and coagulation to patient cervix when trying to insert the cannula into the patient cavity.
- The user should always check if the live video is shown on the screen before inserting the cannula into the patient cavity. If no live image is observed, the user should try connecting and disconnecting the image cable with the hysteroscope up to three times. If still no live video is shown, the cannula might be damaged and should be replaced with a new one.
- Ensure that the HTx Image Processing System has been updated to the latest version of software driver released by AcuVu.
- Installing unauthorized software on the Image Processing System may result in system crash, misdiagnosis and/or wrong treatment.
- Ensure that the system power cord is plugged to the power sockets (e.g., wall outlet, power strip outlet) in a reliable manner.
- Exercise caution with USB memory stick. Don't use any memory stick that might have been compromised, e.g., previously inserted into a computer lacking proper cyber security safeguards.
- Test and inspect the device before each use to verify adequacy for the planned procedure.
 - If a new cannula was not sealed properly, do not use it. Cannulas without intact packaging are not sterile anymore and should not be used. If a cannula is expired, do not use it either.
 - The cannula has standard Luers so exercise caution to connect only the fluids approved by the operating physician.
 - Do not look directly at the LEDs in close proximity as that may damage the user's eyes.
 - If the connection between the cannula and the image cable is loose, or artifacts appears after connecting the cannula to the image cable, one can try pulling out the cable and reconnecting.
 - If there are any issues with the camera/video, LEDs, or software, refer to the Troubleshooting section.
- Take caution when inserting or moving the cannula in patient body. Improper operation of the cannula may cause perforation of the uterus or an injury to the cervix, the surrounding tissue, or anywhere in the vagina.
- If there is a facility power failure during the procedure, carefully withdraw the device from the patient body before conducting any troubleshooting.
- Do not drop or let go of the handle during the procedure.
- If the software crashes, carefully withdraw the device from the patient body before conducting any troubleshooting.
- In case the image blacks out, freezes, flips, or has great artifacts during procedure, immediately and carefully withdraw the device from the patient body before conducting any troubleshooting.
- The HTx disposable hysteroscope system is designed for single use only, do NOT resterilize or reuse the hysteroscope. Reusing a cannula in any form may cause cross

infections and is strictly prohibited. Likewise, do not attempt to use a cannula if the system recognizes it to have already been used.

- Improper disposal of the cannula can lead to contamination of the environment or anything near them and may cause biological hazards. Follow the proper disposal procedure acknowledged by your local regulatory authority.
- If stored under inappropriate conditions, the system may be defective, broken or unusable.
- Using a hysteroscope with an expired shelf life can trigger a warning message by the system and the user will be recommended to switch to a new hysteroscope before expiration date.
- This medical device is not intended for joint use with flammable agents or in oxygen-rich environment.

1.2 Compliance

Name	Value
Electromagnetic Compatibility	Complies with IEC 60601-1-2:2014 Emission: CISPR 11, Class A
Electrical Safety	Complies with IEC 60601-1. Hysteroscope (applied part): Type BF Image Processing System: Class I
Light Safety	Exempt Group per IEC 62471:2006

1.3 Signal Word

The following signal word is used throughout this manual:

















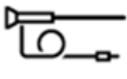






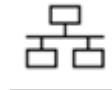

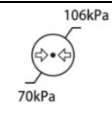


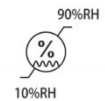
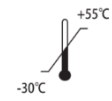
WARNING

Indicates a potential hazardous situation which, if not avoided, could result in injury. It may also be used to alert against unsafe practices or potential equipment damage.

1.4 Symbols and Labels

The meaning(s) of the symbol(s) shown on the package labels, on the device labels, and as referenced in this instruction manual are as follows:

	Catalog number ISO 15223-1:2021		General Warning sign ISO 7010-W001
	Consult Instructions for Use ISO 15223-1:2021		Date of Manufacture ISO 15223-1:2021
	Type BF Applied Part IEC 60417-5333		Use-by date ISO 15223-1:2021

	Do not reuse ISO 15223-1:2021			Do not use if package is damaged ISO 15223-1:2021
	Keep away from sunlight ISO 15223-1:2021			Keep dry ISO 15223-1:2021
	Batch code ISO 15223-1:2021			Manufacturer ISO 15223-1:2021
	Manufacturer brand logo			No pushing ISO 7010-P017
	Prescription device 21 CFR 801.109			Recycle: Electronic Equipment EN50419
	Read operators manual ISO 7010-M002			Serial number ISO 15223-1:2021
	Sterilized Using Ethylene Oxide ISO 15223-1:2021			Equipotentiality IEC 60417-5021
	Endoscope IEC 60601-2-18-101			Warning, electricity ISO 7010-W012
	Electrostatic sensitive devices IEC 60417-5134			Fuse F2AH250V IEC 60417-5016
	Protective Earth IEC 60417-5019			Alternating current IEC 60417-5032
	UDI number			Computer network IEC 60417-5988
	Video output IEC 60417-5029A			Atmospheric pressure limitation ISO 15223-1:2021
	USB port USB IF			Fragile, handle with care ISO 15223-1:2021
	Humidity limitation ISO 15223-1:2021			Temperature limit ISO 15223-1:2021

1.5 Normal Use

1.5.1 Intended Use

HTx disposable hysteroscope system enters the uterine cavity through the cervix for observation and treatment of uterine cavity lesions. HTx disposable hysteroscope system is mainly used to diagnose diseases in the uterine cavity (i.e., uterine polyps, uterine fibroids, endometritis, endometrial cancer, Intrauterine adhesions, etc.). HTx disposable hysteroscope system can also be used in conjunction with surgical instruments as part of a simple procedure, such as endometrial biopsy, IUD removal, and hysteroscopic embryo removal.

AcuVu HTx disposable hysteroscope system is used to permit viewing of the adult cervical canal and uterine cavity for the purpose of performing diagnostic and operative procedure. The HTx disposable hysteroscope system will be used mainly in gynecology, reproductive surgery outpatient operating rooms (day operating rooms), inpatient operating rooms, and doctor's offices. The main population operating HTx disposable hysteroscope system are doctors trained in hysteroscopy and induced abortion.

1.5.2 Indication for Use

HTx disposable hysteroscope system is intended to be used for viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and operative procedures.

1.5.3 Essential Performance

The essential performance of HTx disposable hysteroscope system is: provide continuous video output during hysteroscopic procedure.

1.5.4 Contraindications

The system used for hysteroscopy may be contraindicated by the following conditions depending on their severity or extent:

- Inability to distend the uterus
- Cervical Stenosis
- Cervical/Vaginal infection
- Uterine bleeding or menses
- Known pregnancy
- Known carcinoma of the cervix and/or the uterus
- Recent uterine perforation
- Known Pelvic Inflammatory Disease (PID)
- Medical contraindication or intolerance to anesthesia

WARNING

Suspicion of pregnancy should suggest a pregnancy test before the performance of hysteroscopy.

1.5.5 User Qualification

The operator of this product must be doctors and medical assistants with a relevant specialist qualification.

1.5.6 Instrument Compatibility

Ensure equipment compatibility by referring to the System Description section. Using incompatible modules or accessories may compromise the safety of the patient and/or operator, and it may also result in equipment damage as well as void of warranty.

1.5.7 Reprocessing Before First Use / After Each Use

Unlike the cannula which is sterilized and sealed in individual pouches, the Image Processing System and other optional modules are packed and shipped without sterilization. It is recommended that the user clean and disinfect these items before first use and after each use. Refer to the section Cleaning and Disinfection for details.

1.5.8 Facility Environment

This product is intended for use in a professional healthcare facility environment per IEC 60601-1-2 (e.g., clinics, physician offices and hospitals). Using the instrument in any other environment may void the warranty and compromises the safety of the patient and/or operator.

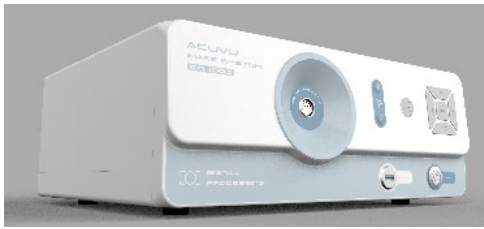
1.5.9 Prohibition of Improper Repair or Modification

Never repair or modify the system by persons other than AcuVu-qualified technicians, otherwise may result in injury of the patient or operator as well as damage to the system. The system does not contain any user-serviceable parts.

In case of any system malfunction that the user cannot solve after referring to Troubleshooting section, please contact AcuVu for technical support.

2 Introduction

2.1 Nomenclature



HTx1000 Image Processing System



HTx Disposable Hysteroscope (applied part)

- The HTx1000 Image Processing System is composed of an Image Processing Unit (control box) and an image cable (for connecting the hysteroscope)
- The HTx Disposable Hysteroscope is the applied part of the device that will directly contact the patient body. It comes in three different models:
 - HTx60 / HTx60s
 - HTx40
- PIMC is the abbreviation for Patient Information Management Component which is an optional software application running on the user's computer.

2.2 Glossary

Term	Description
Field of View	Size of the object field viewed through an optical endoscope, expressed as the vertex angle (in degrees) of the cone whose vertex is at the distal window surface of the endoscope.
Direction of View	Location of the center of the object field relative to the normal axis of the endoscope, expressed as the angle (in degrees) between the normal axis of the endoscope (0°) and the central axis of the field of view.
French (Fr)	Measurement of the size of certain circular or non-circular cross-section endoscopes defined as: $Fr = 3 u/\pi$ where u is the perimeter of the cross-section, expressed in millimeters.
Distal	Any location of that portion of an endoscope which is farther from the user than some referenced point.
Proximal	Any location of that portion of an endoscope which is closer to user than some referenced point.
Graphical User Interface (GUI)	A computer interface that allows the user to interact with a device through graphical elements such as picture icons.
Water / Fluid channel	Portion of an endoscope through which saline or equivalent fluid/water is intended to pass.
Cannula	Sometimes used as a synonym for hysteroscope.

2.3 System Description

2.3.1 General Description

- The AcuVu HTx Disposable Hysteroscope System mainly contains a disposable hysteroscope module (model: HTx40 / HTx60 /HTx60s) and a reusable Image Processing System (model: HTx1000).
- The HTx40 and HTx60/HTx60s hysteroscopes are designed for diagnostic and simple treatment procedures, respectively.
- There're also a couple of optional peripherals for information input/output such as a LCD monitor, a keyboard, a barcode reader and the PIMC software for patient data management.

2.3.2 HTx Disposable Hysteroscope

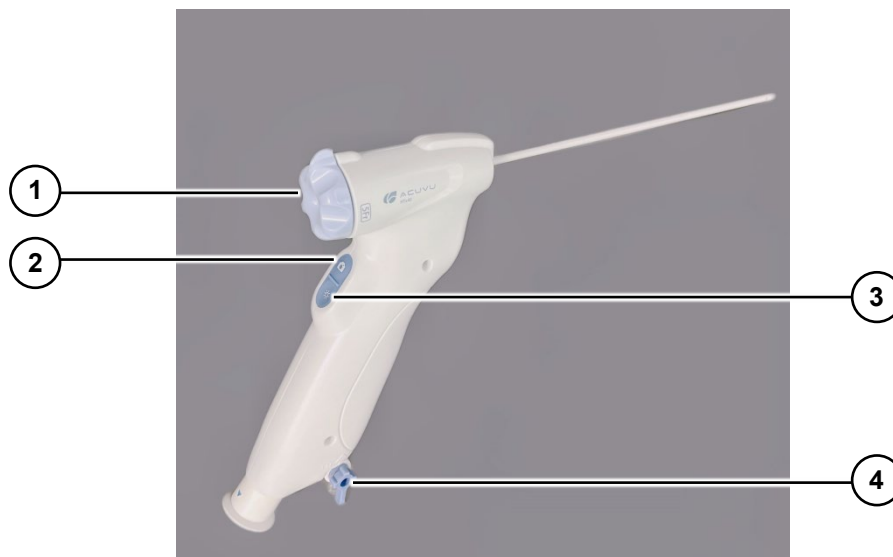


Figure 1 Control elements of hysteroscope

#	Name	Description
1	Rotation knob	Adjusts the Direction of View
2	Photo/Video button	1) To capture a picture: short click (< 2s) 2) To record a video: start by long pressing (>2s), end by a second long pressing.
3	LED control button	Adjusts the intensity of the LEDs at the tip of the cannula
4	Fluid connector	Inflow & outflow with one-way stopcock for on/off control. Continuous flow is achieved when both inflow and outflow stopcocks are opened.

2.3.3 HTx1000 Image Processing System

The HTx1000 Image Processing System is mainly used to process image signal captured from the disposable hysteroscope and present it to a display or to an external PC. It is also used as a central connection hub to external devices through various interfaces.

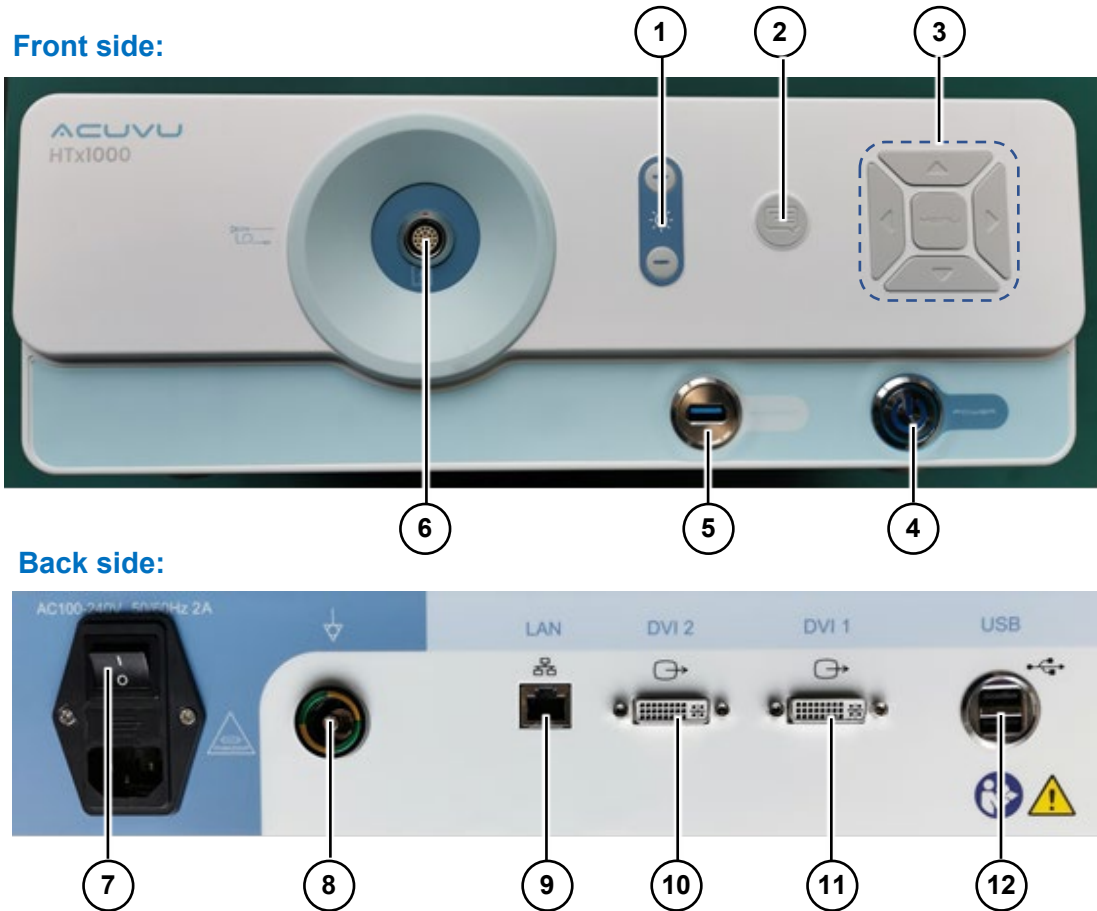


Figure 2 Interfaces of the Image Processing System

#	Name	Description
1	LED control buttons	Adjust the intensity of the LEDs at the tip of the cannula
2	Data Export button	Exports patient data from the embedded SD card to an external USB disk
3	Navigation/Menu buttons	Reviews and changes various system settings: <ul style="list-style-type: none"> Press the central button to show up the system menu Press the four arrow buttons to navigate
4	Power button	Turns on/off the Image Processing System
5	Front USB port	Connects to a peripheral device with USB interface (e.g., keyboard, barcode reader, USB stick, etc.)
6	Image cable socket	Connects to an image cable
7	Power socket	Connects to the power cord and controls power on/off
8	PE socket	Connects to a Potential Equalization cable
9	LAN port (RJ45)	Connects to an Ethernet cable for LAN communication

10	DVI video output ports	For video output to displays via DVI cables
11		
12	Back USB ports (dual)	Able to connect to two external USB devices

2.3.4 Optional Peripherals and Accessories

Please refer to the Appendix for detailed list of optional modules and accessories.

WARNING

- Using incompatible devices in conjunction with the HTx hysteroscope system could result in patient or operator injury and/or equipment damage. It will be the user's own responsibility for using any devices or components that are not part of the HTx disposable hysteroscope system.
- The HTx disposable hysteroscope and Image Processing System can be damaged if powered with a voltage higher than the rated value.
- Make sure the system power cord is plugged reliably at both ends to avoid accidental power off.
- The HTx disposable hysteroscope system needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
- Exercise caution with USB memory stick. Don't use any memory stick that might have been compromised, e.g., previously inserted into a computer lacking proper cyber security safeguards.

2.4 Technical Data

2.4.1 Environment

Operating Environment

Operating Temperature	10° C to 35° C
Operating Relative Humidity	>35% relative humidity
Operating Air Pressure	70Kpa ~ 106Kpa

Storage and Transportation Environment

Temperature	-30° C to 55° C
Relative Humidity	90% RH @ 55° C to 10% RH @ 0° C
Air Pressure	70Kpa ~ 106Kpa

2.4.2 System Performance

Optical Specifications

Direction of View	HTx60: 12° HTx60s: 0° HTx40: 8°
Field of View (FOV)	>115°
Depth of Field (DOF)	5 mm to 50 mm

Electrical Properties

Mains Voltage	100 VAC -240VAC single phase at 50/60 Hz
Mains Supply Current	<10 Amps
Fuse	F2AH250V

Mechanical Properties

Cannula Shaft outer diameter	HTx40: < 4.5 mm HTx60 / HTx60s: < 6.2 mm
Working length	190 mm to 250 mm
Overall length	280 mm to 340 mm
Fluid connector	HTx40 & HTx60: Luer-lock connector HTx60s: 2-in-1 connector (Luer & 1/4" Barb)

Lifetime

Service life of the HTx1000 Image Processing System	5 years
Shelf life of the HTx Disposable Hysteroscope	3 years

3 Device Operation

WARNING

This device should only be operated by trained medical personnel.

3.1 Preparation

3.1.1 Preparing the Image Processing System and Other Modules

- 1) Clean and disinfect the HTx1000 Image Processing System (especially the image cable) and all optional modules (if any) before use.
- 2) Connecting the image cable to the Image Processing Unit. Align the red dot on the image cable connector with the one on the socket of HTx Image Processing System (see the picture below), then apply the insertion. The cable should not be dragged on floor to prevent tripping and stepping of others.

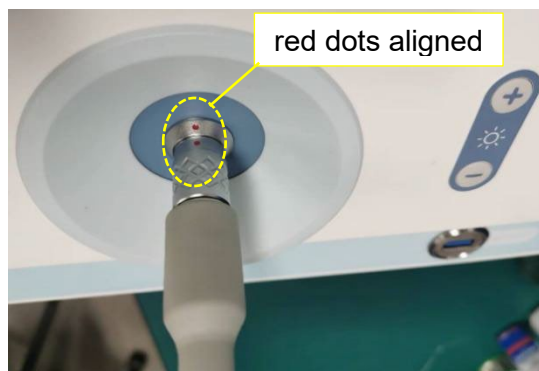


Figure 3 Connecting the image cable to the Image Processing Unit

- 3) Connect Image Processing System to a monitor via the DVI interface and to a keyboard via the USB port (see Figure 2 for details of the connection interfaces).
- 4) Configure the system and image settings using the navigation buttons on the front panel of the Image Processing System. Press the Menu button at the center to show up the Settings Menu (see Figure 4 below), and then use the arrow buttons to navigate and change the respective values for each parameter.

Settings	
Brightness	50
Saturation	50
Hue	50
Contrast	50
Zoom	2X
Mask	Round
Photo Format	JPG
Language	English
White Balance	
System Upgrade	
Password	
Network	
Date & Time	
Storage Clean-up	
Factory reset	
Export Data	
User Mode	Convenient
Save & Exit	

IPC V1.1.5

Figure 4 Image Processing System setting

The function of each item in the Settings Menu as shown in Figure 4 is briefly explained as follows:

Menu	Function
Brightness	Controls the overall brightness of the image
Saturation	Controls the color saturation of the image
Hue	Controls the hue of the image (e.g., to make the image appear more reddish or bluish)
Contrast	Controls the overall contrast of the image
Zoom	Controls the magnification of the image
Mask	Controls the clipping shape of the image
Photo Format	Controls the file format of the saved images
Language	Controls the system language (English or Chinese)
White Balance	Allows the user to do a white balance calibration if the hue of the image appears abnormal. Note Make sure the following conditions are met when you do a white balance calibration: 1) The hysteroscope shall be facing a white piece of paper with its LED light illuminating the paper. The output image appears bright but not saturated yet; 2) The ambient light is dimmed to a minimum level.
System Upgrade	To upgrade the system software
Password	To set the password for user authentication
Network	To set the IP address of the system
Date & Time	To set the date and time of the system
Storage clean-up	To clear the internal SD card used for storing patient data. ! WARNING Clearing the SD card will result in the permanent deleting of all patient data stored on it.
Factory Reset	Reset to factory settings
Export Data	Exports patient data from the embedded SD card to an external USB disk
User Mode	Controls the user mode of the patient data. Two export modes are available for user configuration: Convenient Mode and Normal Mode, please refer to <i>Section 3.3.2 Patient Data Export</i> for details.
Save & Exit	To save the change and exit the system setting.

3.1.2 Inspecting and Unpacking the Hysteroscope

- 1) Each HTx disposable hysteroscope is packed and sealed in a Tyvek-pouched plastic container and has been sterilized by Ethylene Oxide (EO).
- 2) Make sure the expiration date on the hysteroscope label has not passed before use.
- 3) Check that the container's sterilization seal is intact and then peel off the Tyvek cover.
- 4) Take off the fixation plastic piece on the hysteroscope (see figure below) and take out the hysteroscope

- 5) Inspect the cannula. Ensure there is no sharp edges, rough surfaces, or visible damages.



Figure 5 Take off the plastic sheet on the hysteroscope

! WARNING

- Do not use the hysteroscope if the sterile sealing is damaged.
- Do not use the hysteroscope if it is expired.
- Do not touch the cannula tip before running fluid test to prevent damage by electrostatic discharge.
- Do not use the hysteroscope if the distal end of the cannula has a sharp edge.

3.1.3 Connecting and Checking the Hysteroscope

- 1) Align the arrow on the hysteroscope socket and the one on the connector of imaging cable (see the figure below), then insert the connector into the socket to establish a reliable connection.

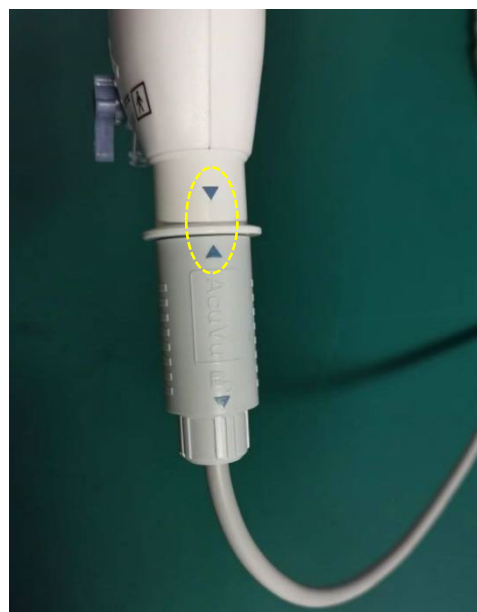


Figure 6 Align the arrows for correct connection

- 2) If possible, apply a sterile drape to cover the cable as shown below. Tighten the drape opening around the ring at the bottom of the hysteroscope handle to prevent leaked fluid from contaminating the cable.

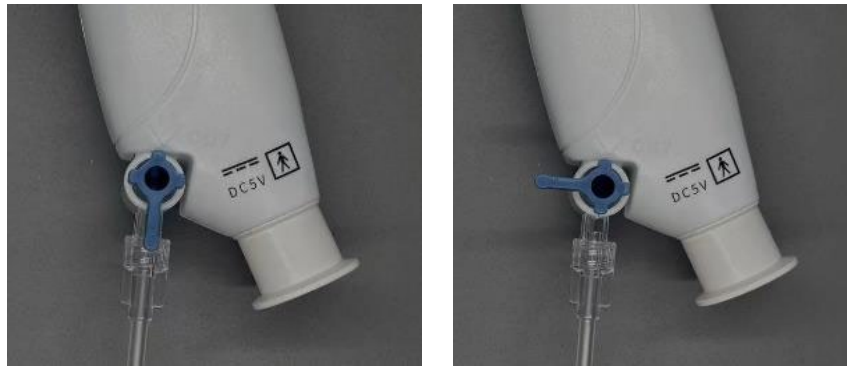


Figure 7 Sleeve the image cable with a sterile drape for anti-contamination

- 3) Check that the live video coming from the hysteroscope and shown on the screen doesn't exhibit any artifacts that prohibits the essential performance of the device.
- 4) Check that both LEDs at the tip of the cannula are illuminating normally.
- 5) The user may want to calibrate the white balance of the camera if a color distortion is observed. To do the white balancing, first turn off the room background lighting, aim the camera at a piece of white paper within a distance from 5mm to 50mm and activate the "White Balance Calibration" menu shown in Figure 4. Keep the cannula still until the white balance calibration is completed.

3.1.4 Flush the Cannula with Distension Fluid

- 1) Close the stopcock of both Luer-lock connectors on the hysteroscope (see Figure 8 below).
Note: if the stopcock grip (the small stick or handle) is parallel to the fluid inflow/outflow direction (as shown in the left figure below), the passage is open. If the grip is perpendicular to the fluid inflow/outflow direction, the passage is closed and no fluid will pass through.
- 2) Connect the inflow tubing to the Luer connector marked with "IN". To enable infusion, the other end of the inflow tubing can be attached to a pre-filled syringe, a fluid infusion pump or a saline bag hung above the ground at about 1m higher than the patient.
- 3) Connect the outflow tubing to the Luer connector with the mark "OUT".
- 4) Test the fluid channel by opening the Luer connectors and see if the fluid runs through the cannula. Flush the fluid through the cannula until all air bubbles have cleared from the tubing.
Note: for HTx60s, it also incorporates a barb connector on top of the Luer connector therefore can mate a 1/4-inch bare water tubing as well.



(a) stopcock opened

(b) stopcock closed

Figure 8 Controlling the open/close of the stopcock

! WARNING

Distension can usually be accomplished with a fluid pressure of 35 - 75 mmHg. Unless the patient's systemic blood pressure is excessively high, pressures greater than 80 mmHg is usually not necessary and can possibly result in complications such as hyponatremia and uterine pain.

The drainage fluid tube in the accessory list is designed for draining the fluid out of the cannula and guiding it into a drainage collection bag. Make sure it connects to the outflow Luer connector marked with "OUT". DO NOT connect it to the inflow port marked with "IN".

3.2 Procedure Start

- 1) When ready, gently insert the cannula into the patient's uterine cavity.
- 2) If the images are too dark, adjust the brightness of the LED illumination by pressing the LED control button on the handle. Multiple pressings of the button will toggle among different intensity levels (0, 20%, 40%, 60%, 80% and 100%) in cycles.
- 3) During the procedure, the user can take photos or record videos conveniently by short or long pressing of the Photo/video button on the handle.
- 4) If needed, the user can slightly shift the Field of View by rotating the knob at the top of the handle. This allows the user to enlarge the observable area in the uterine cavity. Note that the image orientation will remain unchanged when the knob is being rotated, which is a favorable feature for many physicians.

! WARNING

- If image artifacts (strip, flicker, etc.) or black screen is observed after plugging the image cable to the hysteroscope, one should try unplugging and re-plugging the cable once again. If the image abnormality does not vanish after the plugging/unplugging operation has been repeated for 3 times, the user should try with another hysteroscope. If the problem still exists, then the image cable may need to be replaced.
- In case the image blacks out, freezes, flips, or has great artifacts during the procedure, immediately and carefully withdraw the cannula from the patient body before conducting any troubleshooting.
- The user should carefully monitor the pressure and flow rate of the distension fluid. If abnormal uterus pressure is observed, carefully withdraw the cannula from the patient body and check if any tissue debris or silt is blocking the fluid channel.

- Fluid intake and output shall be strictly monitored during the procedure. Intrauterine instillation exceeding 1000ml should be followed with great care to prevent fluid overload of the patient.

3.3 Patient Data Management

3.3.1 Patient Registration

The HTx Image Processing System allows the user to quickly register patient information and store the associated videos and images for future review purposes.

Patient registration can be done in either of the following ways:

- Basic method: when there's no menu shown on the screen, hit the Enter key of the keyboard and you will see a dialog box popping out, then input the patient ID, patient name, and other information using the keyboard.
- Efficient method: attach an optional barcode reader to one of the USB ports on the Image Processing System and use the device to scan the patient barcode. All patient information will be registered automatically once the scanning is done.

All videos and images will be stored in a folder specific to the currently registered patient.

3.3.2 Patient Data Export

The patient data would be stored on the SD card inside the Image Processing System for 30 days if the storage space is not used up. It is suggested that the user export the data to an external storage device (a hard drive or USB stick) for backup on a regular basis.

- 1) Insert an external storage device into the one of the USB ports on the Image Processing System.
- 2) Click the Data Export button on the front panel (see Figure 2). The exporting process may take several seconds to a couple of minutes depending on the data volume to be exported.

Note:

- All data on the SD card will be exported automatically. The user cannot selectively export the data of a particular patient.
- Once exported, the original data will be cleared to release storage space for new data.
- The supported file system format of the external storage device is NTFS and FAT32.
- The user can switch the user mode through the System Setting menu of the Image Processing System (see "User Mode" in Figure 4). When "Convenient Mode" is active, exporting files does not require entering a password for authentication. If "Normal Mode" is active, however, the user will be asked to pass the authentication before data export can be done.
- The default password for exporting the data is **acuvu123**. The user is encouraged to set his/her own password through the System Setting menu of the Image Processing System (see "Password Settings" in Figure 4).

3.3.3 Patient Data Management on External PC

The HTx Hysteroscope System comes with an optional software called Patient Information Management Component (PIMC) which runs on the user's PC and communicates with the Image Processing System through an Ethernet cable. The PIMC can display and record live video/pictures, or backup the recorded data in the Image Processing System to create, save and print patient reports on user's computer. For detailed description please refer to the user manual of PIMC.

Note:

The PIMC is a proprietary software application. To activate the PIMC, a USB dongle provided by AcuVu has to be attached to the user's computer. Please contact AcuVu sales representative or dealer for more information about the dongle.

! WARNING

The video / images displayed on the external PC are for reference only, please do NOT use them for diagnostic purposes.

3.4 Post Procedure

3.4.1 Unplugging the Image Cable from the Hysteroscope

To unplug the image cable from the hysteroscope, firmly hold the cylindrical sleeve of the cable connector using your thumb finger and index finger, and then pull it along the direction as indicated in the figure below to release the connector.



Figure 9 How to pull out the cable connector from the hysteroscope

! WARNING

- Pulling other parts of the cable other than the one indicated in the figure above will not help release the locking buckle of the connector and will fail to unplug the cable.
- Before unplugging the cable connector, make sure there's no fluid leaking out and dripping down the handle, otherwise the fluid may drop into the opening of connector when it's pulled out, resulting in malfunctions of the cable and image artifacts.

3.4.2 Disposal of the Single-Use Hysteroscope

The disposal of hysteroscopes should be done after each procedure.

- First remove the fluid tubing, then disconnect the used cannula from the imaging cable. Place the cable in a safe place for next time use.
- Follow hospital or clinic biohazard handling procedure. Find a safe, isolated bin to temporarily store the used cannulas so that they won't contaminate the air or the surrounding environment.

 **WARNING**

- The HTx disposable hysteroscope must be disposed after the procedure and should not be re-used for another patient.
 - Do not use a cannula if the system recognizes it to have already been used. Reusing a cannula in any form may cause infections or other hazardous exposures to foreign microbes.
 - The used cannula must be disposed of as biohazardous waste according to the safety regulations of the user's facility/institution and local government.
-

4 Cleaning and Disinfection

After performing each procedure, the user should clean and disinfect the cables, the Image Processing System, and all peripheral devices & reusable accessories touched or used in the procedure.

Note: AcuVu recommends that the HTx Image Processing System, the display monitor, and all peripherals (keyboards, barcode readers, etc.) be cleaned and disinfected on a daily basis, and the image cable to be cleaned and disinfected after each procedure.

4.1 Cleaning and Disinfecting the Image Cable

Follow the instructions below to clean and disinfect the image cable:

- 1) Use a piece of non-woven cloth soaked with 70% isopropyl alcohol (IPA) to wipe down the cable (especially the connector where there are grooves or seams that are easy to host dirt/soil). Remove all visible contamination on the cable surface by the wiping, then discard the cloth.
- 2) Repeat the cleaning using another piece of cloth soaked with 70% IPA. Continue the wiping for at least 30 seconds to make sure all surfaces are wetted and cleaned. Discard the cloth.
- 3) Use a third fresh piece of cloth soaked with 70% IPA to thoroughly wipe the cable, especially the connector to the cannula. Keep all touchable surfaces of the cable visibly wet for about 3 minutes.
- 4) Air dry the cable before use.

WARNING

During the cleaning process, hold the cable with the opening of connector facing upward so that the cleaning agent will not flow into the connector through any tiny seams. Be careful not to wet the opening or the inside of the connector.

4.2 Disinfection of Other Modules

To clean other modules (Image Processing Unit, keyboard, display, etc.), please follow the procedure below as a reference:

- 1) Power off the device to be cleaned.
- 2) Use a piece of non-woven cloth soaked with 70% isopropyl alcohol (IPA) to wipe all surfaces of the device and remove all visible stain/soil. Discard the cloth.
- 3) Use a new piece of non-woven cloth with 70% IPA to thoroughly clean and wet the surfaces. Make sure the surfaces remain clearly wet for 3 minutes.
- 4) Air dry the device.

WARNING

During cleaning/disinfecting, take special care to prevent excessive liquid from entering the sockets or ports of the power supply, USB, LAN, or DVI interfaces.

5 Troubleshooting

The information in this section is intended to provide simple guidance for users to find simple solutions to some basic problems that he/she may encounter. For any issue beyond the scope of this basic troubleshooting guide, please contact the AcuVu service personnel.

Problem	Action
<p>No video output but just a message on screen saying “No signal detected. Please check endoscope or cable connection”</p>	<p>Follow the steps below until you see the video on screen:</p> <ol style="list-style-type: none"> 1. Make sure the image cable is fully inserted at both ends. 2. Unplug the cable from the canula and re-plug it. Repeat this operation for up to 3 times until you see the video 3. Reboot the Image Processing System 4. Replace the cannula with a new one. 5. Replace the cable with a new one. 6. Contact AcuVu Customer Service
<p>The menu button and data export button on the front panel do not work</p>	<p>Reboot the image processor and check if there’s a message on the screen indicating “Error Code: B01”. If yes, there may be some faults on front panel PCBA. Before contacting AcuVu Customer Service for solving the PCBA problem, you can temporarily achieve the button functions using a keyboard:</p> <ol style="list-style-type: none"> 1. Connect a keyboard to the USB port of HTx1000 2. Press “→” button of the keyboard to show up the menu on screen. 3. Navigate the menu items using “↑” and “↓” buttons. 4. Change the system setting using “←”, “→” and “Enter” button. If you want to export patient data, navigate to the “Export Data” item and press “Enter” button. 5. Exit system menu by pressing “Esc” button.
<p>Image has strips, flickers, or suddenly freezes / blacks out</p>	<ol style="list-style-type: none"> 1. Withdraw the cannula from the patient body. 2. Check if the cable connector is wetted inside by leaked fluid. If yes, replace the cable. 3. If problem still exists, ensure the cable is firmly inserted. Disconnect and reconnect the cannula for up to 3 times.
<p>Image is too dark</p>	<ol style="list-style-type: none"> 1. Check if both LEDs are illuminating. If not, try re-plugging the cable connector or replacing the cannula. 2. Increase the LED intensity by pressing the LED brightness control button on the handle.
<p>No data transferrable to an external USB storage device.</p>	<p>Make sure the file system format of the USB storage device is either NTFS or FAT32. Other formats are currently not supported by the Image Processing System.</p>

The user forgets his/her password for data export.	Contact AcuVu Customer Service to reset the password.
Fail to launch the PIMC	<ol style="list-style-type: none"> 1. Make sure you have inserted the associated USB dongle to your computer. 2. Reboot the computer and run the software again.
The PIMC gets stuck and is not responding.	Close the software and run it again. If the problem persists, reboot the computer.

6 Service and Maintenance

6.1 Software Update

The user can check the version of software embedded in HTx Image Processing System by simply clicking the “Menu” button on the front panel. The version information will be shown at the bottom of the System Setting window that pops up. In case a new version has been released, please contact AcuVu Customer Service for updating.

6.2 Data Backup

It is recommended that the user backup the data from the embedded SD card to an external USB storage device on a regular basis. Note that the maximum duration that the data can exist on the SD card is 30 days, beyond that period the system will prompt a warning message asking the user if the data should be exported or otherwise be deleted automatically.

6.3 Regular Inspection

Regardless of the customer’s national accident prevention regulations and testing intervals for medical devices, it is recommended that safety inspection of the Image Processing System be performed on an annual basis according to IEC 62353. Detailed specifications regarding the scope and execution of the safety inspection can be found in the service manual.

6.4 Warranty

The HTx Image Processing System is warranted to be free from defects in workmanship and materials for 12 months from date of sale. If failure occurs from such defects during the applicable warranty period, AcuVu will repair or replace the defective item at no charge to the customer.

Note:

- This warranty is valid only if the product is supplied to the end user by an AcuVu approved agent or distributor and has been operated and maintained in compliance with the procedures given in this manual.
- For all reusable accessories or optional modules of the system, warranty will be determined according to the policy of the original equipment manufacturer.

7 Electromagnetic Compatibility (EMC)

7.1 General Notes

- Use of HTx disposable hysteroscope system 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.
- Use of accessories, transducers and cables other than those specified in the Appendix or provided by AcuVu could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment.
- The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If it is used in a residential environment (for which CISPR 11 Class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- The HTx disposable hysteroscope system is intended to be used with the tip immersed in water. Do not touch the cannula tip before fluid test to prevent damage by ESD (ElectroStatic Discharge).
- When ESD, surges, Electrical Fast Transient (EFT) or voltage dip strikes the system, black screen, flashes or image artifacts might appear on the live image. The user should wait till these phenomena disappear to perform diagnosis.
- When severe EFT passes through the system, it might temporarily cause disfunction of the USB connected devices (keyboard, barcode reader and USB stick). The user might need to unplug and re-plug the impacted device to restore the function.

7.2 Electromagnetic Emissions

This product is suitable for use in professional healthcare facility environment, e.g., physician offices, clinics and hospitals (outside the HF-shielded room of an ME system for MRT). It complies with the following emission requirements:

Test item	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group1	This product doesn't have any RF transmitters. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	The instrument's harmonic emissions are low and are not likely to cause problems in the typical power supply connected to this instrument
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	The instrument's inrush current and rated current is very low and therefore has little effect such as flicker.

7.3 Electromagnetic Immunity

The product is intended for use in a professional healthcare facility environment with the electromagnetic condition specified in the table below. Using the product in an electromagnetic environment with higher disturbances than the specified level may result in degradation or total loss of the essential performance and phenomenon like severe image artifacts (e.g., image flips, heavy flickers, image freeze or even black screen) could be encountered.

Test item	Test and compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for ac power lines ±1 kV for input/output lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV line-to-line ±2 kV line-to-ground	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips and interruption IEC 61000-4-11	Dip: 0% U_T , 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T ; 1 cycle and 70% U_T ; 25/35 cycles, Single phase: at 0° Interruption: 0 % U_T 250/300 cycle	If the user of HTx disposable hysteroscope system requires continuous operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery.
Magnetic fields at the power frequency (50/60 Hz) IEC 61000-4-8	30A/m, 50Hz and 60Hz	Power frequency magnetic fields should be at levels typical of business and hospital environments.
Radiated RF EM fields IEC 61000-4-3	3 V/m, 80 MHz - 2.7 GHz, 80% AM at 1 kHz	Field strengths from fixed RF transmitters (e.g., base stations for cellular phones, radio broadcast and TV broadcast) as determined by an electromagnetic site survey, should be less than the compliance level 3V/m (also applies to frequency range 150 kHz to 80 MHz). If the measured field strength exceeds this level, the product should be observed to verify normal operation. If abnormal performance is observed (e.g., image artifacts), additional measures such as re-orienting or relocating the system may be necessary.
Conducted disturbances included by RF field IEC 61000-4-6	3 V, 150 kHz – 80 MHz, 6 V in ISM bands between 0.15 MHz – 80 MHz, 80% AM at 1 kHz	Portable RF communication 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 HTx disposable hysteroscope system, including cables specified by the manufacturer. Note: interference may occur in the vicinity of equipment marked with the following symbol: 

Proximity fields from RF wireless communication equipment IEC 61000-4-3	Table 9 of IEC 60601-1-2:2014, please refer to Section 7.3.2 for details.	Portable RF communication 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 HTx disposable hysteroscope system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this product could occur.
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7.3.1 Test Levels for Proximity Fields from RF Wireless Communication Equipment

Frequency (MHz)	Modulation	Test level
385	Pulse modulation, 18 Hz	27 V/m
450	FM, +/-5 kHz deviation, 1 kHz sine	28 V/m
710, 745, 780	Pulse modulation, 217 Hz	9 V/m
810, 870, 930	Pulse modulation, 18 Hz	28 V/m
1720, 1845, 1970	Pulse modulation, 217 Hz	28 V/m
2450	Pulse modulation, 217 Hz	28 V/m
5240, 5500, 5785	Pulse modulation, 217 Hz	9 V/m

Appendix: Cables and Accessories

Cables for EMC compliance			
No.	Name	Manufacturer / Length	Model
1	Power cord	Yung Li / 2.8m	YP-18/YC-12
2	Image cable	AcuVu / 2.5m	HTx250
3	PE cable	Shenzhen Brilliant / 3m	LS01007
4	DVI cable	Jusha / 2.9 m	/

Accessories List			
No.	Device	Model	Manufacturer
1	LCD monitor	E240AG	Jusha
2	Silicone keyboard	CleanType Prime Pro+ KSI-U10200	Gett
3	Barcode reader	14952	Deli
4	Drainage fluid tube	5.0mm*6.7mm*1000mm	AcuVu
5	Disposable sterile drape	150*15.2cm	AcuVu



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