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ZebraScope

CE 0344

Digital Endoscope System

Single Use Digital Flexible Ureteroscope w/ Pressure Monitoring

User Manual

Product models:
HUS-M101R
HUS-M102R
HUS-M105R
HUS-M101S
HUS-M102S
HUS-M105S

Anhui Happiness Workshop Medical Instruments Co., Ltd

Pioneering Innovation

Empowering Healthcare

Forward

The Digital Endoscope System is designed for physicians to access, visualize, and perform procedures in the urinary tract. The system includes Videoscope Imaging Processor, Renal Pressure Monitoring Processor and Single Use Digital Flexible Ureteroscope w/ Pressure Monitoring. The instrument enables delivery and use of accessories such as laser optical fiber, guide wire and stone retrieval baskets during surgery.

Thanks for purchasing Single Use Digital Flexible Ureteroscope w/ Pressure Monitoring. Before using the device, please read this user manual and the instructions for all peripheral equipment carefully and follow the operational guidelines.

Store all relevant instruction manuals in a safe and easily accessible place. For any questions or comments regarding this manual, please contact Anhui Happiness Workshop Medical Instruments Co., Ltd (hereinafter referred to as “Happiness Works”).

In case of any serious incidents, report them to Happiness Works and the competent authority.

Product: Single Use Digital Flexible Ureteroscope w/ Pressure Monitoring
Product models:
HUS-M101R
HUS-M102R
HUS-M105R
HUS-M101S
HUS-M102S
HUS-M105S



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Contents

Chapter 1 Overview 1
Chapter 2 Basic Information 4
2.1 Marking Instruction 4
2.2 Product Models 5
2.3 Product Parameter 5
2.4 Environmental Requirements 6
2.5 Security Classification 6
Chapter 3 Product Composition 7
3.1 System Diagram 7
3.2 Product Composition 7
Chapter 4 Operation and Use 9
4.1 User Requirements 9
4.2 Product Preparation 9
4.3 Setup 10
4.4 Deflect the Distal End of the Ureteroscope 12
4.5 Check Working Channel Device Entry 12
4.6 Connect the Irrigation/Contrast Interface 13
4.7 Insertion, Observation and Treatment 13
4.8 Insertion and Removal of Surgical Accessories 13
Chapter 5 Intended Purpose 16
Chapter 6 Contraindications 17
Chapter 7 Warnings 18
Chapter 8 Attentions 21
Chapter 9 Side Effects 23
Chapter 10 Troubleshooting 24
10.1 Image Distortion or No Image Displayed 24
10.2 Deflection Control Failure 25
10.3 Difficulty Capturing an Image or Recording a Video 26
10.4 Pressure Sensor 26
Chapter 11 Electromagnetic Compatibility 27

Chapter 1 Overview

This product is sterilized using ethylene oxide (EO). Do not use the product if the sterile packaging is damaged. This device is intended for single use only and must not be reused, reprocessed, or resterilized. Reusing or reprocessing may compromise the structural integrity of the device, leading to failure, injury, illness, or even death. Reuse also increases the risk of cross-infection, which may result in serious infectious diseases.

After use, dispose of the product and packaging in accordance with hospital, administrative agency and/or local government policies.

The Single Use Digital Flexible Ureteroscope w/ Pressure Monitoring is provided in a sterile condition and consists of two primary components: a handle with direction control lever and signal cables, and a flexible insertion portion.

The Single Use Digital Flexible Ureteroscope w/ Pressure Monitoring can also be referred to as Ureteroscope hereinafter. The ureteroscope is compatible with surgical accessories such as laser optical fiber, a guide wire and stone retrieval baskets. The deflection section of the ureteroscope allows for 275° deflection in both directions, enabling precise control during procedures.

The flexible insertion portion of the ureteroscope includes a working channel for the passage of accessories and the introduction of irrigation or contrast fluid. The handle is equipped with a direction control lever to manipulate the distal end, while the working channel device entry and irrigation port facilitate the use of surgical accessories and irrigation/contrast fluid.

Please note that this product has not been validated for use in an MRI environment.

Operating principle:

The ureteroscope operates by utilizing the natural urinary tract of the human body. A thin, flexible insertion tube is introduced into the ureter and kidney via the urethra and bladder, or alternatively, a percutaneous channel is established from the skin to the kidney. Through this channel, the ureteroscope is inserted into the kidney. Equipped with an image sensor (CMOS) and pressure sensor at its distal end and advanced electronic imaging technology, the ureteroscope provides a clear live image of the area in front of its distal end. Additionally, the working channel of the ureteroscope can be used in conjunction with various accessories for examination or treatment purposes.

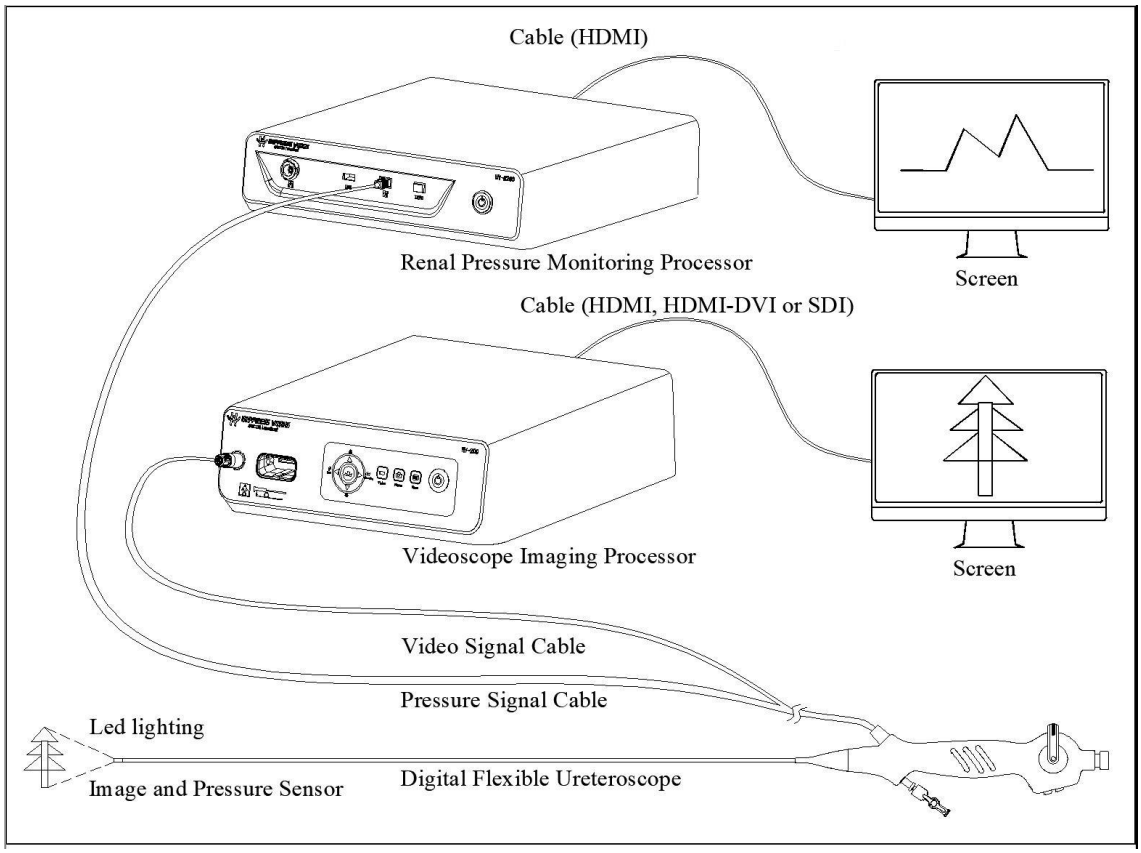
These two signals (image and pressure) can be output to external monitors in two ways.

The first way is that the Videoscope Imaging Processor and the Renal Pressure Monitoring Processor output their signals to two separate external monitors respectively.

The second way is that the Renal Pressure Monitoring Processor outputs its signal to the Videoscope Imaging Processor via an RS232 cable first, and then the Videoscope Imaging Processor integrates the imaging and pressure information and outputs them to a single external monitor.

The Videoscope Imaging Processor powers the LED and CMOS at the distal end via a video signal cable. The LED illuminates the mucosa, and the CMOS sensor captures the reflected light, converting it into an electrical signal. This signal is transmitted to the Videoscope Imaging Processor through the video signal cable. The processor then converts the electrical signal into an image signal, which is displayed on the monitor screen.

The Renal Pressure Monitoring Processor supplies power to the pressure sensor at the distal end through a pressure signal cable. The fiber optical sensing demodulator in the Renal Pressure Monitoring Processor sends a certain wavelength of generated light to the pressure sensor, this light is transmitted to the pressure sensing film of the FP cavity through the optical fiber and then reflected, and the reflected light is transmitted to the demodulator through the optical fiber.



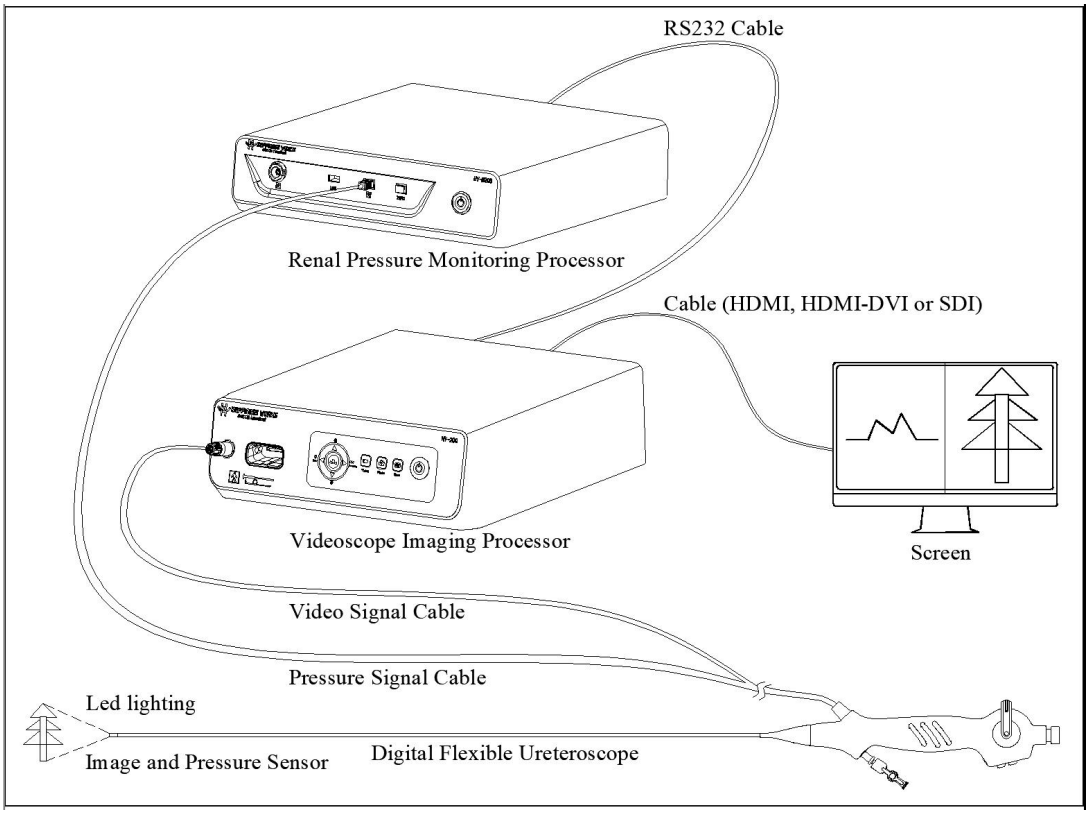
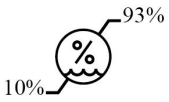
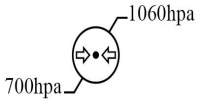
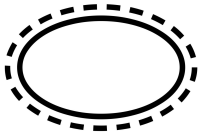


Figure 1 Digital Endoscope System Working Principle

Chapter 2 Basic Information

2.1 Marking Instruction

No.	Symbol	Symbol title	No.	Symbol	Symbol title
1	**ZebraScope**	Product trademark	15		Sterilized using ethylene oxide
2		Medical device	16		Storage/Transportation temperature limitation
3	IPX7	Water proof 7	17		Storage/Transportation humidity limitation
4		Catalogue number	18		Storage/Transportation atmospheric pressure limitation
5		Batch code	19		Manufacturer
6		Single sterile barrier system with protective packaging outside	20		Authorized representative in the European Community/ European Union
7		Date of manufacture	21		This way UP
8		Use-by date	22		DO NOT ROLL
9		Do not re-use	23		Fragile, handle with care
10		Do not resterilize	24		Keep dry
11		BF type application part	25		Keep away from sunlight
12		Do not use if package is damaged and	26		Stacking limit by number
13		Follow instructions for use	27		General warning sign
14		Non-ionizing electromagnetic radiation			

2.2 Product Models

The ureteroscope is available in six models, differentiated by their working lengths and deflection types.

Table 1 Product Models

Product Model	Description	Allowance
HUS-M101R	Working length 670mm with reverse deflection	+10mm
HUS-M102R	Working length 660mm with reverse deflection	+10mm
HUS-M105R	Working length 380mm with reverse deflection	+10mm
HUS-M101S	Working length 670mm with standard deflection	+10mm
HUS-M102S	Working length 660mm with standard deflection	+10mm
HUS-M105S	Working length 380mm with standard deflection	+10mm

Figure 2 Standard Deflection

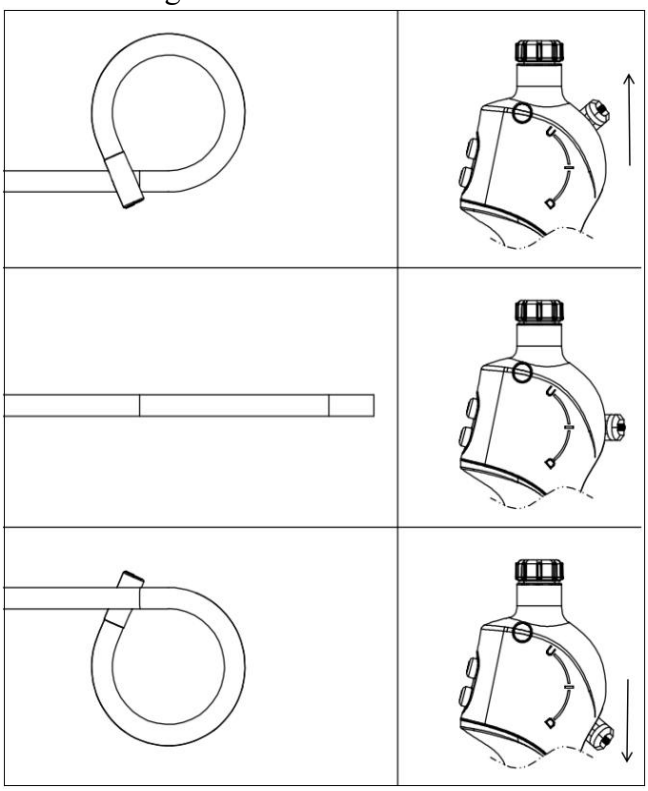
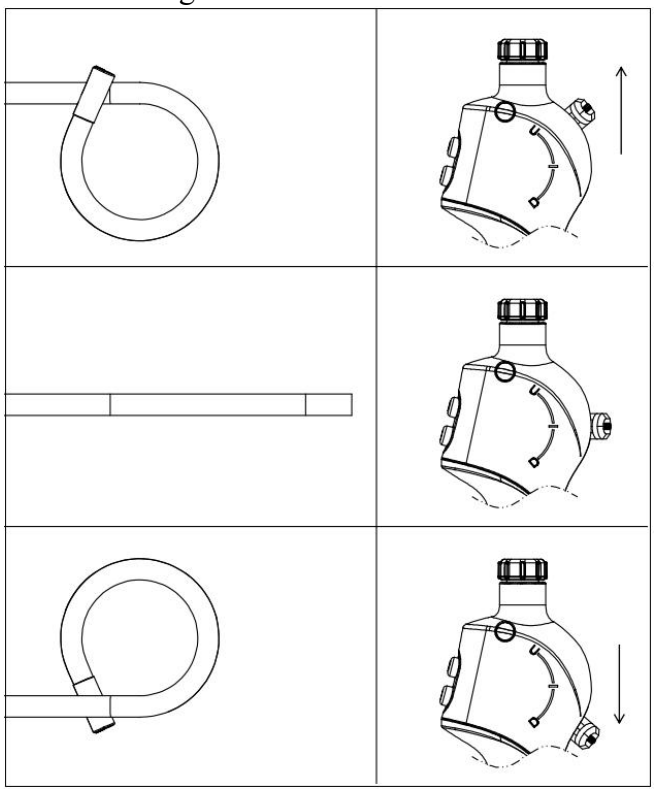


Figure 3 Reverse Deflection



2.3 Product Parameter

Table 2 Main Parameters

Specification		Value
Basic Data	Maximum width of insertion portion (distal end)	9.9Fr (3.3mm)
	Maximum width of flexible section	8.4Fr (2.8mm), tolerance +5%, excluding the lower limit
	Minimum width of instrument channel	3.6Fr (1.2mm)
Optical Index	Direction of view	0±10°
	Field of view	110°±10%
	Depth of field	2mm～50mm
	Edge uniformity	$U_L \leq 25\%$
Deflection	Deflection angle range	275°Up/ 275°Down, tolerance ±15°

Pressure range	-30mmHg~300mmHg

2.4 Environmental Requirements

(1) Operating environment

Ambient temperature: 10~40°C (50~104°F)

Relative humidity: 20~85%RH

Atmospheric pressure: 700~1060hPa (0.7~1.1kgf/cm^2) (10.2~15.4psi)

(2) Transportation and storage environment

Ambient temperature: -40~+50°C (-40~122°F)

Relative humidity: 10~93%RH

Atmospheric pressure: 700~1060hPa (0.7~1.1kgf/cm^2) (10.2~15.4psi)

2.5 Security Classification

(1) Classified according to the type of electric shock prevention: not applicable;

(2) Classified according to the degree of electric shock protection: when connected to the Videoscope Imaging Processor, it becomes the Type BF applied part;

(3) Classified according to the degree of protection against ingress of liquid: insertion portion of IPX7;

(4) Classification according to the safety degree when used in the case of flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide: non-AP/non-APG type;

(5) Classified by operating mode: not applicable;

(6) Rated voltage and frequency of the equipment: not applicable;

(7) Input power of equipment: not applicable;

(8) Does the equipment have an applied part to protect against defibrillation discharge effects: no;

(9) Whether the equipment has a signal input or output parts: yes, it has a signal input/output parts;

(10) Permanent or non-permanent installation equipment: non-permanent installation equipment.

CAUTION

● The ureteroscope is provided sterile and can be used directly.

● The ureteroscope is known to withstand exposure to the following procedural fluids: blood, urine, saline, contrast media, and water-based lubricants.

Chapter 3 Product Composition

3.1 System Diagram

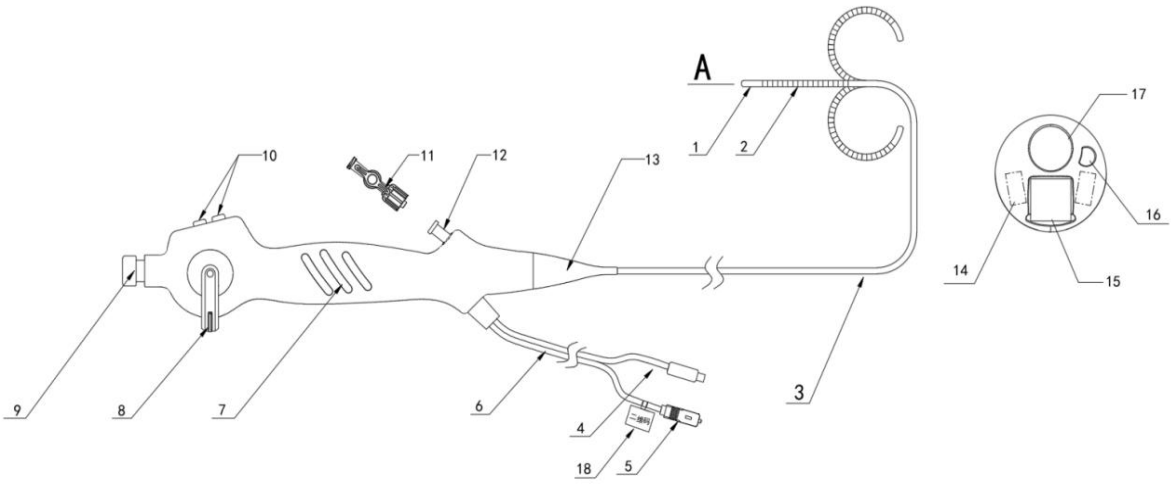


Figure 4 System Diagram

1. Distal end
2. Deflection section
3. Flexible section
4. Video signal cable plug
5. Pressure signal cable plug
6. Signal cable
7. Handle
8. Direction control lever
9. Working channel device entry
10. Buttons
11. Two-way valve
12. Irrigation port
13. Rubber sheath
14. Lighting source (LED)
15. CMOS
16. Pressure sensor
17. Working channel
18. Sensor information QR code

3.2 Product Composition

Applied parts of the product:

(1) Distal end

(2) Deflection section

(3) Flexible section

The handle is used to operate the insertion, withdrawal, deflection, and rotation of the flexible insertion tube. The handle (7) comprises a direction control lever (8), a working channel device entry (9), buttons (10), an irrigation port (12) and a signal cable (6) with plugs (4) and (5).

Direction control lever (8): Used to control the up and down deflection of the distal end. The deflection section can be Standard (lever up = distal end up) or Reverse (lever up = distal end down), depending on the model. When the direction control lever is in the neutral position, the distal end (1) returns to the undeflected position.

Working channel device entry (9): An inlet for surgical accessories.

Buttons (10): The factory settings designate the “A” button for taking photos and the “B” button for

recording videos. Specific functions can be configured through the Videoscope Imaging Processor - five options (photo taking, video recording, freezing, white balance, zoom in/out).

Irrigation port (12): Luer interface, where irrigation and/or contrast solutions can be delivered.

Video signal cable plug (4) and Pressure signal cable plug (5): Provide the electrical connection to the ureteroscope and transmits video and pressure signals back to the Videoscope Imaging Processor and Renal Pressure Monitoring Processor for processing.

WARNING ●Do not modify this equipment without the authorization of the Happiness Works.

Chapter 4 Operation and Use

4.1 User Requirements

Before use, please read this user manual carefully, paying close attention to the labels for safe operation and storage, and use the product as instructed.

Only physicians who have been professionally trained may use this product. Before using the ureteroscope, please understand the technical principles, clinical applications and potential risks associated with its use. This includes, but is not limited to, surgical accessories and equipment used to assist with observation and treatment procedures, such as laser optical fiber, guide wire and stone retrieval baskets.

4.2 Product Preparation

(1) Unpacking

Upon receipt, check the shipping carton and its contents for any damage. Confirm that the sterile packaging is intact and check the expiration date. Do not use a ureteroscope that is damaged or past the expiration date. After removing the ureteroscope from the package, perform the following inspection.

(2) Inspection

Open the sterile barrier by peeling back the header on the handle side of the paper-plastic bag. Remove the ureteroscope from the bag by gripping the handle and signal cable.

Carefully remove the protective sleeve from the insertion portion to avoid unintended deflection before use.

Hold the two-way valve and firmly insert the male luer connector into the irrigation port on the handle of the ureteroscope.

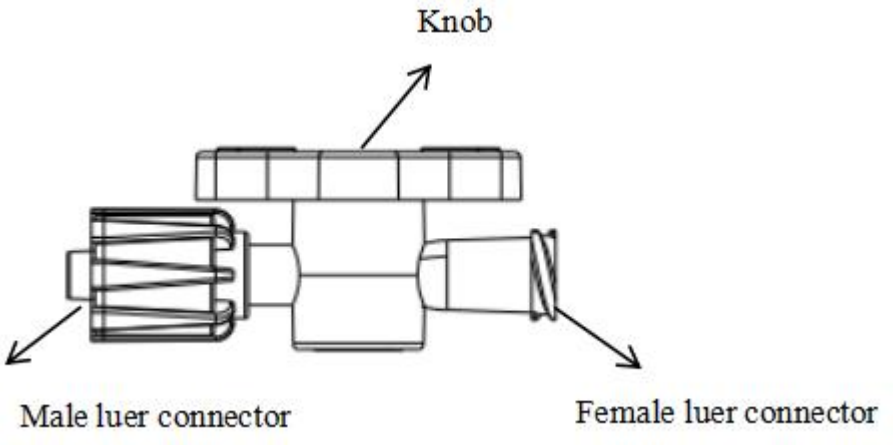


Figure 5 Two-way Valve Diagram

WARNING

- Failure to check the product and accessories for damage before use may result in improper device performance and patient injury.

- Visually inspect the entire surface of the flexible insertion portion. Examine the handle, direction control lever, and irrigation port to ensure that no components are loose, bent, broken, missing, or have sharp edges.
- Visually inspect the distal end for any flaws, including dents, protrusions, tears, or holes.
- Check the deflection direction and angle of the ureteroscope to ensure they operate smoothly. Do not force the direction control lever to straighten or deflect the distal end, as this may damage the mechanism.
- Visually inspect the signal cables and both plugs for damage or visible contamination.

4.3 Setup

(1) Insert the video signal cable plug of the ureteroscope fully into the Lemo socket of the Videoscope Imaging Processor (see Figure 6). After turning on the device, ensure that the monitordisplays a real-time image with the correct orientation.

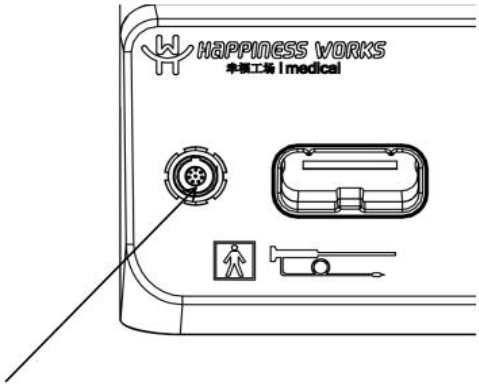


Figure 6 Connect the Ureteroscope with Videoscope Imaging Processor

(2) Insert the pressure signal cable plug of the ureteroscope fully into the socket of the Renal Pressure Monitoring Processor (see Figure 7).

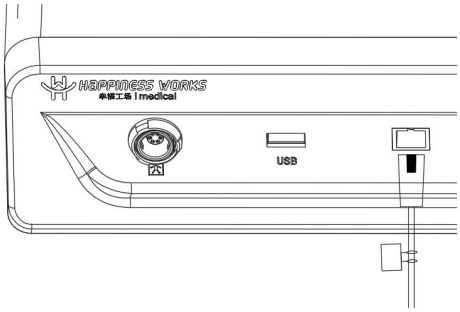


Figure 7 Connect the Ureteroscope with Renal Pressure Monitoring Processor

(3) Verify that the illumination at the distal end of the ureteroscope is operating as expected.

WARNING

Dispose of the malfunctioning ureteroscope (see “Disposal of Ureteroscope and Packaging Materials”) and replace it with a new one.

(4) Set the handle button functions according to the instructions for the Videoscope Imaging Processor

to confirm whether the buttons function normally.

WARNING

Before insertion, ensure that the protrusions on both the video signal cable plug and the pressure signal cable plug are properly aligned with the corresponding grooves on the sockets of the Videoscope Imaging Processor and the Renal Pressure Monitoring Processor. Misalignment will prevent insertion. Forcing the connection may damage the ureteroscope, the Videoscope Imaging Processor, or the Renal Pressure Monitoring Processor.

(5) White Balance Adjustment

To ensure a clear display, use the distal end of the ureteroscope to view a white object at a distance equivalent to the diameter of the insertion tube. Press the WB (white balance) button on the Videoscope Imaging Processor and wait for the adjustment to complete (see Figure 8).

CAUTION

The Videoscope Imaging Processor features an automatic white balance function that can be adjusted using the white balance button.

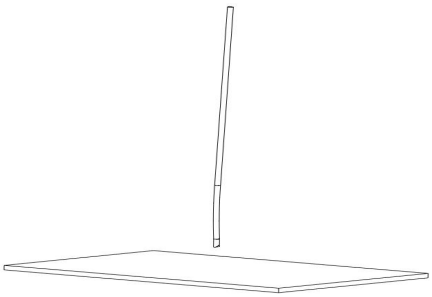


Figure 8 White Balance Adjustment

(6) Zero Calibration

Connect the USB port of the barcode scanner to the input port on the rear panel of the Renal Pressure Monitoring Processor (see Figure 9). Scan the QR code with the barcode scanner; zero calibration must be performed before inserting the device into the human body.

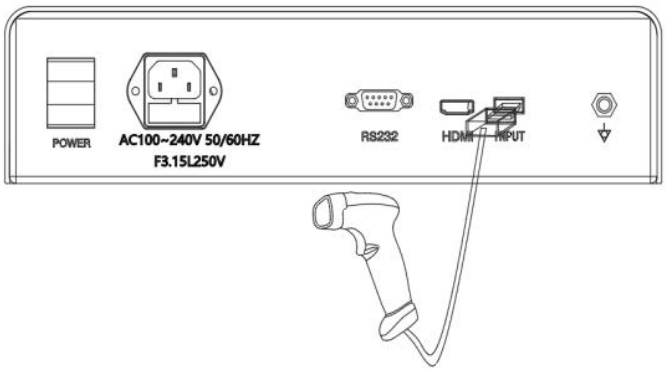


Figure 9 Zero Calibration

CAUTION

The Renal Pressure Monitoring Processor is equipped with a manual zero calibration function. To perform zero calibration, press the zero calibration button as instructed.

4.4 Deflect the Distal End of the Ureteroscope

To deflect the distal end of the ureteroscope, use your thumb to manipulate the direction control lever located on the handle(see Figure 10).

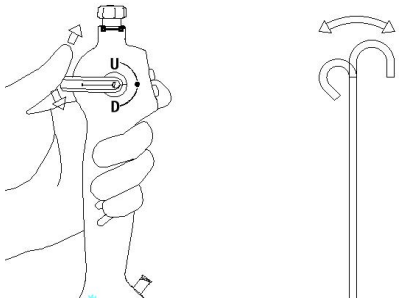


Figure 10 Adjust the Deflection Direction and Angle

WARNING

For standard-type ureteroscopes, moving the direction control lever upward will move the distal end upward. Conversely, moving the direction control lever downward will move the distal end downward (see Figure 2).

For reverse-type ureteroscopes, moving the direction control lever upward will move the distal end downward. Conversely, moving the direction control lever downward will move the distal end upward (see Figure 3).

4.5 Check Working Channel Device Entry

There are markings next to the working channel device entry on the handle, as shown in Figure 11. The marking on the left indicates the locking direction, while the marking on the right indicates the unlocking direction.

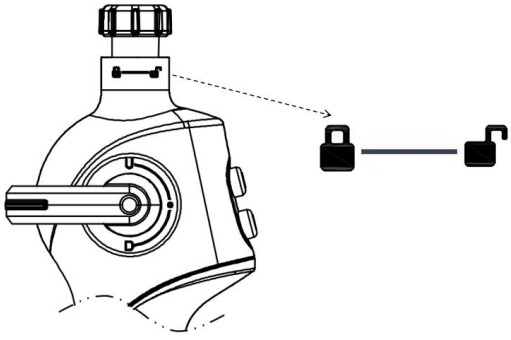


Figure 11 Adjust the Working Channel Device Entry

CAUTION

Ensure that the working channel device entry is securely locked before use.

4.6 Connect the Irrigation/Contrast Interface

Connect the female luer connector of the two-way valve to the irrigation/contrast supply tubing from a compatible source.

Ensure that the direction of the knob is aligned parallel to the direction of the two-way valve to allow irrigation/contrast. If necessary, rotate the knob 90 degrees to a position perpendicular to the two-way valve to stop the irrigation/contrast.

WARNING

We recommend using the lowest possible irrigant pressures during ureterorenoscopy to maintain adequate visibility.

4.7 Insertion, Observation and Treatment

(1) Gently insert the ureteroscope into the desired treatment area. (Hold the ureteroscope near the urethral opening and gradually advance it to prevent deflection. If using a ureteroscope through the PCNL cannula, grasp the ureteroscope near the cannula and gradually advance it through.)

WARNING

- If using a sheath, do not deflect the ureteroscope inside the ureteral access sheath.
- Do not apply excessive force to the direction control lever.

(2) Use imaging to determine the position of the endoscopically placed ureteroscope and the deflection angle of the distal end.

WARNING

- When inserting the ureteroscope, proceed based on an anatomical landmarks, using real-time video or other imaging modes to confirm the progress of the distal end.
- If the image or pressure data is lost during the procedure and does not return after restarting Videoscope Imaging Processor, replace the ureteroscope immediately.

4.8 Insertion and Removal of Surgical Accessories

(1) Insertion of the surgical accessories: Before inserting the surgical accessories, straighten the deflection section of the ureteroscope. Then, slowly insert the surgical accessories. Once the image appears, withdraw the surgical accessories to the working channel at the distal end. Secure the surgical accessories by turning the locking knob valve at the entrance of the working channel device entry. After the ureteroscope reaches the target position, slowly push the surgical accessories out through the working channel for the corresponding examination and treatment.

WARNING

● Ensure that the distal end of the ureteroscope does not contact the inner wall of the body before using the surgical accessories. Failure to maintain a gap between the distal end and the inner wall may result in perforation when the instrument extends beyond the distal end.

● Insert the required surgical accessories into the ureteroscope through the working channel. During this operation, do not shake the handle to maintain image stability and avoid injury to the patient or damage to the ureteroscope.

● For laser lithotripsy, the laser fiber must extend 8~10mm beyond the mouth of the ureteroscope before starting the procedure. Otherwise, the tip of the laser optical fiber may damage the product.

● The working channel provided by this product can be used with laser optical fiber, stone retrieval basket and guide wire, etc. (Happiness Works does not supply these accessories). These devices enter through the working channel and reach the distal end exit for operation. Refer to the table below for the dimensional specifications of the accessories.

Table 3 Dimensional Specifications of the Accessories

Accessories name	Dimensions
Laser optical fiber	≤276um
Stone retrieval basket	≤2.2Fr
Guide wire	≤0.89mm

(2) Removal of surgical accessories: Ensure that the distal end of the accessories is closed and the deflection section of the ureteroscope is straight.Then, slowly withdraw the accessories through the working channel.

CAUTION

● When inserting, withdrawing, or operating the deflection section, always view the real-time image on the display device. Image freezing may cause mucosal or tissue damage.

● If resistance is encountered while advancing or withdrawing the ureteroscope or surgical accessories, check the image to confirm that the distal end of the ureteroscope is not in contact with tissue. Ensure the direction control lever is in a neutral position, so the distal end of the ureteroscope is not deflected. Additionally, confirm that the surgical accessories are in the correct form, such as the stone retrieval basket is closed and the guide wire does not knot.

● When using a laser lithotripsy system, select a system with adjustable strength or pulse settings. Adjust the laser intensity or pulse to ensure the target stones are clearly displayed in real time. Do not activate any surgical accessory, including laser lithotripsy equipment, without a clear image display. If the image is clear but the laser cannot be properly adjusted, terminate the operation.

(3) Once the surgical accessories are visible on the image, proceed slowly, paying close attention to the real-time video images.

(4) When the surgical accessories appear on the image, use the direction control lever to deflect the distal end and the manipulate the accessories to achieve the desired treatment.

(5) Before removing the surgical accessories, ensure that the distal end of the accessories is closed and can be safely withdrawn through the working channel.

4.9 Remove Ureteroscope from Patient

(1) Return the direction control lever to the neutral position to ensure the distal end of the ureteroscope is in a non-deflected position.

WARNING

● When removing the ureteroscope from the patient, ensure that the direction control lever is in the neutral position.

(2) While observing the image, slowly withdraw the ureteroscope from the patient. If resistance is encountered, use another imaging tool to identify the source of resistance before continuing withdraw.

4.10 Post-Operation

Turn off the power switches of the Videoscope Imaging Processor and Renal Pressure Monitoring Processor, and disconnect the ureteroscope plugs from the processors.

Dispose of used ureteroscopes as outlined in the “Disposal of Ureteroscope and Packaging Materials” section.

4.11 Disposal of Ureteroscope and Packaging Materials

After use, ensure that the product and its packaging are discarded in accordance with the policies of hospitals, administrative agencies, and/or local governments. Dispose of any medical waste in compliance with all applicable national and local laws and regulations to prevent environment pollution.

Chapter 5 Intended Purpose

Single Use Digital Flexible Ureteroscope w/ Pressure Monitoring is intended to visualize organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral or percutaneous access routes with pressure monitoring. It monitored the intraluminal pressure in the ureter and kidney. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.

Indication: The urinary tract and kidney disease diagnosis and provide access for treatment.

Intended users: This equipment should only be used by physicians who have thoroughly studied all the characteristics of this equipment and who are familiar with the proper techniques of endoscopic examination.

Intended patient population: This product is intended for patients indicated for flexible ureteroscopy or percutaneous procedures. Age, weight, gender and language should have no bearing on the physician using this technology as long as the patient is indicated for the procedure.

Intended working environment: Hospital settings.

Clinical benefit: The device provide access to treat urinary tract and kidney diseases such as ureteral stones, tumours, ureteric strictures. Considering the device itself does not provide direct therapeutic function, the clinical benefit is defined as indirect.

Equipment expected to be used in patient environment: Single Use Digital Flexible Ureteroscope w/ Pressure Monitoring.

Intended part of the body or type of tissue applied to or interacted with: The insert tube of the Single Use Digital Flexible Ureteroscope w/ Pressure Monitoring contacts with the urinary tract (urethra, bladder, ureter, calyces and renal papillae) of the human body directly. The materials used in this product are bio-compatible.

Chapter 6 Contraindications

Diagnostic or therapeutic ureteroscopy is contraindicated in people with an untreated urinary tract infection. Other contraindications to therapeutic ureteroscopy (e.g., lithotripsy, endopyelotomy, tumor therapy) are more numerous and can mirror those associated with the corresponding open surgical interventions. Patients on anticoagulants or with coagulopathies should be managed appropriately.

Chapter 7 Warnings

● Images should not be used as the sole basis for diagnosing pathology. Doing so may lead to misdiagnosis or failure to diagnose. Physicians must use other methods to corroborate findings based on the patient's clinical condition.

● Before each use, or after inserting accessories or changing settings, verify that the images observed through the ureteroscope are real-time (not stored images) and have the correct orientation.

● Ensure image clarity before using the ureteroscope. Failure to do so may increase the risk of perforation, avulsion, bleeding, or ureteral skin injury.

● Do not use the pressure monitoring function before performing zero calibration, as this may lead to inaccurate readings and potential patient injury.

●If the image is lost during use, stop using the ureteroscope and do not insert related surgical accessories, as this may cause patient injury, such as perforation, avulsion bleeding, or ureteral skin injury.

● In the event of pressure signal loss, do not continue use or insert any surgical accessories. Doing so may cause severe patient injury, such as perforation, avulsion bleeding, or ureteral epithelial damage.

● Excessive force when advancing or retreating the device may result in injury such as perforation, avulsion bleeding or ureteral skin injury. If the resistance is encountered during advancement or retraction, investigate the cause and take appropriate remedial measures (e.g. contrast injection).

● Do not use the ureteroscope to puncture the lateral wall of the ureter or pelvis, as this may lead to patient injury, such as perforation, avulsion, bleeding, or ureteral skin injury.

● Do not forcefully insert or withdraw surgical accessories, as this may result in patient injury (such as perforation, avulsion, bleeding, ureteral skin injury) or damage to the ureteroscope.

● When advancing or using surgical accessories, ensure that image and pressure information are displayed normally. Proceeding without this information may lead to patient injury.

● Do not pull the laser optical fiber into the ureteroscope working channel while the laser is active. Doing so may cause injury to the patient and/or damage the ureteroscope. Review the laser equipment's operating instructions to understand the emission parameters and protect against eye injuries.

● When the ureteroscope is equipped with an energy-containing endoscopic accessories, the leakage current to the patient may increase.

● Do not look directly at the light emitted from the ureteroscope, as doing so it may cause eye injury.

● When the ureteroscope outlet window transmits high-energy radiant light, it will cause high-temperature hazard at the emission window. With long-term use or with energy accessories, the distal end may exceed 41℃/105.8°F, but the maximum temperature will not exceed 43℃/109.4°F (ambient temperature). Therefore, minimize the use time and reduce the energy levels of the accessories as much as possible. In

operation, saline irrigation is recommended to maintain appropriate temperatures and prevent tissue damage. If the ureteroscope is not immediately required, it is advisable to turn off the light until needed.

● Do not open the handle of the ureteroscope, as this may damage the seal and cause the risk of electric shock.

●The ureteroscope is a single-use device. It must not be reused or repaired. If damaged or non-sterile, dispose of it according to the instructions. Reuse or reprocessing can compromise the structural integrity of the device, leading to failure and increased infection risk.

● Do not excessively deflect the flexible insertion portion and deflection section of the ureteroscope, as this may cause breakage or distortion of the product.

● If the ureteroscope is damaged or malfunctions during operation, stop using immediately. Refer to the troubleshooting section for more information on adjustments. A new ureteroscope may be used as appropriate.

● Before using a cardiac defibrillator, remove the ureteroscope from the patient. Failure to do so may result in injury to the patient and damage to the ureteroscope due to the defibrillator's discharge.

● This product is not compatible with high-frequency surgical equipment.

● Do not use if the aseptic packaging is damaged. This product is for single use, do not reuse, reprocess or disinfect. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the product and/or cause product failure, potentially resulting in injury, illness or death of the patient. It may also lead to cross-infection.

● If the pressure sensor is obstructed (e.g., by tissue, biomaterial, debris, or stones), pressure readings may be inaccurate. Do not rely on the readings under such conditions, as this may lead to excessive fluid or pressure delivery and result in patient injury, including infection, distension, or other fluid overload-related complications.

● When considering the pressure readings, exercise clinical judgment as the clinical implication of intrarenal pressure measurements may vary depending upon a variety of patient and procedural factors.

● When the pressure limit set for the procedure is exceeded, before continuing to irrigate, exercise clinical judgment as the clinical implication of intrarenal pressure measurements may vary depending upon a variety of patient and procedural factors.

● Consult the operating manuals of all electromedical energy sources used with endoscopic instruments for appropriate instructions, warnings, and cautions prior to use.

● Do not place ureteroscope on a non-sterile surface when not in use. Using the device after contact with a non-sterile object could result in infection.

● Use the ureteroscope with caution in patients who have undergone previous urinary tract reconstructive

surgery or have known strictures, as these conditions may prevent passage of the flexible ureteroscope shaft.

● After being connected to the Videoscope Imaging Processor, the ureteroscope's usage time is limited to ≤ 40h.

Chapter 8 Attentions

The ureteroscope can only be used in conjunction with Videoscope Imaging Processor (HV-200) and Renal Pressure Monitoring Processor (HV-M200), which are supplied by **A**nhui Happiness Workshop Medical Instruments Co., Ltd. Connecting to other devices may cause equipment damage or harm to the operator. The display configuration must include at least one HDMI, DVI or SDI interface.

Only trained physicians should operate the ureteroscope. Before use, it is essential to consult relevant technical data and medical literature regarding possible complications and side effects.

Before each use, it is necessary to check whether there are any rough surfaces, sharp edges or protrusions that cause safety hazards in the part of the ureteroscope and accessories inserted into the body.

In order to prevent obstruction of the flexible insertion tube, please use caution for those who have undergone urinary reconstruction surgery or have known ureteral stenosis.

Always straighten the distal end of the ureteroscope before advancing or withdrawing surgical instruments. Follow the instructions for the use of surgical accessories to prevent patient injury or damage to the equipment.

The ureteroscope features a rubber sheath at the transition from the handle to the flexible tube. The rubber sheath protects the device during use. To prevent damage to the flexible tube and/or light fiber, do not deflect the flexible tube sharply (see Figure 12).

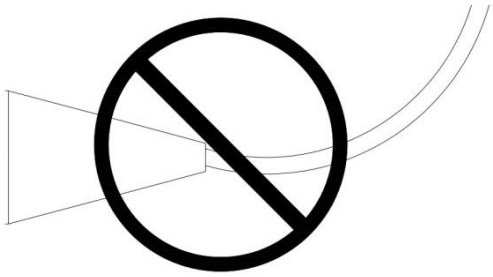


Figure 12 Do not Deflect the Flexible Tube Sharply

The insertion portion can only use normal saline or contrast agent compatible with the ureteroscope. Avoid using accessories that do not meet the compatibility requirements, as this can damage both the ureteroscope and its accessories.

Do not forcibly pull video or pressure signal cables, as this may lead to system performance deterioration or damage.

Intraoperative irrigation: if the hanging bag is used, the irrigation liquid can be suspended at 1.2m height gravity-fed. The suspension height should be adjusted in time according to clinical conditions; For other irrigation methods, maintain low pressure and low flow while ensuring clear visibility. During the irrigation process, the entrance of the working channel must be locked when not in use, otherwise the irrigation cannot function properly.

If the function of the ureteroscope is lost, in order to avoid safety hazards, a backup ureteroscope, Videoscope Imaging Processor and Renal Pressure Monitoring Processor should be available before surgery. If the lighting source (LED) is not bright and the troubleshooting is unsuccessful, a new ureteroscope should be used immediately. The light source (LED) of the ureteroscope cannot be replaced.

Failure to thoroughly understand and follow all instructions, cautions, and warnings provided in the Ureteroscope Instructions for Use, Renal Pressure Monitoring Processor and the Videoscope Imaging Processor User's Manual may result in injury to the patient and/or user; and/or may result in damage to, or malfunction of, this equipment. Additionally, damage to other equipment or property may result. Follow all instructions, cautions, and warnings provided with all products and equipment to be used in conjunction with the Digital Endoscope System to avoid any possible hazards due to device incompatibility.

Placing the console near other medical electrical equipment may result in electromagnetic interference (EMI) which may degrade the video image. Additionally, EMI from the console may interfere with other equipment in the operating room.

Verify ground isolation when setting up and using accessories from different manufacturers. Failure to do so can result in user/patient injury such as electric shock, tissue damage, additional intervention, and prolonged procedure, and accessory malfunction leading to patient injury.

Verify that all electrical equipment is working properly before starting the procedure. Failure to do so may result in equipment not working, possibly resulting in either a delay of the procedure or a side effect.

Do not remove the signal cable from the Processor by pulling on the cable as poor video performance or damage to the system may result.

Electromagnetic interference* (EMI) may occur in this instrument near equipment marked with the following symbol (). Electromagnetic interference may occur in this instrument near other portable and mobile radio frequency (RF) communication equipment, for example, cellular phones. To check for EMI, verify the system's operation in which it will be used. Should EMI occur, employ mitigation measures like reorienting or repositioning the instrument, or shielding its location. Placing this instrument near other medical equipment or mobile RF communications equipment may result in EMI, which may degrade the device performance.

Chapter 9 Side Effects

Possible complications include, but may not be limited to:

- Bleeding
- Avulsion
- Stenosis / Stricture
- Inflammation
- Laceration
- Pain
- Discomfort
- Urinoma
- Infection
- Fever
- Sepsis
- Extravasation
- Perforation (ureter, renal pelvis or bladder)
- Burn
- Ureteral Reflux
- Hematoma
- Urothelial damage

Chapter 10 Troubleshooting

10.1 Image Distortion or No Image Displayed

WARNING

● If there is image distortion or the image is lost during the procedure, immediately stop the insertion, propulsion, or operation of the ureteroscope and any equipment in the working channel to avoid injury or device damage.

Follow these steps:

(1) Turn off the Videoscope Imaging Processor and Renal Pressure Monitoring Processor. Disconnect the ureteroscope from the Videoscope Imaging Processor and Renal Pressure Monitoring Processor.

(2) Ensure that the video and pressure signal cable, signal cable plugs, cord sets and sockets for both the Videoscope Imaging Processor and Renal Pressure Monitoring Processor, as well as the RS232 cable and barcode scanner for Renal Pressure Monitoring Processor, are intact and clean.

(3) Reconnect the ureteroscope to the Videoscope Imaging Processor and Renal Pressure Monitoring Processor, and ensure that the signal cable of the ureteroscope is fully connected to the Processors.

(4) Check whether the real-time image is displayed. If not, proceed to step (5).

(5) Power off and restart the Videoscope Imaging Processor and Renal Pressure Monitoring Processor.

If the image cannot be restored, stop using the ureteroscope and remove it using the following steps:

1) Return the direction control lever to the neutral position to allow the distal end to return to its non-deflection state. Confirm the deflection status of the ureteroscope by observing the real-time image.

2) Carefully remove the ureteroscope from the patient. If resistance is felt, use imaging to identify the source before continuing with endoscope removal.

3) Discard the ureteroscope (see “Disposal of Ureteroscope and Packaging Materials”) and use a new one.

10.2 Deflection Control Failure

WARNING

● If control fails, stop the propulsion of the ureteroscope, as well as the insertion, propulsion or operation of any surgical accessories to the working channel.

If direction control lever fails to respond, stop using the ureteroscope by the following steps:

(1) Return the direction control lever to a neutral position.

(2) Confirm that the insertion portion is straightened using real-time images.

(3) If the distal end is still deflected, use the direction control lever and image to correct the distal end.

(4) If the direction control lever cannot correct the distal end, use a guide wire (0.035 inches/0.89mm or thicker) to straighten it through the following steps:

1) Hold the handle of the ureteroscope and insert the guide wire (provided by the hospital) through the working channel device entry of the ureteroscope.

2) The operator push the guide wire slowly pushes forward and observe the real-time status when the guide wire is inserted into the image screen.

3) When the real-time screen observes the front of the guide wire, stop the guide wire propulsion.

(5) By fluoroscopic imaging or other imaging methods, confirm the ureteroscope deflection section has been straightened.

(6) Slowly pull out the ureteroscope from the patient. Monitor the extraction process by fluoroscopic imaging or other imaging methods. If resistance is felt, identify the source and take remedial measures before continuing to withdraw the ureteroscope.

(7) Dispose of the ureteroscope (See “Disposal of Ureteroscope and Packaging Materials”) and use a new one.

10.3 Difficulty Capturing an Image or Recording a Video

WARNING

(1) Ensure that the ureteroscope is correctly connected to the Videoscope Imaging Processor and the Renal Pressure Monitoring Processor.

(2) Confirm that the buttons are activated.

(3) Verify that the buttons for photo, video, white balance, zoom, and image freeze are functioning correctly by checking the screen.

(4) Replace the ureteroscope if necessary.

10.4 Pressure Sensor

WARNING

● The ureteroscope can function without the pressure sensor. To proceed without pressure monitoring, ensure the real-time video image is intact.

(1) Ensure that the ureteroscope is correctly connected to both the Videoscope Imaging Processor and the Renal Pressure Monitoring Processor.

(2) Remove the ureteroscope from the patient.

(3) Power off and restart both the Videoscope Imaging Processor and the Renal Pressure Monitoring Processor. Then repeat the “Set-up” steps from Chapter 4, scan the QR code, and perform zero calibration before re-inserting the ureteroscope.

(4) If pressure monitoring does not resume after following these steps, replace the ureteroscope with a new one or proceed without the pressure monitoring function.

Chapter 11 Electromagnetic Compatibility

CAUTION

● Users and operators of the Videoscope Imaging Processor, Renal Pressure Monitoring Processor, and ureteroscope shall ensure that the Digital Endoscope System is used under the conditions specified in this chapter. Failure to do so may prevent the Digital Endoscope System from functioning properly.

● Portable and mobile radio-frequency communication equipment may affect the normal use of the Videoscope Imaging Processor, Renal Pressure Monitoring Processor and ureteroscope. Use the Digital Endoscope System only in the recommended electromagnetic environment.

WARNING

● The use of accessories and cables other than those supplied by Happiness Works as spare parts may increase emissions or decrease immunity, potentially resulting in improper operation.

● Use of the Videoscope Imaging Processor, Renal Pressure Monitoring Processor and Ureteroscope adjacent to or stacked with other equipment should be avoided, as this may result in improper operation. If such use is unavoidable, the devices should be observed and verify that they are operating normally.

● Do not use the system near active high-frequency (HF) surgical equipment or in RF-shielded rooms of medical equipment systems for magnetic resonance imaging (MRI), where electromagnetic interference (EMI) levels are high. Active medical devices require special electromagnetic compatibility (EMC) precautions and must be installed and operated in accordance with these guidelines.

● Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30 cm) to any part of the equipment, including the cables specified by the manufacturer, to avoid performance degradation.

The Essential Performance:

1) There is no unacceptable risk if the view observed by the operator has an unexpected image orientation;
2) There is no unacceptable risk that the operator is viewing the live image during an endoscopic procedure, rather than a recorded image;
3) There is no unacceptable risk that work normally in the pressure range of -30mmHg- 300mmHg.

Pressure monitoring error: When the pressure is in the range of -30mmHg- 200mmHg, the monitoring error shall be ± 4mmHg or ±4% of the reading (whichever is greater), and when the pressure is in the range of 200mmHg (excluding 200mmHg) - 300mmHg, the monitoring error shall be ±10% of the reading.

Ureteroscope is CISPR 11 Class A device.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	RF emissions from Ureteroscope is very low and

		are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Ureteroscope is only suitable for medical institutions or institutions with professional training.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guide and the Manufacturer's Declaration for Electromagnetic Immunity

Immunity test	IEC 60601 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, 8 kV, ± 15 kV air
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines
Surge IEC 61000-4-5	± 1 kV line (s) to line (s) ± 2 kV line (s) to earth	± 1 kV line (s) to line (s) ± 2 kV line (s) to earth
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle 70 % U_T; 25/ 30 cycles 0 % U_T; 250/ 300 cycles	0 % U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle 70 % U_T; 25/ 30 cycles 0 % UT; 250/ 300 cycles
Power frequency magnetic field IEC 61000-4-8	30 A/m 50/ 60Hz	30 A/m 50/ 60Hz
Conducted RF IEC 61000-4-6	3 V r m s 150 kHz to 80 MHz 6 V r m s in the ISM bands between 0.15 MHz and 80 MHz	3V r m s 150 kHz to 80 MHz 6 V r m s in the ISM bands between 0.15 MHz and 80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz

Guidance and Manufacturer's Declaration - IMMUNITY to proximity fields from RF wireless communications equipment

Immunity test	IEC60601 test level				Compliance level
	Test frequency	Modulation	Maximum power	Immunity level	
Radiated RF IEC 61000-4-3	385 MHz	**Pulse Modulation: 18Hz	1.8W	27 V/m	27 V/m
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2 W	28 V/m	28 V/m

	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	2450 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m

Note* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.
Note* - The carrier shall be modulated using a 50 % duty cycle square wave signal.

Guidance and Manufacturer's Declaration - IMMUNITY to proximity magnetic fields

Test frequency	Modulation	Immunity level (A/m)
30 kHz	CW	8
134.2 kHz	*Pulse Modulation 2.1 kHz	**65
13.56 MHz	*Pulse Modulation 50 kHz	**7.5

Note* - The carrier shall be modulated using a 50 % duty cycle square wave signal.
Note* - r.m.s., before modulation is applied.