CE 0344

# Digital Endoscope System

## Single Use
## Digital Flexible
## Ureteroscope (7.5F)

## User manual

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Anhui Happiness Workshop Medical Instruments Co., Ltd

Pioneering Innovation
Empowering Healthcare

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**Forward**

The Digital Endoscope System is designed for physicians to access, visualize, and perform procedures within the urinary tract and kidneys. The system comprises a Videoscope Imaging Processor and a Single Use Digital Flexible Ureteroscope (7.5F). The device enables delivery and the use of accessories such as laser fibers, guide wires, and stone retrieval baskets during surgery.

Thank you for purchasing the Single Use Digital Flexible Ureteroscope (7.5F). 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 relevant regulatory authorities.

Product: Single Use Digital Flexible Ureteroscope (7.5F)

Product models:

HUS-T101R
HUS-T102R
HUS-T105R
HUS-T101S
HUS-T102S
HUS-T105S




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Lotus NL B.V.
Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

3 years

**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 re-sterilized. 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 device and packaging in accordance with hospital guidelines, healthcare regulations, and local government policies.

The Single Use Digital Flexible Ureteroscope (7.5F) is provided in a sterile condition and consists of two primary components: a handle with a direction control lever and video signal cable, and a flexible insertion portion.

The Single Use Digital Flexible Ureteroscope (7.5F) can also be referred to as Ureteroscope hereinafter. The Ureteroscope is compatible with surgical accessories such as laser fibers, guide wires, and stone retrieval baskets. The deflection section of the Ureteroscope allows for 285° deflection in both directions, enabling precise control during procedures. The flexible insertion portion 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 ports facilitate the use of surgical accessories and fluids.

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 a image sensor (CMOS) 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.

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.

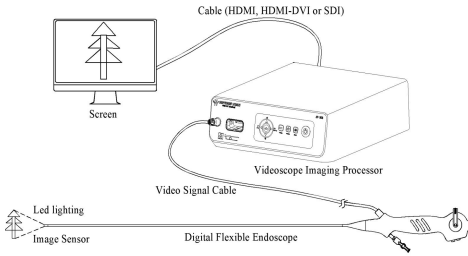



Figure 1 Digital Endoscope System Operating Principle

**Chapter 2 Basic Information**

**2.1 Marking Instruction**

| Symbol | Symbol title | Symbol | Symbol title |
|---|---|---|---|
| **ZebraScope** | Product trademark | STERILE EO | Sterilized using ethylene oxide |
| MD | Medical device | +50°C -40°C | Storage/ Transportation temperature limitation |
| **IPX7** | Water proof 7 | 93% 10% | Storage/ Transportation humidity limitation |
| REF | Catalogue number | 1060hpa 700hpa | Storage/ Transportation atmospheric pressure limitation |
| LOT | Batch code | | Manufacturer |
| | Single sterile barrier system with protective packaging outside | EU REP | Authorized representative in the European Community/ European Union |
| | Date of manufacture | | This way UP |
| | Use-by date | | DO NOT ROLL |
| | Do not re-use | | Fragile, handle with care |
| | Do not resterilize | | Keep dry |
| | BF type application part | | Keep away from sunlight |
| | Do not use if package is damaged and consult instructions for use | 5 | Stacking limit by number |
| | Follow instructions for use | | General warning sign |
| | Non-ionizing electromagnetic radiation | | Separate collection |

**2.2 Product Models and Specifications**

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

Table 1 Product Models

| Product Model | Description | Allowance |
|---|---|---|
| HUS-T101R | Working length 670mm with reverse deflection | +10mm |
| HUS-T102R | Working length 660mm with reverse deflection | +10mm |
| HUS-T105R | Working length 380mm with reverse deflection | +10mm |
| HUS-T101S | Working length 670mm with standard deflection | +10mm |
| HUS-T102S | Working length 660mm with standard deflection | +10mm |
| HUS-T105S | Working length 380mm with standard deflection | +10mm |

Figure 2 Standard Deflection

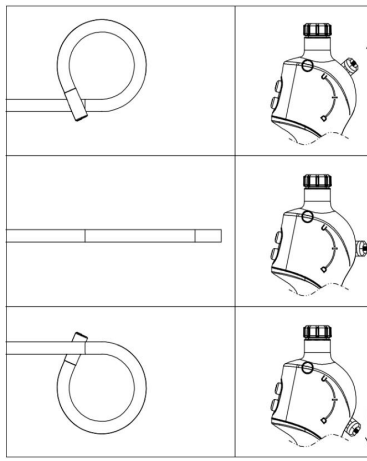
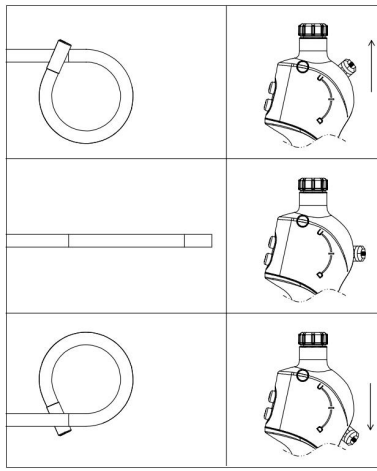


Figure 3 Reverse Deflection



**2.3 Product Parameters**

Table 2 Main Parameters

| Specification | | Value |
|---|---|---|
| Basic Data | Maximum width of insertion portion (distal end) | 8.6Fr/2.85mm |
| | Maximum width of flexible section | 7.5Fr/2.5mm, tolerance +5%, excluding the lower limit |
| | Minimum width of working channel | 3.6Fr/1.2mm |
| Optical Index | Direction of view | 0°±10° |
| | Field of view | 110°±10% |
| | Depth of field | 2mm~50mm |
| | Image intensity uniformity | $U_L$≤25% |
| Deflection | Deflection angle range | 285° Up/ 285° Down, tolerance ±15° |

**2.4 Environmental Requirements**

**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)

**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**

- Type of Electric Shock Prevention: Not applicable
- Degree of Electric Shock Protection: After connecting with the Videoscope Imaging Processor, it becomes a BF type applied part
- Ingress Protection Rating: Insertion portion rated IPX7
- Safety in Presence of Flammable Anesthetic Gas mixed with air or with oxygen or nitrous oxide: Non-AP/APG type
- Operating Mode: Not applicable
- Rated Voltage and Frequency: Not applicable
- Input Power: Not applicable
- Protection Against Defibrillation Discharge Effects: No
- Signal Output/Input: Equipped with signal input/output part
- Installation Type: Non-permanent installation equipment
- Signal Output/Input Capability: Yes;

**WARNING**

- The Ureteroscope is a sterile package and can be used directly.
- The Ureteroscope is designed 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**

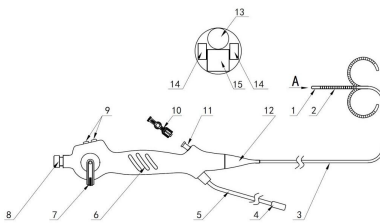



Figure 4 System Diagram

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

**3.2 Product Composition**
Applied parts of the product:
(1) Distal end
(2) Deflection section
(3) Flexible section

Distal End (1): The part that interacts directly with the target area.
Deflection Section (2): Allows for the maneuverability of the distal end.
Insertion Portion (3): The flexible tube that is inserted into the urinary tract.
The handle is designed for operating the insertion, withdrawal, and turning of the flexible insertion tube. It includes:

Direction Control Lever (7): Used to control the up and down deflection of the distal end. The deflection can be standard (lever up = distal end up) or reverse (lever up = distal end down), depending on the model. When the control lever is in the neutral position, the distal end returns to the non-deflected position.
Working Channel Device Entry (8): An inlet for surgical accessories.
Buttons (9): The factory settings designate the "A" button for taking photos and the "B" button for recording videos. Specific functions can be configured through the Processor.
Irrigation Port (11): A Luer interface for administering irrigation and/or contrast solutions.
Video Signal Cable with Plug (4) (5): Provides the electrical connection to the Ureteroscope and transmits the video signal back to the Videoscope Imaging Processor for processing.

**WARNING:** Do not modify this equipment without authorization from Happiness Works.

**Chapter 4 Operation and Use**

**4.1 User Requirements**
Before use, please read this instruction manual carefully, paying close attention to labels for safe operation and storage, and use the product as required. Only physicians who are professionally trained may use this product. Before using the Ureteroscope, please understand its technical principles, clinical applications, and potential risks. This includes, but is not limited to, surgical accessories and equipment that assist with the observation and treatment, such as laser fibers, guide wires, and stone retrieval baskets.

**4.2 Product Preparation**
(1) Unpacking
Upon receipt, inspect 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 its expiration date. After removing the Ureteroscope from the package, perform the following inspection.

Inspection
Open the sterile barrier by peeling back the header on the handle side of the bag. Remove the Ureteroscope from the bag by gripping the handle and signal cable. Carefully remove the protective sleeve from the insertion portion to prevent deflection before use. Hold the Two-way valve, insert the Luer taper of the two-way valve into the irrigation port on the handle of the Ureteroscope firmly.

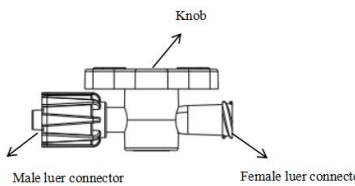


Figure 5 Two-way Valve Diagram

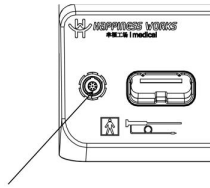
**WARNING:** Failure to check for damage to the product and accessories before use may result in improper device performance and patient injury.

Inspect the entire surface of the flexible insertion portion visually. Examine the handle, direction control lever, and irrigation port to ensure no components are loose, bent, broken, or have sharp edges. Examine the distal end for any flaws, including dents, protrusions, tears, and holes. Check that the deflection direction and angle of the Ureteroscope operate smoothly. Avoid forcing the control lever to straighten or deflect the distal end, as this may damage the

mechanism.Visually inspect the video signal cable and plug for damage or visible impurity.

**4.3 Setup**
(1) Insert the video signal cable plug of the Ureteroscope fully into the Lemo socket of the Videoscope Imaging Processor.

Figure 6 Connect the Ureteroscope with Videoscope Imaging



Processor
(2) Set the handle button functions according to the instructions for the Videoscope Imaging Processor and confirm that the buttons function normally.
(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.

**WARNING:** Ensure that the protrusion on the video signal cable plug aligns with the groove on the socket of the Videoscope Imaging Processor before inserting. If it is not aligned,it cannot be inserted. Forcing the connection may damage either the Ureteroscope or the Videoscope Imaging Processor.

(4) White Balance Adjustment
To ensure 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.

**WARNING**: The Processor features an automatic white balance function that can be adjusted using the white balance button.

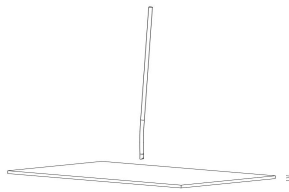


Figure 7 White Balance Adjustment

**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. (Refer to Figure 8)

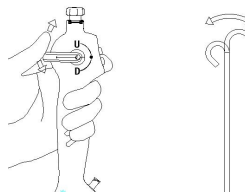



Figure 8 Adjust the Deflection Direction and Angle

**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 on the handle, as shown in Figure 9 below. The marking on the left indicates the locking direction, while the marking on the right indicates the unlocking direction.

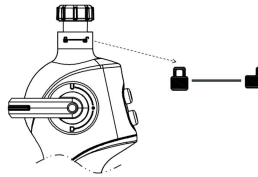


Figure 9 Adjust the Working Channel Device Entry

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

**4.6 Connect the Irrigation/Contrast Interface**
Remove the sealing cap from the two-way valve by rotating it counterclockwise. Connect the port of the two-way valve to the irrigation/contrast supply tubing from a compatible source. Ensure that the knob is aligned parallel to the direction of the two-way valve to allow irrigation/contrast. If necessary, rotate the knob 90 degrees 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 anatomical landmarks, using real-time video or other imaging modes to confirm the progress of the distal end.
- If the image is lost during the procedure and does not return after restarting the Videoscope imaging processor, replace the Ureteroscope immediately.

**4.8 Insertion and Removal of Surgical Accessories**
(1) Insertion of 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. 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. If the gap between the distal end of the Ureteroscope and the inner wall is not maintained, perforation may occur 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 ensure image stability and avoid injury to the patient or damage to the Ureteroscope.
- For laser lithotripsy, the laser fiber must extend 8-10 mm beyond the mouth of the Ureteroscope before starting the operation. Otherwise, the tip of the laser fiber may damage the product.

- The working channel provided by this product can be used with laser fibers, stone retrieval baskets, guide wires, 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.

**WARNING**

- 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, ensure that the surgical accessories are in the correct form, such as confirming that the stone retrieval basket is closed and the guide wire is not knotted.

- When using a laser lithotripsy system, select a system with adjustable strength or pulse settings. Adjust the intensity or pulse of the laser to ensure the gravel target is 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 and 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 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 Removing the Ureteroscope from the 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 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 to withdraw the Ureteroscope.

**4.10 Post-Operation**

Turn off the power switch of the Videoscope Imaging Processor and disconnect the Ureteroscope plug from the processor. 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 environmental pollution.

**Chapter 5 Intended Purpose**

Single Use Digital Flexible Ureteroscope (7.5F) 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. It can also be used in conjunction with

endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.

**Indications**: 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 Benefits**: 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.

**Expected Equipment Use:** The Single Use Digital Flexible Ureteroscope (7.5F).

**Contact Areas**: The insertion tube directly contacts the urinary tract (urethra, bladder, ureter, renal calyces, and renal papillae). The materials used in this product are biocompatible.

**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**

**Image Use**: Images captured 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.

**Real-Time Verification**: Ensure that images observed through the Ureteroscope are real-time (not stored images) and properly oriented before each use or after inserting accessories.

**Clear Image**: Ensure image clarity before using the Ureteroscope. Failure to do so may increase the risk of perforation, avulsion, bleeding, or injury to the ureter.

**Loss of Image**: If the image is lost during use, do not insert related surgical accessories as this may cause injury to the patient, such as perforation, avulsion, bleeding,or ureteral skin injury.

**Use of Force**: Excessive force when advancing or retracting the device may result in injury. If resistance is encountered during advancement or retraction, investigate the source of the resistance and take remedial measures (such as comparative injection).

**Contact with Tissue**: 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.

**Surgical Accessories**: Do not forcefully insert or withdraw surgical accessories, as this may result in patient injury or damage to the Ureteroscope.

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

**Radiant Light Exposure**: When the Ureteroscope is equipped with an energy-containing endoscopic accessory, the leakage current of the patient will increase. Do not look directly at the light emitted from the Ureteroscope, as doing so may cause eye injury. The Ureteroscope's light source can reach high temperatures. During

long-term use or when used with energy-based accessories, the distal end may exceed 41℃/105.8°F, though not more than 43°C/109.4°F (ambient temperature).Therefore, minimize the use time and reduce the energy levels of the accessories as much as possible. 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. Opening the handle may damage the seal, increasing the risk of electric shock.

**Single Use**: 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 it 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 only; 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.

- After connecting to the Videoscope Imaging Processor, the Ureteroscope's usage time is limited to ≤ 40 hours.

- 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 the 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.

**Chapter 8 Precautions**

The Ureteroscope can only be used in conjunction with the HV-200 Videoscope Imaging Processor, which is supplied by Anhui Happiness Workshop Medical Instruments Co. Ltd. Using other devices may cause equipment damage or harm to the operator.The display configuration must include at least one HDMI, DVI, or SDI interface.

**Qualified Personnel**: 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.

**Pre-Use Inspection**: Before each use, inspect the Ureteroscope for rough surfaces, sharp edges, or protrusions that may pose safety risks. Ensure there is no physical damage.

**Caution with Reconstructed Ureters**: For patients with previous urinary tract reconstructive surgery or known strictures, extra care is required to avoid complications when advancing the flexible insertion portion.

**Handling Surgical Accessories**: 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.

**Avoid Excessive Deflection**: Avoid forcing the deflection mechanism of the Ureteroscope. Forcing the deflection may cause damage to the flexible insertion portion (Figure 10).

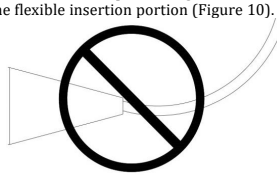


Figure 10 Do not force deflection

**Compatibility and Lubrication Guidelines:** Only use normal saline or developing agent approved for use with the Ureteroscope for the inserted portion. 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/signal cables, as this may lead to system performance degradation or damage.

**Intraoperative Irrigation**: If using a hanging irrigation bag, adjust the height according to clinical conditions (the recommended height is 1.2m). 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 be normal.

**Emergency Ureteroscope Backup**: In case the Ureteroscope loses functionality, a backup Ureteroscope and Videoscope Imaging Processor should be available before surgery. If the light source (LED) fails, use a replacement Ureteroscope immediately.

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

**Electromagnetic Interference (EMI):** Placing the Ureteroscope near other medical electrical equipment may cause electromagnetic interference (EMI), which could degrade the image quality. Ensure ground isolation when using accessories from different manufacturers. Failure to do so may result in electric shock, tissue damage, additional interventions, extended procedure times, and accessory malfunctions.Ensure that all electrical equipment operates properly before the procedure.Do not pull the signal cable from the processor, as this may degrade video performance or damage the system. EMI may occur near equipment with the following symbol ( ) or near portable RF communication devices like cell phones. Verify system operation to check for EMI. If EMI occurs, reorient, reposition, or shield the instrument. Placing the instrument near other medical or RF communication equipment may degrade performance.

## Chapter 9 Side Effects

Possible complications and side effects may include, but are not limited to:

- Bleeding
- Pain
- Burn
- Fever
- Vesicoureteral reflux
- Sepsis
- Discomfort
- Hematuria
- Urinary tract dysfunction
- Laceration
- Chronic kidney disease
- Infection
- Inflammation

## 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. Disconnect the Ureteroscope from the Videoscope Imaging Processor.
2. Check the video signal cable, plug, socket ,and power cord for damage, moisture, or contamination.
3. Reconnect the Ureteroscope to the Processor and check if real-time images are displayed.
4. If the issue persists, power off and restart the Videoscope Imaging Processor.
5. If the image cannot be restored, remove the Ureteroscope by returning the control lever to the neutral position, confirm the deflection state of the Ureteroscope through the image(so the distal end returns to its straight position) and carefully withdraw the device. If resistance is felt, use imaging to identify the source before continuing with endoscope removal. 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 device attachments in the working channel.

If the direction control lever fails to respond, follow these steps:
1. Return the direction control lever to its neutral position.
2. Confirm that the insertion portion is straightened using real-time images.
3. If the distal end remains deflected, use a guide wire (0.035 inches or thicker) to straighten the distal end by carefully inserting it through the working channel.
4. Confirm the deflection section of the Ureteroscope is straightened using fluorescence microscopy or other imaging methods.
5. Monitor the guide wire's advancement using real-time images. Once the wire reaches the distal end, stop the advancement and withdraw the Ureteroscope carefully.
6. Monitor the extraction process using point fluorescence images 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 malfunctioning Ureteroscope (See "Disposal of Ureteroscope and Packaging Materials") and replace it with a new one.

**10.3 Difficulty Capturing an Image or Recording a Video**
**WARNING:**
1. Ensure that the Ureteroscope is correctly connected to the processor.
2. Confirm that the buttons are activated.
3. Verify that the buttons for photo, video, white balance, zoom, and freezing capture are functioning correctly by checking the screen.
4. Replace the Ureteroscope if necessary.

**Chapter 11 Electromagnetic Compatibility**

**WARNING**: It is the responsibility of the Ureteroscope and Videoscope Imaging Processor buyers or users to ensure the products are used in the specified electromagnetic environment. Failure to comply with these guidelines may result in improper operation of the Ureteroscope and Videoscope Imaging Processor.

Portable and Mobile RF Communications Equipment: The Ureteroscope and Videoscope Imaging Processor may be affected by portable and mobile radio frequency (RF) communication devices. Please use the Digital Endoscope System in the recommended electromagnetic environment.

Use Near Other Equipment: Avoid using the Videoscope Imaging Processor and Ureteroscope next to or stacked with other equipment to prevent improper operation. If necessary, monitor and verify their normal operation. Avoid using the Ureteroscope near active high-frequency surgical equipment or magnetic resonance imaging (MRI) systems. Active medical devices require special EMC precautions and must be installed according to guidelines. Keep portable RF communications equipment(including antenna cables and external antennas) at least 12 inches (30cm) from any part of the equipment, including manufacturer-specified cables. Such environments may cause strong electromagnetic disturbances, which can degrade the Ureteroscope's performance.

**WARNING**: The use of accessories and cables other than those

provided or recommended by Happiness Works may result in increased emissions or decreased immunity of the system, causing malfunction.

**The Essential Performance**:

- There is no unacceptable risk if the view observed by the operator has an unexpected image orientation;
- There is no unacceptable risk that the operator is viewing the live image during an endoscopic procedure, rather than a recorded image;

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 | 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 | |

| **Guidance and Manufacturer's Declaration – Electromagnetic Immunity** | | |
|---|---|---|
| **Immunity test** | **IEC 60601 Test level** | **Compliance level** |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 8 kV contact<br>± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air | ± 8 kV contact<br>± 2 kV, ± 4 kV, 8 kV, ± 15 kV air |
| Electrical fast transient/ burst IEC 61000-4-4 | ± 2 kV for power supply lines<br>± 1 kV for input/ output lines | ± 2 kV for power supply lines<br>± 1 kV for input/ output lines |
| Surge IEC 61000-4-5 | ± 1 kV line (s) to line (s)<br>± 2 kV line (s) to earth | ± 1 kV line (s) to line (s)<br>± 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<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br>0 % $U_T$; 1 cycle<br>70 % $U_T$; 25/ 30 cycles<br>0 % $U_T$; 250/ 300 cycles | 0 % $U_T$; 0.5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br>0 % $U_T$; 1 cycle<br>70 % $U_T$; 25/ 30 cycles<br>0 % UT; 250/ 300 cycles |
| Power frequency magnetic field IEC 61000-4-8 | 30 A/m<br>50/ 60Hz | 30 A/m<br>50/ 60Hz |
| Conducted RF IEC 61000-4-6 | 3 V r m s<br>150 kHz to 80 MHz<br>6 V r m s in the ISM bands between 0.15 MHz and 80 MHz | 3V r m s<br>150 kHz to 80 MHz<br>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<br>80 MHz to 2.7 GHz<br>80 % AM at 1 kHz | 3 V/m<br>80 MHz to 2.7 GHz<br>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<br>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<br>745 MHz<br>780 MHz | **Pulse Modulation: 217Hz | 0.2 W | 9 V/m | 9 V/m |
| | 810 MHz<br>870 MHz<br>930 MHz | **Pulse Modulation: 18Hz | 2 W | 28 V/m | 28 V/m |

| | | | | | |
|---|---|---|---|---|---|
| | 1720 MHz<br>1845 MHz<br>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<br>5500 MHz<br>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.