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ZebraScope

CE

Digital Endoscope System

Renal Pressure Monitoring Processor

User Manual

Product model:
HV-M200

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 within the urinary tract and the kidneys. The system includes the Renal Pressure Monitoring Processor, Videoscope Imaging Processor and Single Use Digital Flexible Ureteroscope w/ Pressure Monitoring. The ureteroscope enables delivery and use of accessories at a surgical site.

The Renal Pressure Monitoring Processor is used in conjunction with the Single Use Digital Flexible Ureteroscope w/ Pressure Monitoring (hereinafter "Ureteroscope") and Videoscope Imaging Processor in the examination, diagnosis or treatment and pressure monitoring of upper urinary tract diseases in the urinary system. Do not use the device for any other purpose.

This device is to be operated exclusively by physicians who possess a comprehensive understanding of its features and are proficient in endoscopic techniques. It is essential to thoroughly read and familiarize yourself with this manual prior to use. The manual outlines the recommended procedures for inspecting and preparing the Renal Pressure Monitoring Processor before use, as well as guidelines for maintenance and care following use.

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

WARNING

The information contained in this user manual is subject to change without prior notice.

If you encounter any questions or issues during use that cannot be resolved, please contact your local distributor or reach out to customer service via email at service@hwmeds.com for assistance.

In the event of a serious incident, it must be reported to Anhui Happiness Workshop Medical Instruments Co., Ltd (hereinafter referred to as "Happiness Works") and the appropriate regulatory authority.

NOTE

Thank you for purchasing the Renal Pressure Monitoring Processor. Before using the device, thoroughly read this manual as well as the instructions for all associated equipment, and follow the operational guidelines as instructed. Please store all relevant manuals in a safe and accessible location. For any inquiries regarding this manual, please contact Happiness Works.

Product name: Renal Pressure Monitoring Processor

Product model: HV-M200

Software release version: V1

Intended purpose: The Renal Pressure Monitoring Processor is used in conjunction with the Single Use Digital Flexible Ureteroscope w/ Pressure Monitoring and Videoscope Imaging Processor for pressure monitoring during the examination, diagnosis or treatment imaging of the upper urinary tract in urinary system.

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.

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 provides pressure monitoring during these surgical procedures to assess pressure within the urinary tract. Considering the device itself does not provide a direct therapeutic function, the clinical benefit is defined as indirect.

Equipment expected to be used in patient environment: Renal Pressure Monitoring Processor (HV-M200).

Side effects: Please refer to the Instructions for Use of the Ureteroscope (produced by Happiness Works) for details.

Operating principle:

The Renal Pressure Monitoring Processor is used in conjunction with the Ureteroscope and Videoscope Imaging Processor. It provides the light source for the pressure sensor, receives the pressure signals from the Ureteroscope, processes the readings, and outputs pressure information in one of two ways:

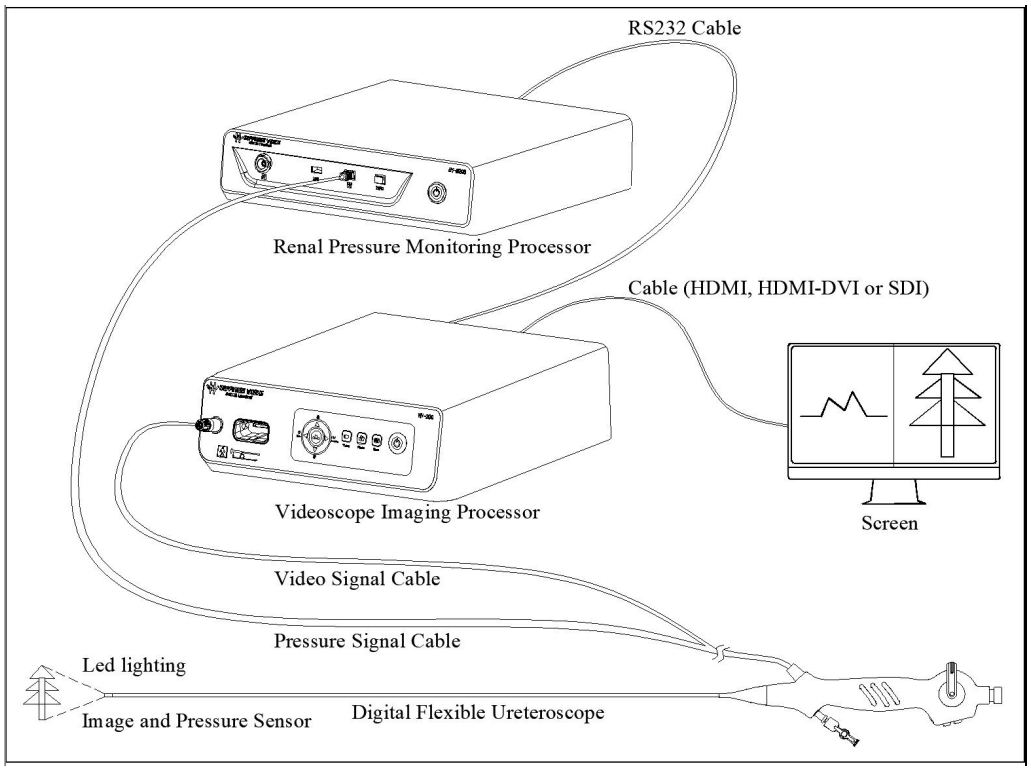
Direct Output: The processed pressure information is transmitted directly to an external monitor via the HDMI port on the back of the Renal Pressure Monitoring Processor.

Integrated Output: The pressure information is sent to the Videoscope Imaging Processor via the RS232 cable. The Videoscope Imaging Processor integrates the video image and pressure information and outputs them together to an external monitor via its SDI, HDMI, or DVI ports.

There are two output configurations for displaying the signals (see Figure 1):

Option 1: The Videoscope Imaging Processor and Renal Pressure Monitoring Processor output their signals to two separate external monitors.

Option 2: The Renal Pressure Monitoring Processor sends its signal to the Videoscope Imaging Processor via the RS232 cable. The Videoscope Imaging Processor integrates both image and pressure data and outputs the combined information to a single external monitor.



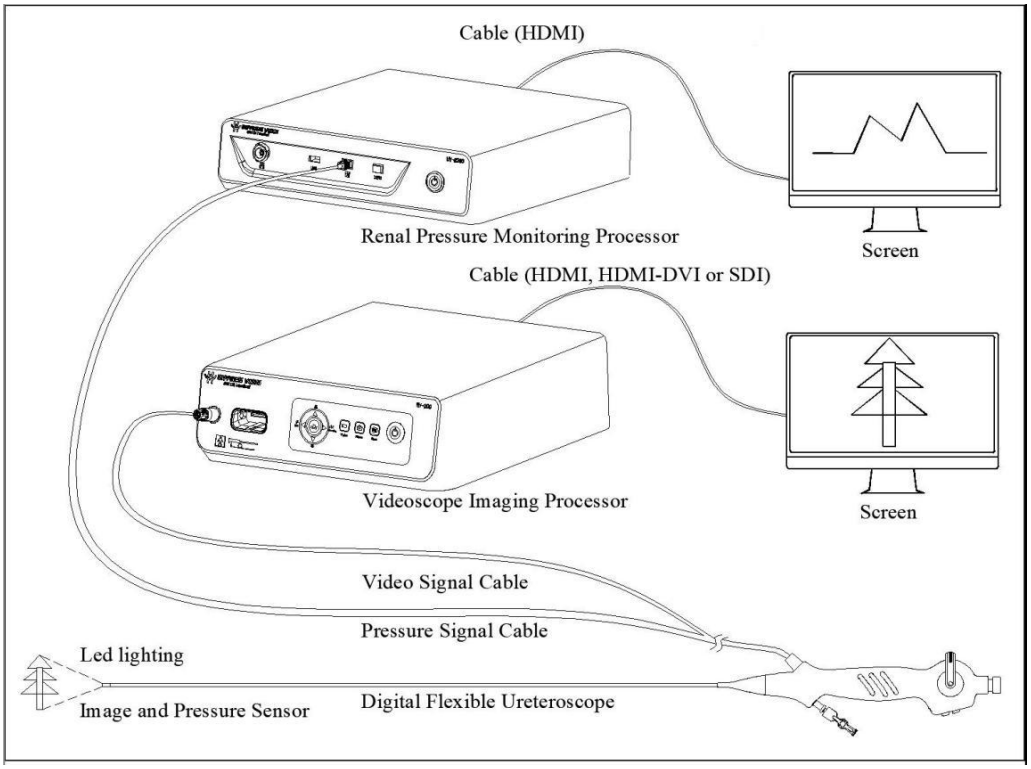


Figure 1 Schematic Diagram of the Two Output Methods

Any serious accident should be reported to Happiness Works and the competent authority.

Product: Renal Pressure Monitoring Processor
Product model:
HV-M200

Anhui Happiness Workshop Medical Instruments Co., Ltd
Address: 1/F, 2/F, 3/F, Building 2, Wisdom Industrial Park, 1300 Jiangqiao Road, Bengshan District, 233000 Bengbu, Anhui Province, China
Email: service@hwmeds.com

EU REP

Certification body: DEKRA Certification B.V.
Lotus NL B.V.
Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Tel: +31644168999 E-mail: peter@lotusnl.com

: 5 years.

File No.: YFV-2317-PI
Version: 1.2
Effective Date: 1st August 2025

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Chapter 1 Device Composition and System Configuration

1.1 Instrument Composition

The Renal Pressure Monitoring Processor consists of the processor unit, power cord, barcode scanner, HDMI cable, and RS232 cable. Structure diagram of the processor is shown in Figure 2:

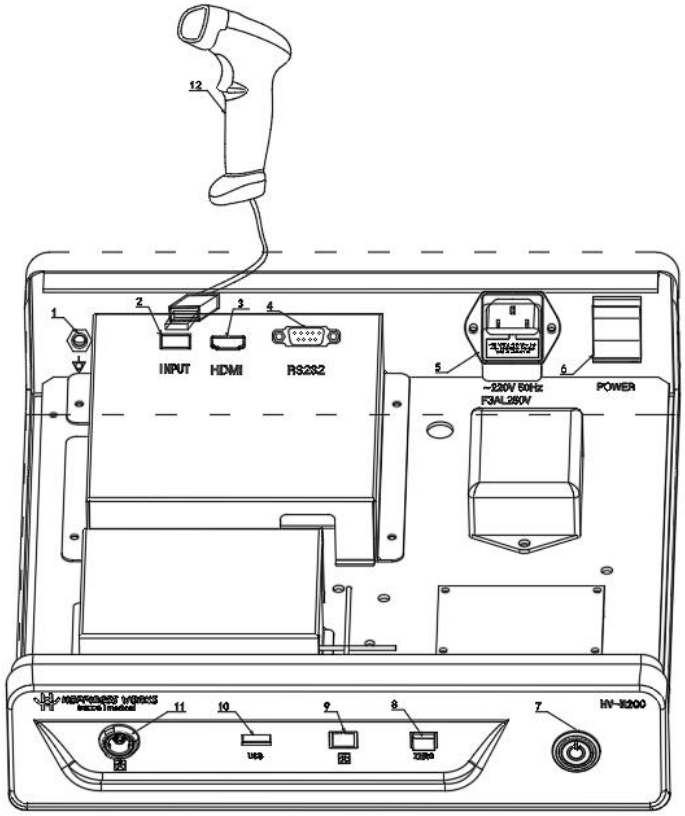


Figure 2 Renal Pressure Monitoring Processor Structure

Table 1 Composition Overview

No.	Name	Explanation
1	Earth (ground)	Equipotential terminal interface **CAUTION** ● Ensure that the hospital's potential equalization wire (common ground) is properly connected to the equipotential terminal when using this product.
2	INPUT port	Connect to the barcode scanner.
3	HDMI	HDMI video cable for connection to the monitor *(Note: Happiness Works supplies an HDMI-to-HDMI cable with the processor)*
4	RS232	Information exchange interface *(Note: Happiness Works provides this data cable with the processor)*

5	Power socket	Supply AC 100-240V power via the power cord
6	Rocker Switch	Controls the on/off function for the 100-240V AC power supply.
7	Control switch	· Turning On: If the processor is in a shutdown state, press the "Rocker Switch" button first, followed by the "Control Switch" button to turn it on. · Turning Off: If the processor is already powered on, press the "Control Switch" button first, followed by the "Rocker Switch" button to shut down the device. Power Control: This button controls the 12V DC power supply to the device.
8	Zero calibration button	Manual zero calibration function
9	Laser optical fiber port	Connects to the pressure signal cable plug of the Ureteroscope.
10	USB port	The USB port allows connection to an external USB drive for storing pressure data. It is also used for system software upgrades performed by authorized personnel from Happiness Works. Notes: · The USB port must not be used for any other purposes, such as supplying power to external devices. · Happiness Works does not supply a USB drive with the processor.
11	Signal cable port	This port is currently inactive and reserved for future use.
12	Barcode scanner	Scan the QR code on the Single Use Digital Flexible Ureteroscope w/ Pressure Monitoring

Table 2 Packaging List

No.	Content	Quantity
1	Renal Pressure Monitoring Processor	1
2	Power Cord	1
3	User Manual	1
4	HDMI-to-HDMI cable	1
5	Barcode Scanner	1
6	RS232 cable	1

WARNING

● The packaging list includes a Power Cord and an HDMI-to-HDMI cable. However, it does not include HDMI-to-DVI or SDI video cables.

● To ensure the safe and effective operation of the processor, users should only use the Power Cord, HDMI cable, RS232 cable, Barcode Scanner provided by Happiness Works.

Note

● Button battery shelf life: ＞ 5 years.

1.2 System Configuration

Figure 3 provides an example of the system configuration using the Renal Pressure Monitoring Processor.

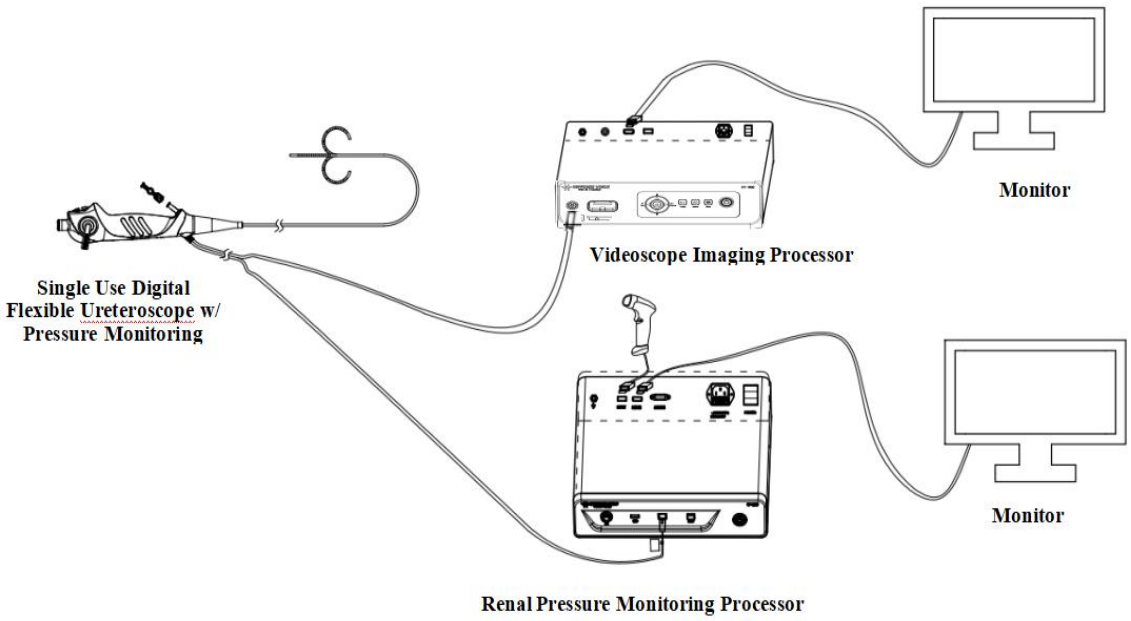


Figure 3 System Configuration

CAUTION

● The Renal Pressure Monitoring Processor is exclusively designed for use with the Ureteroscope and Videoscope Imaging Processor supplied by Happiness Works.

● When used in conjunction with the Videoscope Imaging Processor (HV-200), please place the Videoscope Imaging Processor (HV-200) on top of the Renal Pressure Monitoring Processor (HV-M200).

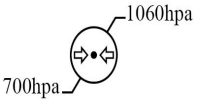
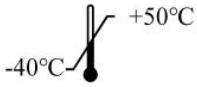
● Recommended monitor or display: E240C from Nanjing Jusha Commercial &Trading Co., Ltd. (UMDNS - Code: 17960) or other CE-certificated that comply with IEC 60601-1 standards.

● Supported USB flash drives: Only CE-certified flash drives in FAT32 or exFAT formats are compatible.

● For optimal visibility of pressure information during clinical procedures, a monitor with a minimum screen size of 19 inches and a resolution of 1920 × 1080 pixels is recommended.

1.3 Relevant Identification

Table 3 Symbols Explanation

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

1.4 Technical Indicators

Table 4 Technical Indicators

Device functions		Pressure zero calibration function
Pressure monitoring performance requirements	Pressure monitoring range	Work normally in the pressure range of -30mmHg - 300mmHg
	Pressure monitoring Accuracy	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.
Maximum video output resolution		The maximum video output resolution of the HDMI video output interface shall not be less than 1920*1080 pixels.
Software function		The processor shall have the functions of displaying pressure, continuous high pressure duration, cumulative high pressure duration, Zebra index and pressure curve.

Chapter 2 Installation

2.1 Precautions Before Installation

● Please install the Renal Pressure Monitoring Processor and peripheral equipment on a stable, flat surface.

● Ensure that the power cord is not twisted, crushed or subjected to excessive tension.

● Please install the Renal Pressure Monitoring Processor in a dust-free environment. Remove dust on the Renal Pressure Monitoring Processor. Accumulation of dust on or within the device can lead to malfunctions, including smoke or fire hazards.

● For safety, it is essential that the equipment is properly grounded.

● Ensure that all power requirements indicated on the nameplate located on the back panel are fulfilled.

● Prevent the Renal Pressure Monitoring Processor from falling or experiencing excessive mechanical shock (greater than 6J of energy), as this may pose safety hazards or cause damage. If the processor endures excessive mechanical impact (greater than 6J of energy), discontinue use immediately and contact your local distributor or customer service for assistance.

● The Processor is shipped non-sterile. Prior to use, inspect the device and its packaging for any damage or defects. Do not use the device if the packaging is damaged or has been inadvertently opened. Additionally, do not use the processor if any labeling is incomplete or illegible, or if any components appear potentially defective.

● Do not install and use Renal Pressure Monitoring Processor in any of the following conditions:

❍ Vertical Installation: Avoid installing the unit vertically, as this may lead to operational failures.

❍ Water Exposure: Do not expose the device to water or other liquids.

❍ Presence of Flammable Gases: Ensure that the installation area is free from flammable or explosive gases.

❍ Environmental Conditions: Do not use the processor outside the specified operating environment.

❍ Direct Sunlight: Keep the device away from direct sunlight to prevent damage.

WARNING

● The product is exclusively compatible with Ureteroscopes and Videoscope Imaging Processor manufactured by Happiness Works. For detailed information regarding compatibility and usage, please consult with Happiness Works directly.

2.2 Connecting the Ureteroscope to the Processors

(1) Connect the ureteroscope to the Renal Pressure Monitoring Processor: Fully insert the pressure signal cable plug of the ureteroscope into the laser optical fiber port on the front panel of the Renal Pressure Monitoring Processor (see Figure 4). For detailed information regarding the ureteroscope, please refer to the User Manual of the ureteroscope.

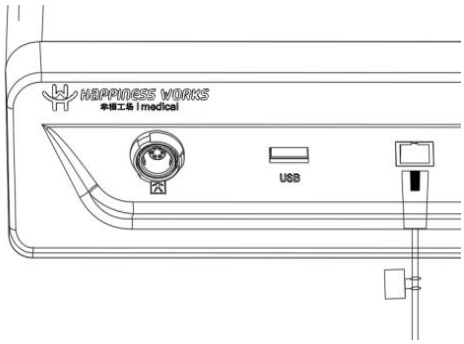


Figure 4 Connect the Ureteroscope to the Renal Pressure Monitoring Processor

(2) Connect the ureteroscope to the Videoscope Imaging Processor: Fully insert the video signal cable plug of the ureteroscope into the Lemo socket on the front panel of the Videoscope Imaging Processor (see Figure 5).

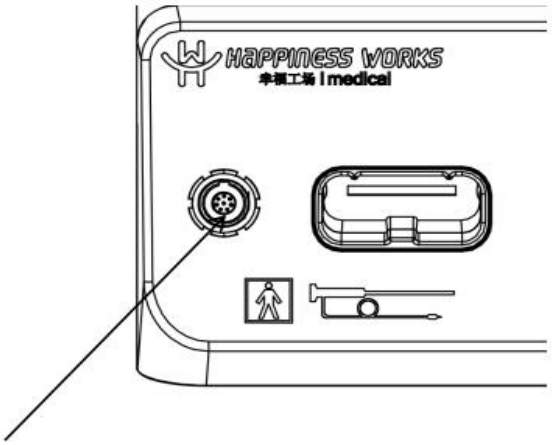


Figure 5 Connect the Ureteroscope to the Videoscope Imaging Processor

(3) Zero Calibration: Connect the USB port of barcode scanner to the Input port (see Figure 6), after power on the processor, scan the QR code on the ureteroscope.

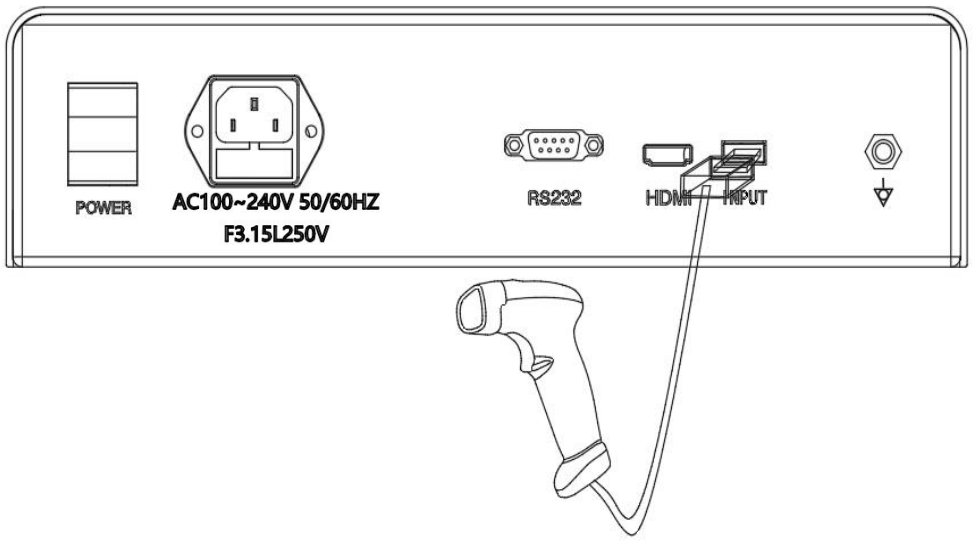


Figure 6 Connect the Barcode Scanner to the Renal Pressure Monitoring Processor

CAUTION

● Before insertion, ensure that the convex grooves on the pressure signal cable plug of the ureteroscope are properly aligned with the corresponding grooves on the laser optical fiber port of the Renal Pressure Monitoring Processor. Misalignment will prevent the pressure signal cable plug from being inserted into the Processor's interface. Forcing the insertion or improper handling may result in damage to both the Ureteroscope and the Processor.

● Do not insert a wet, contaminated, or damaged ureteroscope signal cable plug into the Processor socket, as this may lead to poor video performance or potential damage to the system.

2.3 Connecting the Monitor

When connecting two external monitors: Use an HDMI cable to connect the monitor to the Renal Pressure Monitoring Processor, and use an SDI, HDMI, or DVI cable to connect it to the Videoscope Imaging Processor.

When connecting one external monitor: Use an RS232 cable to connect the Renal Pressure Monitoring Processor to the Videoscope Imaging Processor, and use an SDI, HDMI, or DVI cable to connect the monitor to the Videoscope Imaging Processor.

Ensure that the external monitor meets the specified requirements. Once connected, the external image will be displayed automatically. For further details, please refer to the user manual of the monitor.

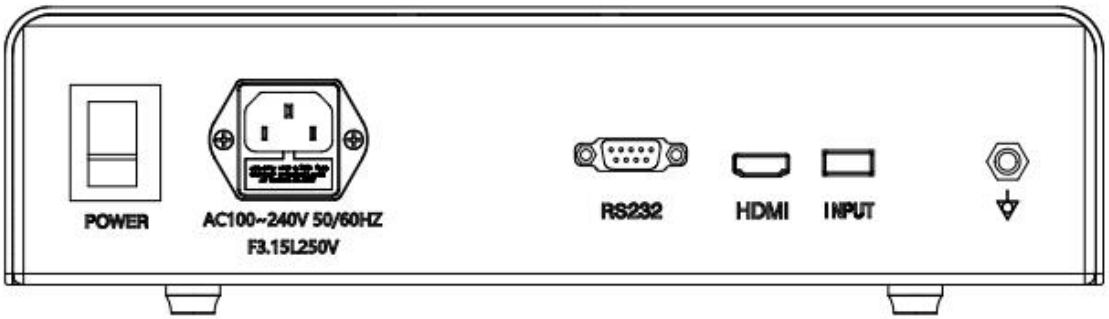


Figure 7 Back Panel of the Renal Pressure Monitoring Processor

● HDMI Port: Connect to the monitor using an HDMI cable.

● Input Port: Connect to the Barcode Scanner.

● RS232 Port: The RS232 cable is designated for use exclusively with the Videoscope Imaging Processor in conjunction with the Renal Pressure Monitoring Processor.

● Recommended Monitor: Use CE-certified monitors that comply with IEC 60601-1 standards.

● Power Connection: Connect the power socket to the hospital's electrical outlet using the power cord, ensuring that both ends are securely connected.

2.4 Method and Function of Equalization Conductor

Usage Method of the Equalization Conductor:

The equipotential conductor, which operates independently from the protective earth terminal or neutral conductor, provides a direct connection between electrical equipment and the potential equalization busbar within the electrical installation. During operation, the equipotential conductor of the device must be connected to the hospital's common grounding system.

Function of the Equalization Conductor:

The equipotential conductor ensures that all conductive components are interconnected with low resistance and are effectively integrated into the grounding system. Non-energized conductors are directly connected to other conductive elements, while energized conductors are securely grounded. This configuration is one of the most effective methods for diverting and dissipating energy from direct lightning strikes and mitigating lightning-induced electromagnetic interference. Additionally, it forms the foundation for the potential equalization and compensation system.

2.5 Introduction to UI Interface

- Monitor screen



■ Pressure curve for the last 2 minutes: This curve displays the pressure readings for the last 2 minutes before the operation. The vertical axis represents pressure, and the horizontal axis represents time.

■ Pressure curve during the entire operation: This curve displays the pressure readings throughout the operation. The vertical axis represents pressure, and the horizontal axis represents time.

(a) When the operation time is less than 1h, the horizontal axis will represent 1h.

(b) When the operation time is between 1h and 1.5 hours, the horizontal axis will represent 1.5 hours.

(c) The maximum duration displayed is 8 hours.

(d) The curve is cleared upon powering off the device.

Real-time pressure (mmHg): This displays the actual pressure in the renal pelvis monitored during the operation, in mmHg.

The font style of the monitored pressure changes as follows:

(a) When the real-time pressure is below the warning pressure, the font size is small, and the font color is white.

(b) When the real-time pressure exceeds the warning pressure, the font color turns red, and the font size is either large or medium. When the pressure falls back below the warning level, the font size reverts to small, and the font color returns to white.

■ Warning pressure 30: The warning pressure threshold for the renal pelvis.

■ Last high pressure duration (s): The duration (in seconds) during which the renal pelvis pressure last exceeded the warning pressure during the operation.

■ Cumulative high pressure duration (s): The total time (in seconds) during which the renal pelvis pressure has exceeded the warning pressure since the device was powered on.

■ Zebra index (mmHg*s): The area during the entire operation where the renal pelvis pressure exceeds the warning pressure, calculated as the integral value of the time-pressure area above the warning pressure.

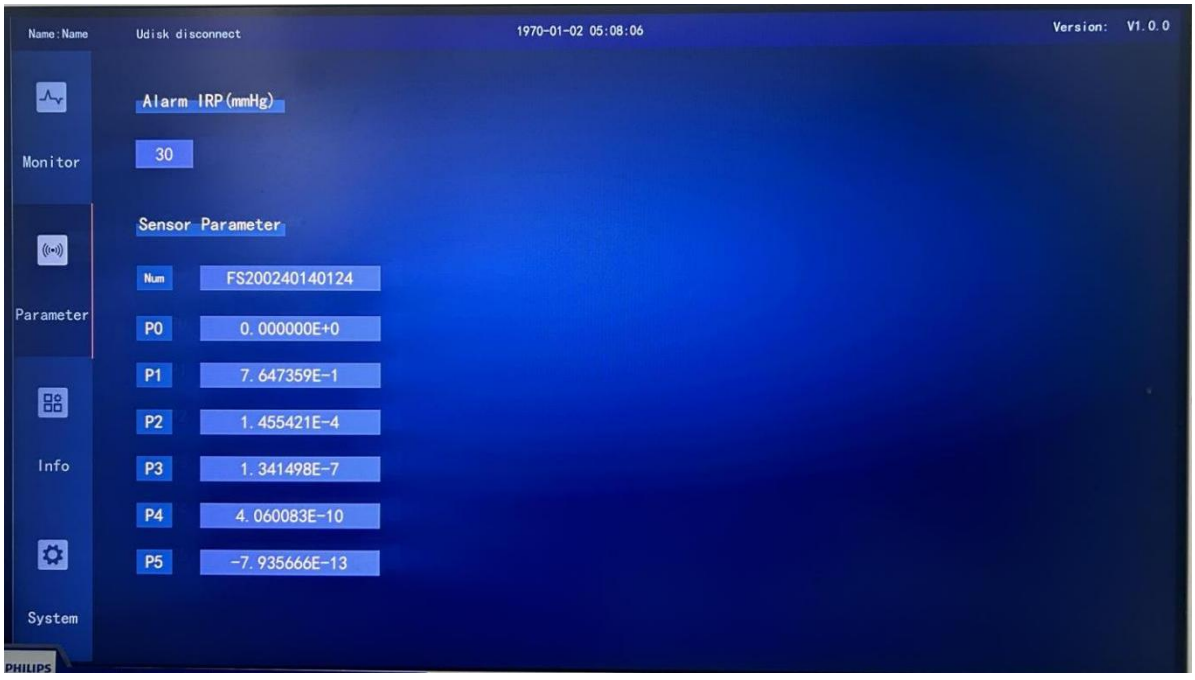
■ Prompts for optical fiber connection:

When the ureteroscope is not connected to the processor, “Sensor not connected!” will be displayed.

When the ureteroscope is connected to the processor and parameters are not entered, “The optical fiber sensor is connected! Sensor parameters are not set!” will be displayed.

When the ureteroscope is connected to the processor and parameters are entered, “The optical fiber sensor is connected! Sensor parameters are set!” will be displayed.

● Parameter setting



Warning pressure (mmHg): warning pressure that can be set for renal pelvis pressure. Setting range is 0 - 40mmHg

Sensor parameter input: parameter setting column of optical fiber sensor. Input can be implemented with barcode scanner and keyboard.

P0 - P5 are the calculation variables required for accurate pressure calculation of the product, which are printed on the front and back of the tag in two ways: QR code and numerical value, and the tag is located on the square connector of the ureteroscope. P0 - P5 can be entered into the product in two ways:

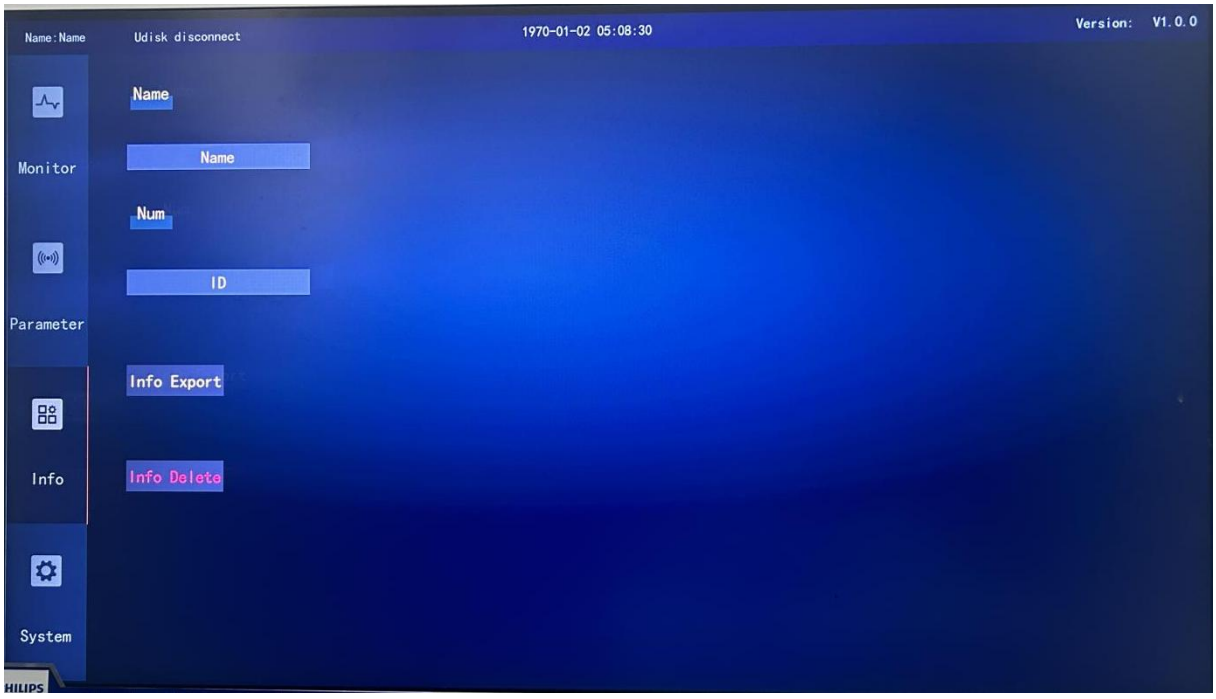
Scan QR code:

The product is equipped with a barcode scanner, which can be connected through the “Input” interface at the back of the processor. After connection, the product can be automatically entered into the processor by scanning the QR code with the barcode scanner.

Entry with keyboard:

When the QR code cannot be scanned due to failure of barcode scanner or QR code, a keyboard can be connected with the “Input port” or “USB port”. After connection, entry can be implemented with the keyboard.

- Patient information



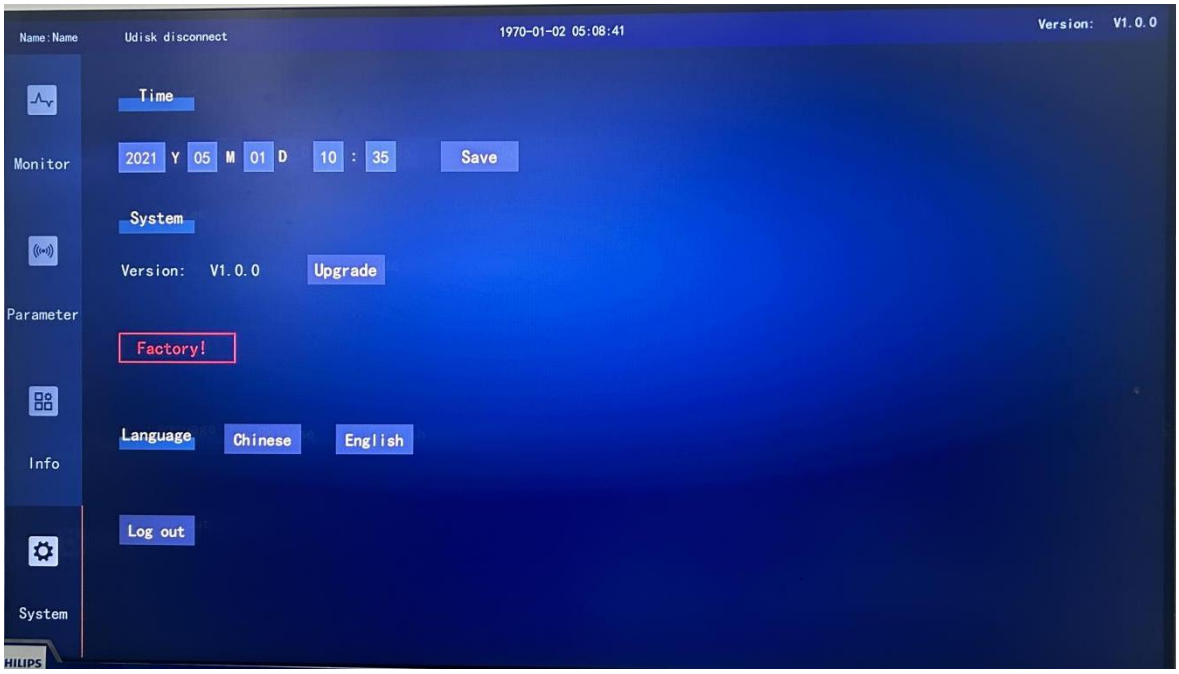
■ Name: name of the patient.

■ ID: ID of the patient.

■ Export information: export the pressure information of the patient during the whole process of operation.

■ Delete information: delete the pressure information of the patient during the whole process of operation.

- System setting



- Time setting: set and save the processor time.
- Version upgrade: upgrade the current software version.
- Restore factory settings: restore the processor system to factory settings.
- System language: switch between Chinese and English.
- Export log: only open to the factory.

WARNING

● 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.

Chapter 3 Pre-Use Inspection

Before operating the Renal Pressure Monitoring Processor, please ensure the following inspection steps are completed. If any abnormalities are detected, cease operation immediately and contact your local distributor or customer service for assistance.

Before inspection, ensure the following:

● The Renal Pressure Monitoring Processor and Videoscope Imaging Processor are powered off.

● The Renal Pressure Monitoring Processor and Videoscope Imaging Processor are securely positioned on a stable, flat surface.

● Ureteroscope and Videoscope Imaging Processor are correctly connected to the Renal Pressure Monitoring Processor.

WARNING

● Insulation Requirement: Ensure insulation (BF type electronic medical equipment) is in place to prevent contact with the ureteroscope. When in use with patients, avoid exposure of the ureteroscope to other devices. Operators should always wear rubber gloves to prevent direct contact.

● Device Compatibility: If using the ureteroscope in conjunction with other devices, verify that all equipment is functioning properly. Other devices must not compromise the operation or safety of the ureteroscope or the Processor. If any component of the ureteroscope or the Processor is not operating correctly, do not proceed with the surgery.

● Malfunction Protocol: In the event of a ureteroscope malfunction, ensure a standby ureteroscope and two Processors are available prior to surgery to mitigate safety risks.

● Do not modify this equipment without prior authorization from Happiness Works.

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

● Before use, or after changing modes/ settings, the operator must confirm that real-time images are being displayed through the ureteroscope and that have the correct image orientation.

● Biohazard Precautions: Utilizing a processor contaminated with patient fluids poses a risk of exposure to biohazardous materials for both the operator and the patient through clinician contact. To mitigate this risk, visually inspect, clean, and disinfect the processor during and between uses following the cleaning procedures outlined in Chapter 5.

● Ground Isolation Verification: When setting up and using accessories from different manufacturers, verify ground isolation to prevent user or patient injury. Failure to do so may lead to electric shock, tissue damage,

increased intervention time, accessory malfunction, and further patient harm.

● Liquid Damage Prevention: Avoid spilling liquids on the processor, as this may cause damage or result in system shutdown. Ensure that no liquids are placed above or in proximity to the processor.

● Inspect all cables and cords (cuts in insulation, fraying or broken wires, dirty or bent connector pins). All attached equipment must comply with applicable electrical safety standards. Proper system functioning must be verified before use. Replace if damaged.

● Processor Enclosure Inspection: Inspect the processor enclosure for any unacceptable damage, including chips, dents, scratches, or marks. Additionally, check for degraded labels or image quality issues on the touchscreen.

Chapter 4 Operational Steps

To ensure safe and effective use of the Renal Pressure Monitoring Processor, please follow these procedures:

1. Pre-Use Inspection: Conduct a thorough inspection of the equipment before use (refer to Chapter 3 for detailed instructions).

2. Power on: Connect the Renal Pressure Monitoring Processor, Videoscope Imaging Processor to the hospital's electrical outlet and power on all peripheral equipment.

3. Activate the Videoscope Imaging Processor: Press the "Rocker Switch" button first, followed by the "Control Switch" button, to turn on the Videoscope Imaging Processor.

4. Activate the Renal Pressure Monitoring Processor: Press the "Rocker Switch" button first, followed by the "Control Switch" button, to turn on the Videoscope Imaging Processor. Follow the instructions in the ureteroscope manual to connect the ureteroscope.

5. Zero Calibration: Scan the QR code on ureteroscope by barcode scanner.

6. Conduct Inspections: Perform any necessary inspections to ensure proper operation.

7. Terminate Examination: Complete the examination process as required.

8. Remove the Ureteroscope: Dispose it according user manual of ureteroscope;

9. Turn off the Processor: Press the "Control Switch" button first, followed by the "Rocker Switch" button, to turn off the Renal Pressure Monitoring Processor and Videoscope Imaging Processor. Disconnect the power cord.

10. Maintenance and Storage: Perform appropriate maintenance and store the Videoscope Imaging Processor and peripheral equipment correctly after use.

WARNING

● Avoid unnecessary long-term use during clinical operation to prevent compromising the safety of patients and users.

● Ensure that patients do not come into contact the Processor.

● To prevent damage to the LCD display and function buttons, avoid using sharp objects to poke or touch them.

● Continuously monitor both the equipment and the patient for any signs of abnormalities.

● If any abnormalities are detected in either the patient or the equipment, take appropriate measures to ensure patient safety.

● In the event of a malfunction with either the ureteroscope or the two Processors during the procedure, resulting in the loss or degradation of the visualization image, or pressure signal loss, return the deflection

section of the ureteroscope to a neutral position, and then carefully withdraw the ureteroscope slowly.

● This equipment must only be used in accordance with the instructions and operating environment specified in this manual. Failure to adhere to these guidelines may result in safety hazards, equipment failure, or damage to the instrument.

● If the image or pressure information is lost during operation and remains absent after restarting the Videoscope Imaging Processor and Renal Pressure Monitoring Processor, promptly replace the ureteroscope with a new one.

● To avoid the risk of electric shock, ensure that this equipment is properly grounded.

● Avoid placing the equipment in locations where disconnection may be difficult.

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

● Do not use accessories that do not meet the compatibility requirements specified in the User Manual, as this may cause damage to the ureteroscope, the Processor, or any connected accessories.

● 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.

● When in air, the pressure values may fluctuate or may show slightly negative values.

Chapter 5 Post-Processing

Post-Processing Procedure for the Renal Pressure Monitoring Processor:

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

(2) Unplug the power cord and disconnect the video cables from the monitor or PC.

5.1 Cleaning Instructions

The Processor is designed to be placed inside the sterile field during clinical use. Cleaning or disinfection is required only when the Processor becomes contaminated during use.

Clean the surface of the Renal Pressure Monitoring Processor using the following steps:

(1) Wipe the surface with gauze moistened with 70-90% ethanol or isopropyl alcohol.

If contamination is suspected, follow these additional cleaning steps:

(2) Use gauze dampened with enzymatic detergent (neutral pH, low foam, mild, and compatible with medical equipment).

(3) Wipe the same area with gauze soaked in clean water to remove any detergent residue.

(4) Dry the surface with a clean, dry gauze or flannelette to eliminate any remaining moisture.

(5) Finally, wipe the surface again with gauze soaked in 70-90% ethanol or isopropyl alcohol for disinfection.

CAUTION

● Ensure that the surface of the Renal Pressure Monitoring Processor is completely dry during post-use maintenance.

● Any presence of water, particularly around connection points, can lead to equipment malfunction or failure.

● Do not attempt to disassemble or repair the Renal Pressure Monitoring Processor yourself. Contact your distributor to have the equipment sent to an authorized service center for professional maintenance.

● Always turn off the Processor when not in use, such as after completing a procedure. Do not disconnect the power cord of the Processor by unplugging it directly from the hospital’s electrical outlet before shutting it down via the “Rocker Switch” and “Control switch”. Failure to follow this procedure may result in equipment damage or pose electrical hazards to the user.

5.2 Disposal

Disassemble all accessories (power cord, cables, etc.) and clean or disinfect the Processor to prevent any cross contamination (refer to “5.1 Cleaning Instructions” section before disposal).

This device and associated electrical and electronic equipment should not be incinerated or included with municipal waste. Do not incinerate any device/component containing a battery and/or electronics. To dispose, take this device to a recovery and recycling designated collection facility for electrical and electronic equipment waste for proper treatment.

5.3 Storage

CAUTION

● Ensure the Processor is turned off and the power cord is unplugged before storage.

● Do not store the Renal Pressure Monitoring Processor in a vertical position, as this increase the risk of failure.

● Do not store the Renal Pressure Monitoring Processor outside its operating operating environment. Avoid exposure to water, moisture, or direct sunlight.

● Keep the Processor in a dust-free area. Excessive dust accumulation inside the Processor can result in malfunction, overheating, smoke, or fire. Regularly clean the device to prevent dust buildup.

● Ensure the Renal Pressure Monitoring Processor is protected from falls or significant mechanical shocks (greater than 6J of energy), as this could create safety hazards or result in damage. If the Processor experiences an impact exceeding this threshold, stop using the device immediately and contact your local distributor or customer service for assistance.

● Confirm that storage area environment adheres to the specifications outlined in Chapter 6 “Environmental Requirements”.

● Ensure the storage area is protected from potential water leaks or splashes.

WARNING

● The exported pressure recording data contains the patient’s name and other sensitive information. Please ensure the protection of patient privacy.

● The processor has a memory capacity of 8GB. When the memory is full, new data will be automatically overwritten.

Chapter 6 Environmental Requirements

(1) Operating environment

- Ambient Temperatures: 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 Temperatures: -40℃~50℃ (-40~122°F)
- Relative humidity: 10%~93%RH
- Atmospheric pressure: 700~1060hPa (0.7~1.1kgf/cm^2) (10.2~15.4psi)

Chapter 7 Maintenance

Before submitting the Renal Pressure Monitoring Processor for maintenance or recall or return or repair, ensure that “5.1 Cleaning Instructions” procedures have been completed to minimize the risk of infection. For detailed instructions, please refer to Chapter 5 Post-Processing.

Upon request, Happiness Works can provide service personnel with circuit diagrams, component part lists, descriptions, calibration instructions, and other technical information necessary for repairing the parts of the equipment that are designated as serviceable by authorized personnel.

CAUTION

When submitting the Renal Pressure Monitoring Processor for maintenance:

● Ensure that appropriate protective packaging is used to prevent further damage to the Renal Pressure Monitoring Processor during transportation. (Using the product’s original packaging is recommended.)

● Please describe the details of the fault, the serial number of the Renal Pressure Monitoring Processor, your name and contact information, and the address of the sender.

● All accessories related to the failure of the Renal Pressure Monitoring Processor should be also sent with the Renal Pressure Monitoring Processor.

WARNING

● Happiness Works is not liable for any injuries to patients or users resulting from maintenance conducted by third parties, nor for any damage or malfunction of the Renal Pressure Monitoring Processor, disinfection, or sterilization issues.

● Installation and software upgrades should only be performed by authorized personnel.

● The power cord plug serves as the disconnection device for isolating the equipment from the AC power supply.

Chapter 8 Troubleshooting

The information provided in this chapter aims to assist users in diagnosing and resolving potential issues that may occur during surgical procedures. The following sections outline possible operational challenges, their potential causes, and recommended solutions.

CAUTION

● If problems persist after implementing the suggested solutions, or if you encounter issues not addressed in this chapter, immediately cease using the ureteroscope and contact Happiness Works for consultation and maintenance.

● The Renal Pressure Monitoring Processor requires the ureteroscope to process and display pressure information simultaneously. To troubleshoot image or pressure related issues, please refer to the troubleshooting section of the ureteroscope manual.

8.1 Unable to Start the Renal Pressure Monitoring Processor

Issue: Power cords are not properly connected.

Solution: Ensure that the power cord is securely connected to the power input interface.

Issue: Fuse test failure.

Solution: Return the Renal Pressure Monitoring Processor for maintenance.

8.2 No Image and /or Pressure Information on the Monitor

Issue: Incorrect monitor settings.

Solutions:

● Power on the monitor.

● Select the correct video input signal.

● Reset the monitor’s parameter adjustment values.

Issue: Cables are not properly connected.

Solution: Ensure all cables are correctly connected.

Issue: Ureteroscope is not properly connected.

Solution: Ensure the ureteroscope is correctly connected.

8.3 Abnormal Operation of Button Function

Issue: The Renal Pressure Monitoring Processor may be damaged.

Solution: Return the Renal Pressure Monitoring Processor for maintenance.

Chapter 9 Production Date and Shelf Life

❍ Production Date: Refer to the product label for specific information.

❍ Shelf Life: 5 years.

❍ Disposal: Disposal of this product should follow all applicable and local laws and regulations regarding medical waste management. Improper disposal may lead to environmental contamination.

Chapter 10 Essential Performance of the Product

- 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;
- 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.

Chapter 11 Safety Classification

❍ Classification by type of electric shock protection: Class I;

❍Classification by degree of electric shock protection: BF type;

❍Classification by degree of protection against ingress of liquid: IPX0;

❍Classification by the safety degree in the case of flammable anesthetic gas mixed with air and with oxygen or nitrous oxide: not applicable;

❍Classification by operation mode: continuous operation;

❍Rated voltage and frequency of the device: AC 100~240V 50/60Hz;

❍Input power of the device: 24 VA;

❍Whether the device has applied parts to protect against discharge effect of defibrillator: no;

❍Whether the device has a signal input or output part: signal input and output part available;

❍ Permanently installed device or non-permanently installed device: non-permanently installed device.

WARNING

● Avoid spilling liquids on the Processor, as this may result in damage or cause it to shut down. Do not position liquids above or near the Processor.

Chapter 12 Electromagnetic Compatibility

● The following cables comply with the standards over interference radiation and immunity standards and have passed EMC testing testing as part of Digital Endoscope System:

Table 5: Overview of Cable

Cables	Length (m)
Power cord	1.5
RS232 cable	1.5
Barcode scanner cable	1.9
HDMI cable	1.5

CAUTION

● Buyers and users of the Digital Endoscope System must ensure that these products are utilized in accordance with the conditions outlined in this chapter. Use under adverse conditions may lead to malfunctions of the Digital Endoscope System.

● Portable and mobile RF communication devices may interfere with the proper functioning of the Processor and Ureteroscope. Please operate these devices under the recommended electromagnetic conditions.

WARNING

● It is advisable to avoid using the Renal Pressure Monitoring Processor, Videoscope Imaging Processor and Ureteroscope in close proximity to, or stacked with, other devices, as this may lead to improper operation. If such usage is unavoidable, closely monitor the equipment to ensure it is functioning correctly.

● Do not operate the device near active high-frequency (HF) surgical equipment or within the RF-shielded room of a magnetic resonance imaging (MRI) system, where electromagnetic interference (EMI) may be significant. Active medical devices require special electromagnetic compatibility (EMC) precautions and must be installed and utilized in accordance with the manufacturer's guidelines.

● Portable RF communication equipment, including peripherals such as antenna cables and external antennas, should be kept at least 12 inches (30cm) away from any part of the equipment, including cables specified by Happiness Works. Failure to maintain this distance may adversely affect the performance of the device.

● The use of accessories and cables not specified or provided by Happiness Works may increase

electromagnetic emissions or reduce the electromagnetic immunity of this equipment, potentially leading to improper operation.

Renal Pressure Monitoring Processor is CISPR 11 Class A device.

<table>
<tr><th colspan="3">Guidance and Manufacturer's Declaration – Electromagnetic Emissions</th></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>RF emissions from Renal Pressure Monitoring Processor is very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class A</td><td rowspan="3">Renal Pressure Monitoring Processor is only suitable for medical institutions or institutions with professional training.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions IEC 61000-3-3</td><td>Complies</td></tr>
<tr><th colspan="3">Guidance and Manufacturer's Declaration – Electromagnetic Immunity</th></tr>
<tr><th>Immunity test</th><th>IEC 60601-1-2 Test level</th><th>Compliance level</th></tr>
<tr><td>Electrostatic discharge (ESD)
IEC 61000-4-2</td><td>± 8 kV contact
± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air</td><td>± 8 kV contact
± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air</td></tr>
<tr><td>Electrical fast transient/ burst
IEC 61000-4-4</td><td>± 2 kV for power supply lines
± 1 kV for input/ output lines</td><td>± 2 kV for power supply lines
± 1 kV for input/ output lines</td></tr>
<tr><td>Surge
IEC 61000-4-5</td><td>± 1 kV line (s) to line (s)
± 2 kV line (s) to earth</td><td>± 1 kV line (s) to line (s)
± 2 kV line (s) to earth</td></tr>
<tr><td>Voltage dips, short interruptions and voltage variations on power supply input lines
IEC 61000-4-11</td><td>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</td><td>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</td></tr>
<tr><td>Power frequency magnetic field IEC 61000-4-8</td><td>30 A/m</td><td>30 A/m</td></tr>
</table>

	50/ 60Hz	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	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
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.

Chapter 13 Specifications and Parameters

Power supply requirement	Voltage	AC 100-240V
	Frequency	50/60Hz
	Input power	24VA
	Input current	0.8-1.5A
Operating environment	Ambient temperature	10℃～40℃
	Relative humidity	20%～85%
	Atmospheric pressure	700hPa～1060hPa
Storage environment	Ambient temperature	-40℃～50℃
	Relative humidity	10%～93%
	Atmospheric pressure	700hPa～1060hPa
Function button	Zero calibration	Manual zero calibration
Image output	HDMI	Video resolution no less than 1920*1080 pixels
Electormagnetic Compatibility	Designed in accordance with	IEC 60601-1:2020 IEC 60601-1-2:2020
Electrical safety	Designed in accordance with	IEC 60601-1:2020 IEC 60601-2-18:2009
Fuse	Fuse Type	Glass fuse: F3.15L 250V
	Operating speed (s) and Breaking capacity	F, L
Software operating environment	The software exists based on firmware. During use, it is unnecessary to connect to the network. It runs on the hardware MCU of the device.	