SEE CLEARLY

TREAT SIMPLY

HTx Disposable Hysteroscope System

Instructions for Use with HTx2000 Image Processor

E2-200066-PL-60001_HTx Disposable Hysteroscope System_UM_Rev-C1_EN_20250623

ACUVU

Table of Contents

1 Safety and Normal Use

1.1 Signal Word

The following signal words are used throughout this manual:

⚠ WARNING	Indicates hazards that, if not avoided, could result in serious injury, device breakdown, or severe property loss.
⚠ CAUTION	Indicates hazards that, if not avoided, could cause minor or moderate injury, device disfunction, or property damage.
NOTE	Indicates additional helpful information for device operation but is not safety related.

1.2 Warnings and Cautions

⚠ WARNING

- To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth if it's not operating in battery-powered mode.
- 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 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.
- 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.
- 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.

- Installing unauthorized software on the Portable Image Processor may result in system crash, misdiagnosis and/or wrong treatment.
- 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.
- Exercise caution with an external display. The display is supposed to meet the standards IEC 60601-1 and IEC 60601-1-2 to guarantee adequate electromagnetic compatibility (EMC) and safety, otherwise a void of basic safety or essential performance of the entire system could occur.
- Avoid using HTx disposable hysteroscope system in the same room with the following devices. If such use is necessary, it must be verified in advance that this device receives no obvious disturbances from other equipment operating at the same time
    - MRI devices.
    - Diathermy devices.
    - Electrocautery devices.
    - Wireless power transfer devices.
    - 5G cellular devices.
- The HTx disposable hysteroscope 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 that it has 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 that passes the expiration date can trigger a warning message by the system and the user will be recommended to switch to a new hysteroscope.
- This medical device is not intended for joint use with flammable agents or in oxygen-rich environment.

⚠ CAUTION

- 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.
    - Always connect to 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, try unplugging the cable and reconnecting.
- 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.

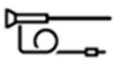
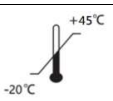
- When Surges, Electrical Fast Transient, voltage dip or magnetic field impacts the system, black screen, flashes or image artifacts might appear on the live image. The user should wait till these phenomena disappear to perform diagnosis.
- When Electrical Fast Transient passes the system, it might temporarily cause disfunction of the USB connected devices (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.
- 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.
- Ensure that the system power cord is plugged to the power sockets (e.g., wall outlet, power strip outlet) in a reliable manner.
- 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.
- 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.
- Ensure that the software of HTx2000 Portable Image Processor has been updated to the latest version.

1.3 Compliance

Name	Value
Electromagnetic Compatibility	Complies with IEC 60601-1-2:2014 + A1:2020 Emission: CISPR 11, Class A
Electrical Safety	Complies with IEC 60601-1. Hysteroscope (applied part): Type BF Portable Image Processor: Class I
Light Safety	Exempt Group per IEC 62471:2006

1.4 Symbols and Labels

The meanings of the symbols 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
	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's brand logo		Distributor ISO 15223-1:2021
	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		Date of Manufacture ISO 15223-1:2021
	Endoscope IEC 60601-2-18-101		Warning, electricity ISO 7010-W012
	Electrostatic sensitive devices IEC 60417-5134		Protective Earth IEC 60417-5019
	UDI number		Alternating current IEC 60417-5032
	Video output IEC 60417-5029A		Computer network IEC 60417-5988
	USB port USB IF		Atmospheric pressure limitation ISO 15223-1:2021
	Humidity limitation ISO 15223-1:2021		Fragile, handle with care ISO 15223-1:2021
	Temperature limit (for PIP) ISO 15223-1:2021		Lithium-ion Battery Operation Label IATA DGR

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.

The 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 Essential Performance

The essential performance of the HTx disposable hysteroscope system is: provide continuous imaging without distortion that affect diagnosis or treatment.

1.5.3 Indications 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.

Note: Hysteroscopes are used as tools for access to the uterine cavity and are not, in and of themselves, a method of surgery.

Diagnostic Hysteroscopy

- Abnormal Uterine Bleeding
- Infertility & Pregnancy Wastage
- Evaluation of Abnormal Hysterosalpingogram
- Intrauterine Foreign Body
- Amenorrhea
- Pelvic Pain

Operative Hysteroscopy

- Directed Biopsy
- Removal of Submucous Fibroids and Large Polyps
- Submucous Myomectomy
- Transection of Intrauterine Adhesions
- Transection of Intrauterine Septa
- Endometrial Ablation

1.5.4 Contraindications, Warnings and Precautions

The HTx disposable hysteroscope system is contraindicated for use in:

- 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
- Acute Pelvic Inflammatory Disease (PID)
- Medical contraindication or intolerance to anesthesia

Contraindications to Endometrial Ablation

Hysteroscopic endometrial ablation, whether by laser or electrosurgery, should not be undertaken without adequate training, preceptorship, and clinical experience. Additionally, endometrial biopsy should be performed prior to any ablation. The following are clinical conditions that can significantly complicate hysteroscopic endometrial ablation:

- Adenomatous Endometrial Hyperplasia
- Uterine Leiomyoma
- Severe Adenomyosis
- Pelvic Pain (Subtle PID)
- Uterine anomalies

Contraindications to Hysteroscopic Myomectomy

Hysteroscopic myomectomy should not be undertaken without adequate training, preceptorship, and clinical experience. The following are clinical conditions that can significantly complicate hysteroscopic myomectomy:

- Severe anemia
- Inability to circumnavigate a myoma due to myoma size. (e.g., predominantly intramural myomas with small submucous components).

⚠ WARNING

- For use only by physicians trained in hysteroscopy.
- Suspicion of pregnancy should suggest a pregnancy test before the performance of hysteroscopy.

For Continuous Flow Hysteroscopy:

If a liquid distention medium is used, strict fluid intake and output surveillance should be maintained. Intrauterine instillation exceeding 1 liter should be followed with great care to the possibility of fluid overload.

Potential Complications of Continuous Flow Hysteroscopy:

- Hyponatremia
- Hypothermia

- Uterine perforation resulting in possible injury to bowel, bladder, major blood vessels, and ureter.
- Pulmonary edema
- Cerebral edema

⚠ CAUTION

- Vaginal ultrasonography before hysteroscopy may identify clinical conditions that will alter patient management.
- Intrauterine distension can usually be accomplished with pressures in the range of 35-75 mmHg. Unless the systemic blood pressure is excessive, it is seldomly necessary to use pressures greater than 75-80 mmHg.

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 Portable Image Processor and other optional modules are packed and shipped without sterilization. It is recommended that the user clean and disinfect some of 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

In case of any system malfunction that the user cannot solve after referring to Troubleshooting section, please contact a local representative for technical support.
The system does not contain any user-serviceable parts. Never repair or modify the system by persons other than qualified technicians.

2 Introduction

2.1 Nomenclature

HTx2000 Portable Image Processor（PIP）

HTx Disposable Hysteroscope with and without a connection cable

- The HTx2000 Portable Image Processor (PIP) includes an image cable that connects to the disposable hysteroscope.
- The HTx Disposable Hysteroscope is the applied part of the device that will directly contact the patient body. It comes in following different models:
  - Hysteroscope with an integrated connection cable: HTx40-L / HTx60-L / HTx60c
  - Hysteroscope without a connection cable: HTx40 / HTx60 / HTx60s / HTx60t

Note: The listed devices may not be available in all countries. Please contact your local representative.

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 μ/π where μ 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 new-generation HTx Disposable Hysteroscope System mainly contains a disposable hysteroscope (model: HTx40 / HTx60 / HTx60s / HTx60t / HTx40-L / HTx60-L / HTx60c) and a reusable Portable Image Processor (model: HTx2000).
- The HTx hysteroscopes are mainly designed for diagnostic and simple treatment procedures, respectively.
- There're also a couple of optional peripherals for information input/output such as a barcode reader.

2.3.2 HTx Disposable Hysteroscope

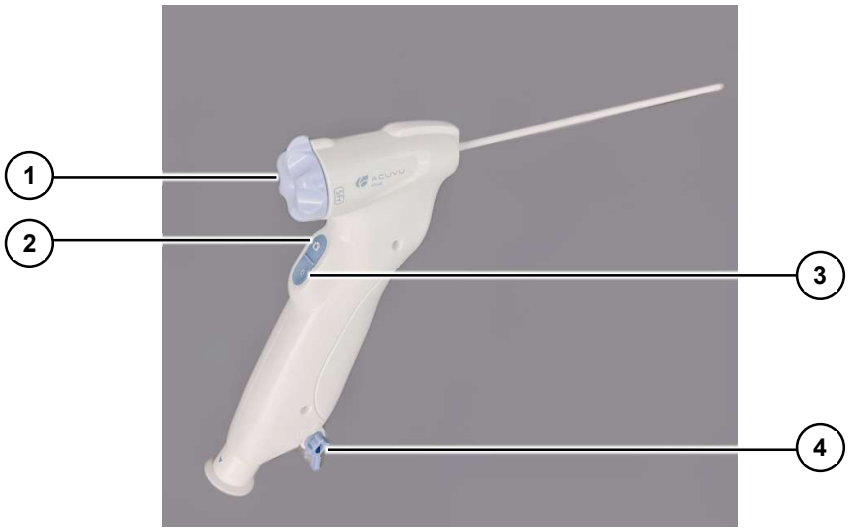


Figure 1 Control elements of hysteroscope

#	Name	Description
1	Rotation knob	Rotate to adjust the Direction of View. The hole at the knob center is for tool insertion.
2	Photo/Video button	1) To capture a picture: single tap / short pressing (< 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 HTx2000 Portable Image Processor

The HTx2000 Portable Image Processor is mainly used to process image signal captured from the disposable hysteroscope and present it on the screen or to an external display. It is also used as a central connection hub to external devices through various interfaces.

Figure 2 Interfaces of the Portable Image Processor

#	Name	Description
1	Power button	Turns on/off the Portable Image Processor
2	Image cable socket	Connects to the HD image cable
3	Power socket	Connects to the power cord and controls power on/off
4	USB ports	Connects to a peripheral device with USB interface (e.g., barcode reader, printer, USB stick, etc.)
5	LAN port (RJ45)	Currently disabled and reserved for future use
6	HDMI video output port	For video output to external display

2.3.4 Optional Peripherals and Accessories

Please refer to the Appendix 1 for detailed list of optional modules and accessories.

⚠ WARNING

- 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 own responsibility for using any devices or components that are not part of the HTx disposable hysteroscope system.
- The HTx disposable hysteroscope and Portable Image Processor can be damaged if powered with a voltage higher than the rated value.
- 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.
- Exercise caution with an external display. The display is supposed to meet the standards IEC 60601-1 and IEC 60601-1-2 to guarantee adequate electromagnetic compatibility (EMC) and safety, otherwise a void of basic safety or essential performance of the entire system could occur.

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	-20°C to 45°C (PIP) -30°C to 55°C (hysteroscope)
Relative Humidity	90%RH@55°C ~ 10%RH@0°C
Air Pressure	70Kpa ~ 106Kpa

2.4.2 System Performance

Optical Specifications (cannula)

Direction of View	HTx40 / HTx40-L: 8° HTx60: 12° HTx60s / HTx60t / HTx60-L /HTx60c: 0°
Field of View (FOV)	>115°
Depth of Field (DOF)	5 mm to 50 mm

Electrical Properties (PIP)

Power Supply	
AC Power	100-240V~, 50/60 Hz, 70VA
DC Power	12VDC, 3.34A
Battery	
Battery Type	7.2 VDC, 9.8 Ah
Battery Operation Time	≥ 6 hours
Battery Charging Time	6 hours
Battery Life	< 30% capacity degradation at 300 cycles of recharging-discharging
Memory	
Storage Capacity	32GB
Display	
Resolution	1920 x 1080 pixels
Display Type	13.3” color TFT LCD
Interface	
2×USB ports	USB2.0
LAN port	Ethernet RJ45 connector
Video port	HDMI

Mechanical Properties

Portable Image Processor	
Dimension（L×H×W）	324mm×46mm×203mm
Weight	2 Kg
Cannula	
Outer diameter	HTx40 / HTx40-L: < 4.5 mm HTx60 / HTx60s / HTx60t / HTx60-L / HTx60c: < 6.2 mm
Working length	190 mm to 250 mm
Overall length	280mm to 340mm
Fluid connector	HTx40 / HTx40-L / HTx60: Luer-lock connector HTx60s / HTx60t / HTx60-L / HTx60c: Luer-lock & Barbed connector

Lifetime

Portable Image Processor	
Service life	5 years
Cannula	
Shelf life	3 years

3 Device Operation

⚠ WARNING

This device should only be operated by trained medical personnel.

3.1 Preparation

3.1.1 Preparing the Portable Image Processor and Other Modules

1) Clean and disinfect the HTx2000 Portable Image Processor and all optional modules (if any) before use. Sterilize the HD image cable if needed.
2) Unfold the supporting plate on the back of the PIP and make it stand on a solid flat surface.
3) Connect the HD image cable to the PIP. Do not drag the cable onto the floor to prevent inadvertent tripping and stepping.
4) Turn on the PIP by pressing the power button on its side. A live image will appear on the screen if a hysteroscope is connected.
5) Check the battery indicator in the upper right corner of the screen. The color of the battery icon indicates the power level. It is recommended to charge the portable image processor if the battery icon is red (see Figure 3 below).

Red: ≤ 20% | Yellow: > 20%, ≤ 40% | White: > 40% | Green with lightning: charging

Figure 3 Battery level and charging indicators

The following table indicates the remaining use time at each battery level.

Battery level	100%	80%	60%	40%	20%	10%
Remaining use time (h)	6.8	5.3	3.8	2.3	1	0.5

To charge the battery, connect one end of the power plug to a mains socket and insert the other end into the power socket on the side of the Portable Image Processor.

6) Connect the Portable Image Processor to an external display via the HDMI port if needed (see Figure 2 for details of the connection interfaces).
7) Configure the image settings by adjusting the setting sliders or pressing the setting buttons. Please refer to Section 3.3.5 for details.

⚠ WARNING

Before powering on the device for the first time, please connect the DC power adapter and charge the device for 6 hours.

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 4 Take off the plastic sheet on the hysteroscope

⚠ CAUTION

- 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 (for HTx40 / HTx60 / HTx60s / HTx60t) or connector socket (for HTx40-L / HTx60-L / HTx60c) 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.

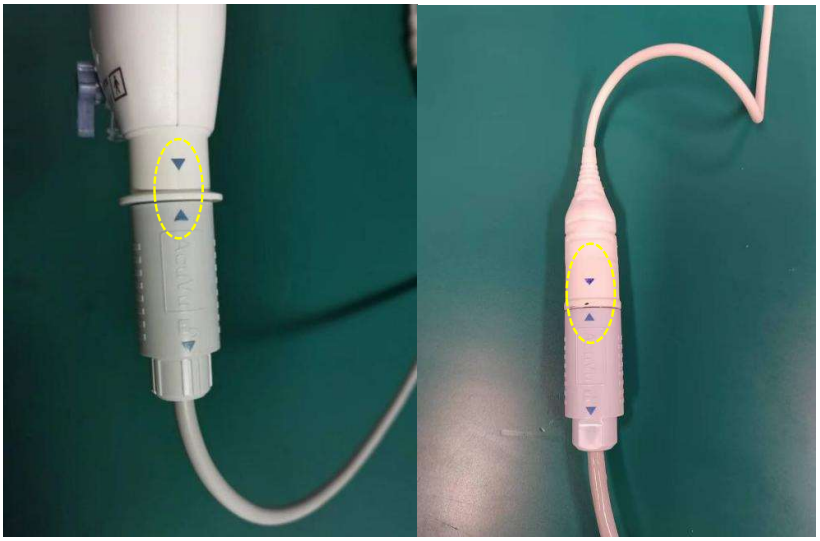


Figure 5 Align the arrows for correct connection

2) If necessary, 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 6 Sleeve the image cable with a sterile drape for anti-contamination

3) Check that the live video 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 then activate the white balance calibration by tapping the icon in the Image Settings pane on the right. Keep the cannula still until the white balance calibration is completed.

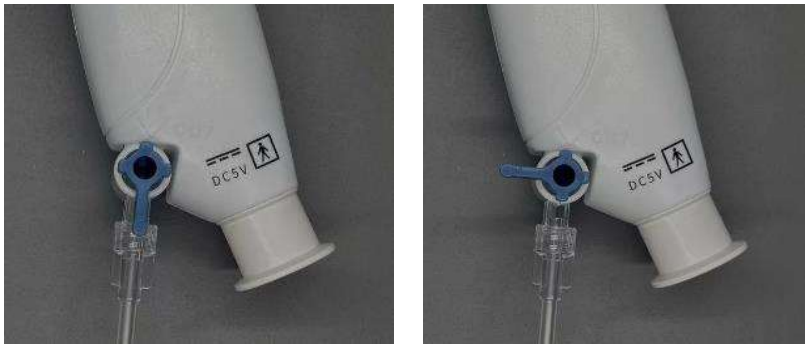
3.1.4 Procedure Pack

1) The Procedure Pack consists of three essential accessories for completing a hysteroscopy procedure:
   - inflow tubing,
   - outflow drainage tubing,
   - under buttocks drape
2) Unfold and place the under buttocks drape beneath the patient's pelvic region, with the fluid collection pouch positioned directly below the vaginal opening. Ensure the drape lies flat and securely under the patient to prevent fluid leakage.

2) To connect the inflow tubing, turn off the stopcock of both fluid connectors on the hysteroscope (see Figure 7 blow).

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.

3) Connect the inflow tubing to the fluid connector marked with “IN”. To enable infusion, spike in the opposite end into a fluid infusion bag through a fluid pump, pressurized saline bag, or a saline bag hung above the ground at about 1 m higher than the patient.
4) Connect the outflow drainage tubing to the connector with the mark “OUT”. Place the other end of the tubing into the fluid collection pouch on the under buttocks drape.
5) Test the fluid channel by opening the 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.



(a) stopcock opened (b) stopcock closed

Figure 7 Controlling the open/close of the stopcock

⚠ CAUTION

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 (optional) 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 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

- The user should always check if the live video is shown on the screen before inserting the cannula into the patient cavity. 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 obvious 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 Operating the Software

3.3.1 Home Screen

The Home screen is subdivided into the left pane, the right pane and the middle live view window that displays the live image of the hysteroscope.

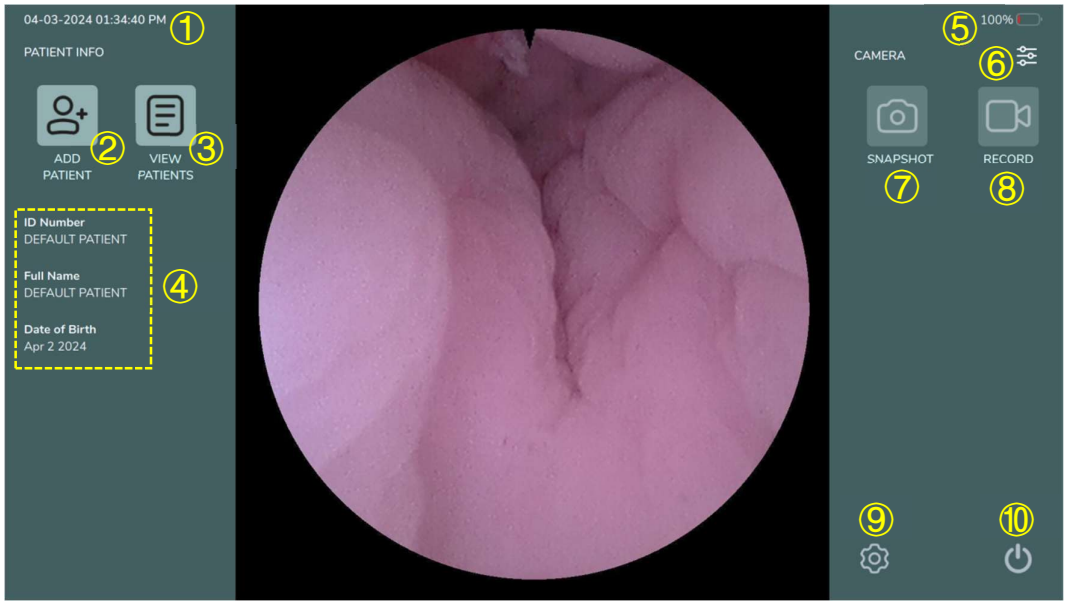


Figure 8 The layout of Home screen

#	Name	Description
①	Date & Time	The current date and time of the system

②	Add Patient	Create a patient account
③	View Patients	View the patient list and associated data
④	Patient Info.	The ID, name and DOB of the current patient
⑤	Battery Level	The remaining battery level in percentage
⑥	Image Settings	Display the Image Settings pane
⑦	Snapshot	Grab an image
⑧	Video Record	Record a video
⑨	System Settings	Display the System Settings screen
⑩	Power On/Off	Turn on/off the Portable Image Processor

3.3.2 User Management

To review or export patient data or to change some system settings, the user must login in by entering his/her account name and password for authorization. There are four types of user accounts with different degree of system access and privileges, as explained below:

- **Default User:** Instant access to live video without login. The default user can also perform snapshot or video recording but has no access to previously recorded data if permission is not granted by the Administrator.
- **Ordinary User:** This is the user account for daily operation. Patient data that recorded by an ordinary user cannot be accessed by other ordinary users.
- **Administrator:** This is the user profile that has higher level of privilege than the Ordinary User in that only the Administrator is authorized to create an Ordinary User account or to change some of the system settings such as the IP address or time zone. The Administrator account name is fixed to be ADMIN, and the default password is 12345678.
- **Service User:** This is the user account for service personnel of the manufacturer or dealer. This user profile is granted with special access to some service-related settings or data such as the system log files. Note that Service User has no access to recorded patient data.

The permission settings for different user profiles are shown in the table below:

Function	Default User	Ordinary User	Administrator	Service User
Login required	×	√	√	√
Live view	√	√	√	√
Video recording	√	√	√	√
Snapshot	√	√	√	√
Image setting	√	√	√	√
Review patient data	*	√	√	×
Add / edit patient	√	√	√	×

Export / import patient	*	√	√	×
Add /edit user	×	×	√	×
Add / edit report	*	√	√	×
System settings	*	*	√	√
Log export	*	*	√	√

√ : Have this permission

× : Do not have this permission

* : Requires authorization by Administrator

To access the user management functions (create, edit, delete or switch the current user), one has to tap on the System Settings icon at the lower right corner of the Home screen (see Figure 8). After user authentication, the User Management window will appear, as illustrated below.

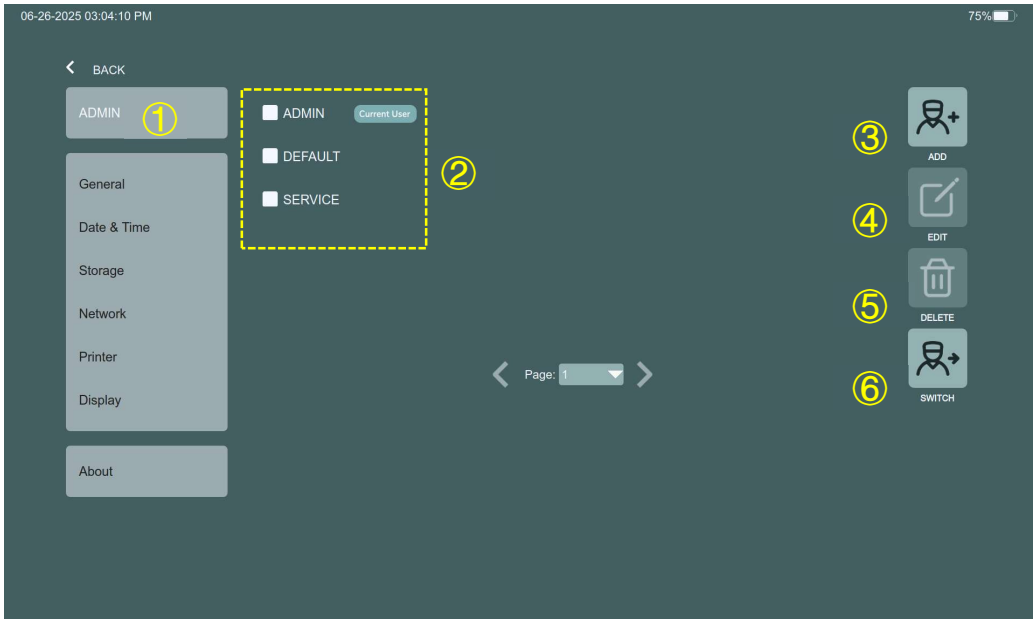


Figure 9 The User Management window

#	Name	Description
①	Current User	The name of the currently logged-in user
②	User List	The list of currently registered users on this system
③	Add User	Add a new user (only enabled for Administrator only)
④	Edit User	Edit the information of the selected user in the user list
⑤	Delete User	Delete the account of the selected user in the user list
⑥	Switch User	Log out the current user and then login as the selected user in the user list

3.3.3 Patient Management

The HTx2000 Portable Image Processor allows the user to quickly register patient information and store the associated videos and images for future review purposes.

Adding a Patient

The user can create a patient account in either of the following ways:

- Basic method: when there's no quick menu shown on the screen, tap anywhere on the screen to show the Home screen, then press the Add Patient icon on the upper left corner and you will see a small window popping out. As illustrated in Figure 10 below, you can tap the New Patient button to create a new patient account and input the patient ID, patient name, and DOB (Date of Birth), or you can choose to load an existing patient in the database by pressing the Existing Patient button.

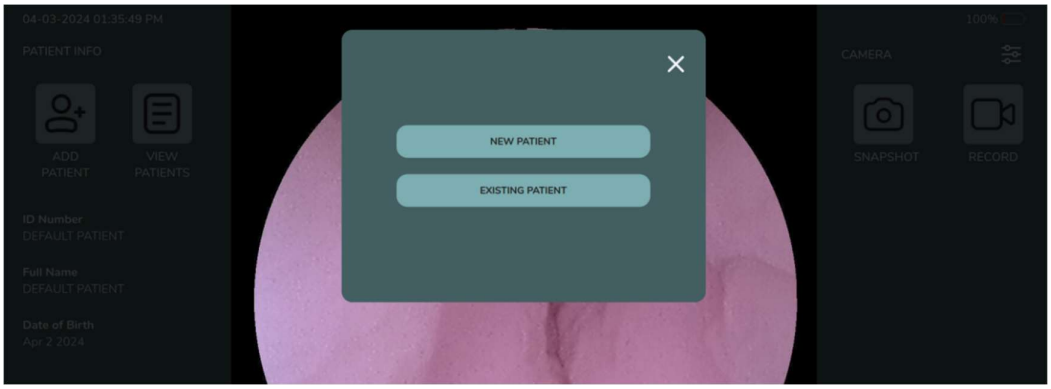


Figure 10 The Add Patient window

- Efficient method: attach an optional barcode reader to one of the USB ports on the Portable Image Processor and use the device to scan the patient barcode. All patient information will be registered automatically once the scanning is done.

NOTE Adding a patient through barcode scanning is currently a customized feature, as different users may have different formats of the patient barcode.

Viewing & Managing Patient Data

On the Home screen, tap the View Patients icon to enter the View Patients screen. All patients created by the current user are listed, as illustrated in Figure 11 below.

NOTE The Administrator can view all patients created by ordinary users.

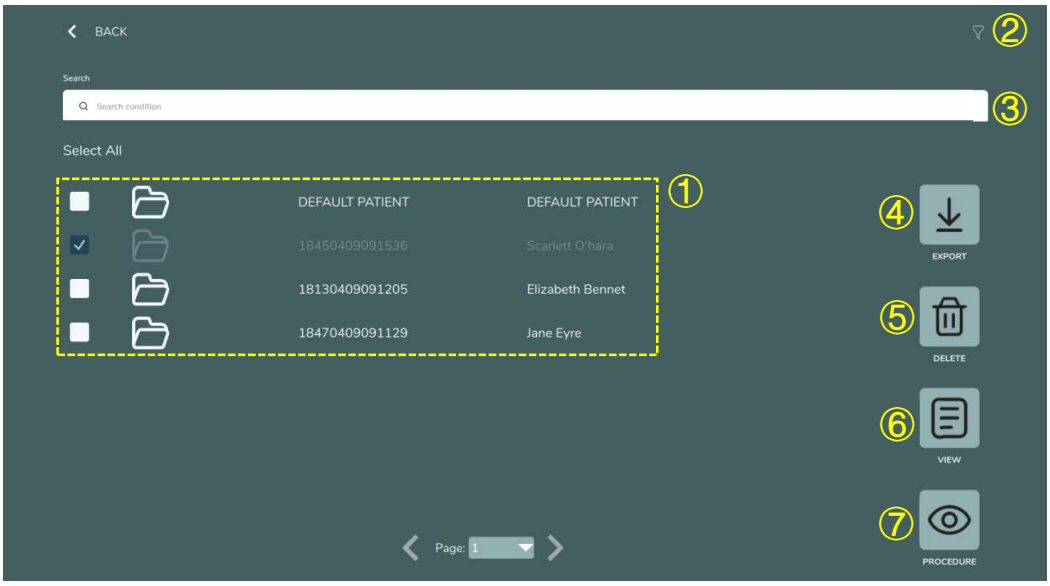


Figure 11 The View Patients screen

#	Name	Description
①	Patient List	Lists all registered patients accessible by the current user. • The 3rd and 4th column in the list shows the patient ID number and name, respectively. • To select a patient for further operation e.g., export, edit or print, just tap the corresponding row and the box in the 1st column will be checked.
②	Funnel Menu	Tapping the funnel-like icon will unfold/fold the pop-up menu as described below. ***New Patient*** — Create a new patient account. ***Edit Patient*** — Modify patient information (e.g., ID or name). ***Name Archive Size*** — Sort the Patient List in different orders. ***Icon List*** — View the Patient List in different modes, choose either Icon or List.
③	Search Patient	Type in the patient ID number or name in the input box to search for the patient.
④	Export Data	Export all data of the selected patients in the Patient List to an external storage device attached to the USB port.
⑤	Delete Data	Delete all data and account information of the patients that are selected in the Patient List.

⑥	View Data	Open the folder of the selected patient in the Patient List. All documents associated with that patient will then be displayed for review.
⑦	View Procedure	Set the selected patient in the Patient List as the current patient of the procedure, and then return to the Home screen.

NOTE The patient data would be stored on the SD card inside the Portable Image Processor 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) or to an external PC for backup on a regular basis.

Printing Patient Data

Open the folder of the selected patient in the Patient List, select the images to be printed and tap the print icon, the selected images will be printed as the format configured in the printing menu, as illustrated in Figure 12 below.

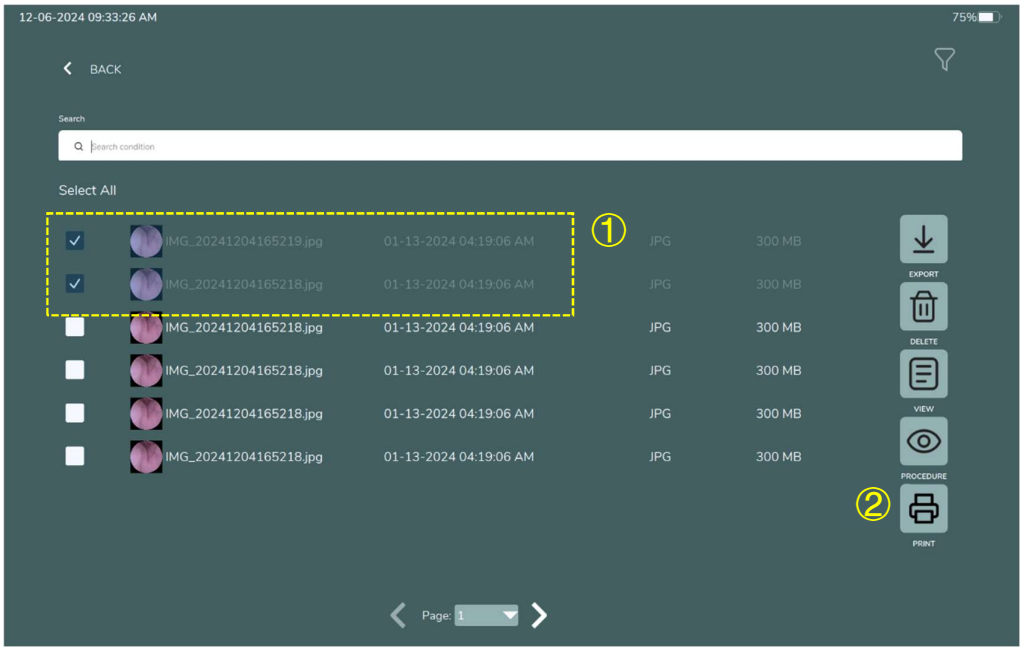


Figure 12 Select images to print

#	Name	Description
①	Image List	Select the images to be printed
②	Print Menu	Tap the print icon to configure the printing format

After tap the print icon, the printing configuration dialog will pop up to let users configure the printing format, as shown in Figure 13.

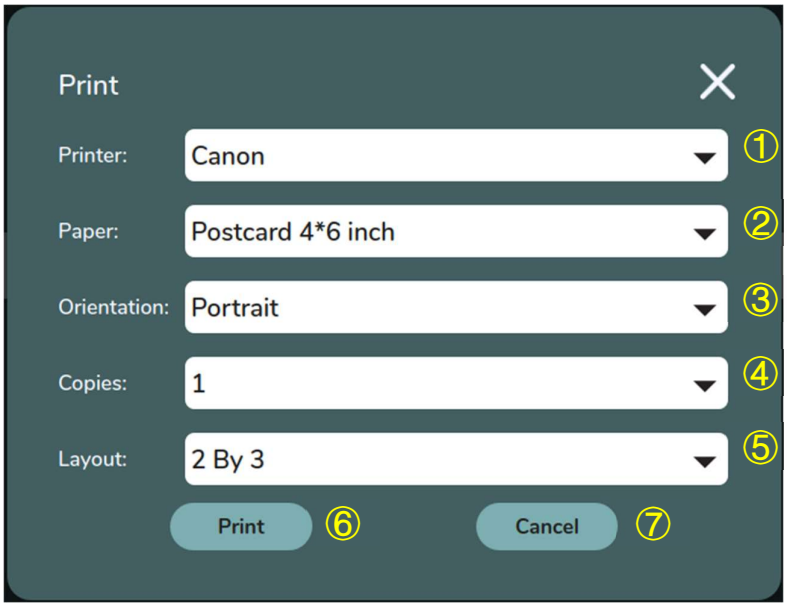


Figure 13 Printing configuration dialog

#	Name	Description
①	Printer name	The name of the connected printer, will be automatically selected according to the connected printer through the USB port.
②	Printer paper	The printer paper to be used, will be automatically selected according to the connected printer through the USB port.
③	Printing orientation	Printing orientation can be selected from: • Landscape • Portrait
④	Printing copies	Select the copies to be printed. The maximum supported printing copy is 10.
⑤	Printing layout	Select the printing layout. When the printing orientation is Portrait, the layout can be selected from: • Single • Side By Side • 2 By 2 • 2 By 3 When the printing orientation is Landscape, the layout can be selected from: • Single • Side By Side • 2 By 2 • 3 By 2
⑥	Print icon	Tap the print icon to proceed the printing.

⑦	Cancel	Cancel the printing procedure.

3.3.4 System Settings

The user can configure various system options such as date, time or language in System Settings, as illustrated below. Many system-level functions such as software upgrade or storage cleanup are also available in System Settings.

To access System Settings, tap on the icon at the lower right corner of the Home screen.

Figure 14 The System Setting screen

NOTE The available options and functions in System Settings depend on the user type. For example, the Administrator user has the access to export log files of the system but the Default user does not.

The table below gives a brief introduction to the options and functions in System Settings for the Administrator:

Category	Description	
General	***Software upgrade***	The user can upgrade the software by inserting a USB drive that contains the upgrade file into the USB port of the image processor, and then pressing “Software upgrade”.
	Export log	The user can tap on this option to export the running log and send it to a service engineer for troubleshooting.

	Convenient mode	When Convenient mode is enabled, user authentication will be exempted for a lot of operations including data export, enabling automatic patient data deletion and disabling USB drive.
	Language	The following system languages are currently available to choose from: ◆ English ◆ Chinese (simplified) ◆ Chinese (traditional) ◆ French ◆ German ◆ Italian ◆ Spanish ◆ Dutch ◆ Portuguese ◆ Greek ◆ Finnish ◆ Norwegian ◆ Swedish ◆ Danish
	Factory reset	Allows the user to reset a number of system options to factory default.
Date & Time	Allows the user to configure the system date and time.	
Storage	***Low space alert threshold***	Sets the threshold for low space alert. Once the free space is lower than the set threshold, an alert or warning message will be popped up to notify the user.
	Image format	Currently the format of the saved images is not user configurable, but fixed to JPEG.
	Storage cleanup	Allows the user to clean up the whole data storage. Note: cleaned data cannot be restored.
	Delete data after export	If this option is enabled, the original data on the internal storage space will be permanently deleted once exported to an external storage device.
	Patient data deletion period	Set the period of automatic patient data deletion. The optional deletion period is monthly, weekly and daily
	Automatic patient data deletion	If this option is enabled, the patient data will be automatically deleted after the deletion period is expired. If this option is disabled, the configured deletion period will be ineffective. This option is disabled by default, and enabling it will need administration authentication when the convenient mode is not enabled.

	Disable USB drive	If this option is enabled, the USB port of the device will be disabled, and data export and software upgrade though USB port will be ineffective. This option is disabled by default, and enabling it will need administration authentication when the convenient mode is not enabled.
Network	Allows the user to configure the network address of the system. Currently the IP address of the system is fixed to 192.168.1.6, and the network connection is disabled.	
Print	***Print on capture***	If this option is enabled, the image will be automatically printed when users capture an image by pressing the capture button on the hysteroscope or the touch screen.
	Include Patient Information	If this option is enabled, the patient name, ID and the date of capture will be printed together with the image.
	Current Connected Printer	The name of the connected printer, will be automatically displayed. The currently validated printers include: • Canon Selphy CP1500 • Sony UP-DR80MD 2021 version
Display	Allows the user to turn on/off the feature of enhancing image sharpness. The default setting is enabled sharpness.	
About	Provides the software and company information of the product.	

3.3.5 Image Settings

Tap on the Image Settings icon on the upper right corner of the Home screen, and the right pane will switch to display the image setting options, as illustrated below.

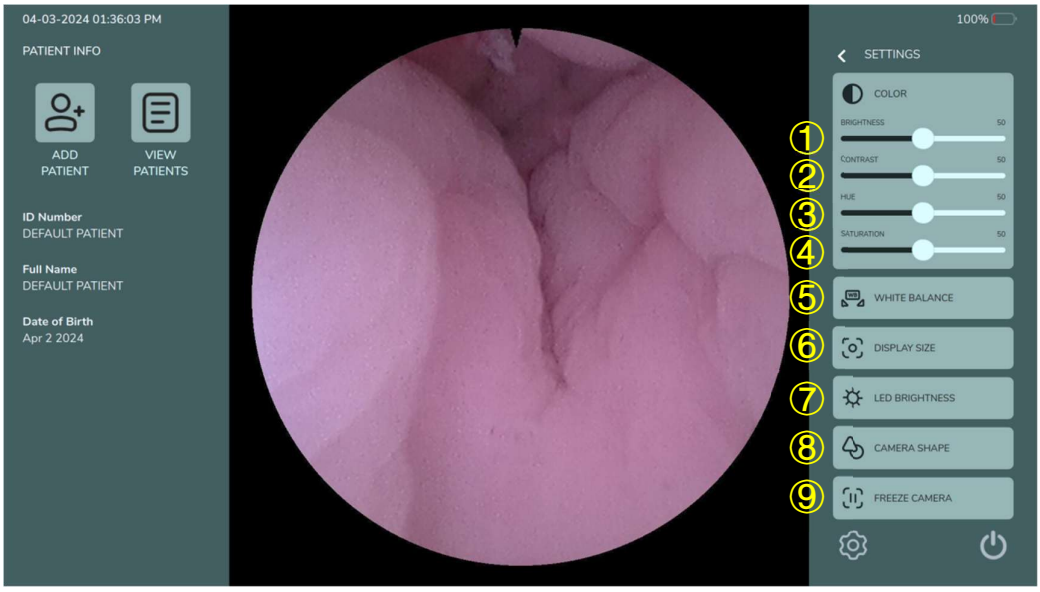


Figure 15 Home Screen

Various configurations of the image can be made via the following icons:

#	Name	Description
①	Brightness	For adjusting the brightness of the image*
②	Contrast	For adjusting the image contrast*
③	Hue	For adjusting the color hue*
④	Saturation	For adjusting the color saturation*
⑤	White Balance	For white balance calibration
⑥	Display Size	For adjusting the size or magnification of the image
⑦	LED Brightness	For adjusting the brightness of the LED illumination
⑧	Camera Shape	For adjusting the displayed image shape
⑨	Freeze Camera	For freezing the image on the screen

* Slide the circle for coarse adjustment, tap the two ends of the bar for fine tuning.

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 16 How to pull out the cable connector from the hysteroscope

⚠ CAUTION

- 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.

3.4.3 Shutting Down the Portable Image Processor

The user can turn off the Portable Image Processor via either software (soft shutdown) or hardware (hard shutdown).

1) Soft shutdown

To do the soft shutdown, tap on the shutdown icon on the Home screen (see Figure 8), and then press "OK" in the pop-up window.

2) Hard shutdown

Locate the power button on the side of the Portable Image Processor (see Figure 2), and long press it for more than 3 seconds, the system will be powered off accordingly.

NOTE In case of a system death halt, use the hard shutdown to turn off the processor and then restart.

3.4.4 Cleaning the Portable Image Processor

Shut down the Portable Image Processor before cleaning. To clean and disinfect the Portable Image Processor, please refer to Section 4.2.

4 Cleaning & Disinfection & Sterilization

Before first use or after performing each procedure, the user should clean and disinfect the image cable, the Portable Image Processor, and all peripheral devices & reusable accessories touched or used in the procedure. If necessary, the user might need to sterilize the image cable.

NOTE It is recommended that the HTx2000 Portable Image Processor and all peripherals (external display, barcode readers, etc.) be cleaned at least once a day, and the image cable to be cleaned and disinfected after each procedure.

4.1 Cleaning and Disinfection of the Image Cable

There are two recommended methods to clean and disinfect the image cable. Please follow the instructions below for proper cleaning and disinfection:

4.1.1 Non-woven cloth

1) Use a piece of non-woven cloth soaked with 70% isopropyl alcohol (IPA) to wipe down the cable (especially the connector that has more exposure to blood and debris). 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 visibly wet 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.

4.1.2 Pre-soaked disinfectant wipe

1) Prepare a pre-soaked surface disinfectant wipe from the approved list below.

- Sani-Cloth® AF3 Germicidal Disposable Wipe
- Super Sani-Cloth® Germicidal Disposable Wipe
- Sani-Cloth® Bleach Germicidal Disposable Wipe
- CaviWipes™ 2.0

2) Use the wipe to remove all visible contaminants from the cable surface. Pay special attention to the end that connects to the hysteroscope, as this area is most likely to be contaminated with blood and debris. Discard the used wipe after initial cleaning.
3) Using a new disinfectant wipe, repeat the cleaning process. Wipe all surfaces thoroughly for at least 30 seconds to ensure complete coverage.

4） With a third fresh disinfectant wipe, clean the surface again, ensuring that all areas remain visibly wet for at least 3 minutes to achieve effective disinfection.
5） Air dry the cable before use.

⚠ CAUTION

During the cleaning process, hold the cable with both connector openings facing upward so that the cleaning agent will not flow into the connector through any tiny seams. Be careful to keep the inside of the connectors dry.

4.2 Disinfection of Other Modules

To clean other modules (Portable Image Processor, the display, mounting rack, 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.

⚠ CAUTION

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

4.3 Sterilization of the Image Cable

Note: This section is only for the customers in USA.
The HD image cable can be sterilized using the Low-Temperature Hydrogen Peroxide Gas Plasma Sterilization method. Sterilization has been validated using the Sterrad@ System listed below.

- *Sterrad@ System 100NX@ Standard Cycle*

Please consult the instructions provided by Sterrad for using Sterrad@ 100NX@ standard cycle.

⚠ WARNING

Do not cross-sterilize the image cable. Using multiple sterilization methods may damage the image cable.

Please follow the guidelines herein to sterilize the image cable.

1) Before sterilization, clean the image cable as recommended in the Section 4.1 Cleaning and Disinfecting the Image Cable.
2) Air dry the image cable.
3) Package and seal each image cable in a Tyvek@ sterilization pouch, as indicated in the following figure.

4) Sterilization has been validated using the parameters below:

Sterilizer	Sterrad® System 100NX
Cycle	STANDARD CYCLE (Full cycle)
Temperature	(47-56) °C
Running time	47 min
Main components and content	Hydrogen peroxide, content 641.0g/L-738.8g/L

5) Store the sterilized image cable in a ventilated and dry environment.

NOTE Before each procedure, please check the system performance as stated in Section 3.1.3 to make sure the sterilized image cable is functioning normally.

5 Troubleshooting

The information in this section is intended to provide guidance for basic trouble shooting procedures. For any issue beyond the scope of this basic troubleshooting guide, please contact the local service personnel.

Problem	Action
No video output. A message on the screen says no cannula is attached.	Follow the steps below until you see the video on screen: 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 Portable Image Processor. 4. Replace the cannula with a new one. 5. Replace the cable with a new one.
Image has strips, flickers, or suddenly freezes / blacks out	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.
Image is too dark	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.
No data transferrable to an external USB storage device.	Unplug the USB storage device and then re-plug. Make sure there's a USB-device icon appearing at the upper right corner of the Home screen. If unsuccessful, try a new USB storage device.
The user forgets his/her password for data export.	Contact the local Customer Service to reset the password.
The software gets stuck and is not responding.	Shut down the system by long pressing the on/off button for 3 seconds and turn it on again. If the problem persists, contact the local service personnel.

6 Service and Maintenance

6.1 Software Upgrading

The user can check the version of software embedded in HTx2000 Portable Image Processor by simply pressing the Settings button on the Home Screen. The version information will be shown at the bottom of the Settings Screen that pops up. In case a new version has been released, please contact the local Customer Service for upgrading.

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 Portable Image Processor be performed on an annual basis according to IEC 62353.

6.4 Warranty

The HTx2000 Portable Image Processor is warranted to be free from defects in workmanship and materials for 12 months from date of sale. For all reusable accessories or optional modules of the system, warranty will be determined according to the policy of the original equipment manufacturer (OEM).

⚠ WARNING

- The warranty is valid only if the product is supplied to the end user by an OEM approved agent or distributor and has been properly operated and maintained in compliance with the procedures given in this manual.
- Only approved service engineers are authorized to disassemble the Portable Image Processor.

6.5 Maintenance of Battery

The battery would be at an over-discharged state by its self-discharge characteristics in case the cell is not used for long time. In order to prevent over-discharging, the battery shall be charged at least once in every six months. The charging should be done at an ambient temperature between 0-45℃.

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 (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. 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.
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	

		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 7.3.1 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.

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 1: Cables and Accessories

Cables for EMC compliance				
No.	**Name**	**Manufacturer / Length**	**Model**	**Applied Standards**
1	Power cord	Yung Li / 2.8m	YP-18/YC-12	CSA C22.2 No 49
2	Power cord	Lai Yu / 1.8m	UBL8008	60227 IEC 52
3	Image cable	AcuVu / 2.5m	HD250	/

Accessories List			
No.	**Device**	**Model**	**Manufacturer**
1	Barcode scanner	14952	Deli
2	HD Image Cable Kit	HD250 (x3)	Acuvu
3	Procedure pack	/	Acuvu

Appendix 2: Cybersecurity Information

- **Cybersecurity features of the device**

The following table lists all the interfaces that are expected to receive and/or send data:

No.	Interface	Port functionality	Direction	Approved destination end-points
1	USB 2.0	1. Used to export patient data and log file into an external USB disk 2. Used for software upgrade	Incoming and outgoing	The destination end-point of incoming path is internal memory of PIP. The destination end-point of outgoing path is USB disk.
2	HDMI	Used for video output to external monitor	Outgoing	External monitors with HDMI input port.
3	Image cable socket	Receive video signals from hysteroscope	Incoming	Internal memory of PIP.

The following table lists cybersecurity bill of materials of PIP.

No.	Name	Version	Description
1	Qt base	5.12.2	Used for the graphical user interface (GUI) library
2	Linux	4.9.10	Used as the operating system of the device. The software application runs on top of kernel and is in user space. The embedded Linux kernel is built from source code by AcuVu.
3	SQLite	3.22.0	Used as the database library of the device for patient and user information management.

- **Cybersecurity control instructions**
  - After login the system as the Administrator, it is recommended to change the default password. To set a secure password, a combination of numbers, letters and special characters is recommended to be used.
  - The LAN port is currently disabled so Ethernet access is not available. Therefore, no special network deployment actions are required.
  - When inserting a USB disk into PIP, please avoid using any disk that might have been infected by virus. The PIP software will mount the USB disk as “noexec”, which means any potential virus in the USB disk cannot be executed by PIP. This provides functionality of anti-malware.
  - When software of new version is available, the local Customer Service will inform users and provide means to obtain manufacturer-authorized software.
  - When anomalous conditions are detected, the relevant information will be logged by PIP and the log files can be exported by Service user.
  - The critical functionality of PIP such as patient data archive is protected by encryption of database that is stored in internal memory of PIP. The device will not automatically backup the patient data, and it is recommended that users backup the patient data into external USB disk regularly.
  - If the device is mis-configured, the administrator account can reset the device to factory setting, so that the device configuration can restore to default value. Note that the patient data will not be erased when resetting to factory mode.
  - After end of life of the device, please delete all patient data and user account information before disposing the device.

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Revision History

No.	Version #	Description	Originator	Release Date
1	A/0	Initial Release	Yaqian Zhu	2022-09-07
2	A/1	Updated according to FDA guidance on labeling	Yaqian Zhu	2023-06-01
3	A/2	Update contraindication according to FDA guidance	Frank Shu	2023-09-05
4	A/3	Add cybersecurity bill of materials in Appendix 2; Add correlation between battery status indicator and the remaining use time in section 3.1.1; Add information of battery charging time in section 2.4.2; Add information of battery life in section 2.4.2; Remove section 7.3.1 regarding separation distance between portable / mobile RF transmitters and the product; Change model of drainage fluid tube to 5.0mm*6.7mm*1000mm; Add warning against using with specific devices including MRI, diathermy, electrocautery, wireless power transfer and 5G cellular devices.	Heping Chen	2023-12-26
5	B/0	Update cybersecurity labeling in appendix 2	Heping Chen	2024-02-20
6	B/1	Added the sterilization procedure for HD image cable	Heping Chen	2024-04-11
7	B/2	Update user manual for the software version V1.2.1	Heping Chen	2024-07-15
8	B/3	Add hysteroscope model HTx60t, HTx60-L and HTx60c	Heping Chen	2024-08-12
9	C/0	Add printing function description in section 3.3.3 and 3.3.4. Add hysteroscope model HTx40-L Combine IFU for USA, Singapore and Malaysia	Heping Chen	2024-12-24
10	C/1	Added Procedure Pack descriptions. Added pre-soaked disinfectant wipes instruction for cable cleaning. Software updated to V1.3.1. The supported languages are added in page 26. Add the display description in page 27.	Frank Huang	2025-06-23

Signature & Review

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