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ZebraScope

CE 0344

Digital Endoscope System

Videoscope Imaging Processor

User manual

Product model:
HV-200

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 the Videoscope Imaging Processor and the Ureteroscope. This instrument facilitates the delivery and use of various accessories at the surgical site.

The Videoscope Imaging Processor, when used with the endoscope, provides imaging for the examination, diagnosis, or treatment of urinary tract conditions. Do not use this 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 Videoscope Imaging 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 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 Videoscope Imaging Processor. Before using the device, carefully read this manual as well as the instructions for all associated equipment, and follow the operational guidelines as specified. Please store all relevant manuals in a safe and accessible location. For any inquiries regarding this manual, please contact Happiness Works.

Product name: Videoscope Imaging Processor

Product model: HV-200

Software version: V1.0.0

Intended purpose: Digital Endoscope System 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.

The Videoscope Imaging Processor, when used with the endoscope, provides imaging for the examination, diagnosis, or treatment of urinary tract conditions.

Indications: the urinary tract and kidney disease diagnosis and provide access for treatment.

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 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.

Equipment expected to be used in patient environment: Videoscope Imaging Processor (HV-200)

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

Operating principle:

The Videoscope Imaging Processor is used in conjunction with the Ureteroscope. It supplies the necessary operating voltage to the Ureteroscope's lighting source (LED) and camera (CMOS), while continuously transmitting both digital and analog signals to the CMOS.

Once the CMOS receives these signals, it converts the analog light signals collected into digital data, which is sent back to the processor. The processor then decodes and processes the data, outputting the final image to the display through SDI, HDMI, or DVI connections located at the rear of the processor.

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Chapter 1 Instrument Composition and System Configuration

1.1 Instrument Composition

The Videoscope Imaging Processor is composed of the processor, power cord and any video cables. The structure of the Videoscope Imaging Processor is illustrated in Figure 1:

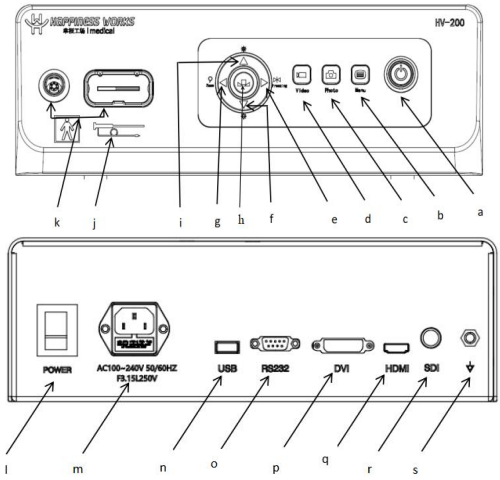


Figure 1 Videoscope Imaging Processor Structure

Table 1 Composition Overview

No.	Name	Explanation
a	Control switch	· Turning On: If the processor is in a shutdown state, press the "Control switch" button to turn it on. · Turning Off: If the processor is already in a startup state, pressing the "Control switch" button will put it into shutdown mode. · Power Control: This button controls the 12V DC power supply to the device.
b	Menu	Pressing this button displays the available product menu options, allowing users to configure settings and operate the device.
c	Photo	Pressing this button captures a photo of the current image displayed on the monitor and saves it in JPG format.
d	Video	Pressing this button initiates the recording of the image currently displayed on the monitor, saving the recording in AVI format.
e	Freezing /Right	· Freezing Button: Pressing this button freezes the image currently displayed on the monitor, allowing for a still view for further examination. · Right Function: After pressing the Menu button, this function allows users to move the cursor to the right within the menu interface.
f	LED- /Down	· LED- Button: Pressing this button decreases the brightness of the LED light on the connected Ureteroscope, allowing for adjustment based on the lighting conditions. · Down Function: After pressing the Menu button, this function enables users to move the cursor down within the menu interface.
g	Zoom /Left	· Zoom Button: Pressing this button allows users to zoom in and out on the currently displayed image on the monitor for detailed examination. · Left Function: After pressing the Menu button, this function enables users to move the cursor to the left within the menu interface.
h	White Balance	Pressing this button automatically adjusts the white balance of the images captured by the connected Ureteroscope, ensuring accurate color representation.

i	LED+ /Up	· LED+ Button: Pressing this button increases the brightness of the LED light on the connected Ureteroscope, allowing for better visibility during procedures. · Up Function: After pressing the Menu button, this function enables users to move the cursor up within the menu interface.
j	Symbol	Endoscope connection
k	Golden Finger socket /Lemo socket	Designed for direct connection between the Ureteroscope and the processor.
l	Rocker Switch	Controls the on/off function for the 100-240V AC power supply.
m	Power socket	Provides AC 100-240V power via the power cord.
n	USB	The USB port allows for connection to an external USB drive, enabling the storage of images and videos. It is also used for system software upgrades conducted by authorized personnel from Happiness Works. Notes: · The USB port should not be used for any other functions, such as providing external power supply. · Happiness Works does not supply a USB drive with the product.
o	RS232	Information exchange interface. (Note: Happiness Works does not supply this data cable)
p	DVI	DVI Video Cable: Used to connect the processor to the monitor. (Note: Happiness Works does not supply this data cable)
q	HDMI	HDMI Video Cable: Used to connect the processor to the monitor. (Note: Happiness Works provides an HDMI to HDMI data cable with the processor)
r	SDI	SDI Video Cable: Used to connect the processor to the monitor. (Note: Happiness Works does not supply this data cable)
s	Earth (ground)	Equipotential terminal interface **CAUTION** ● Ensure that the hospital's potential equalization wire (common ground) is properly connected to the terminal when using this product.

Table 2 Packaging List

No.	Content	Quantity
1	Videoscope Imaging Processor	1
2	Power Cord	1
3	User Manual	1
4	HDMI to HDMI 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, DVI, and SDI cables provided by Happiness Works.

Note

● Button battery shelf life: ＞ 5 years.

1.2 System Configuration

Figure 2 provides an example of the system configuration using the Videoscope Imaging Processor.

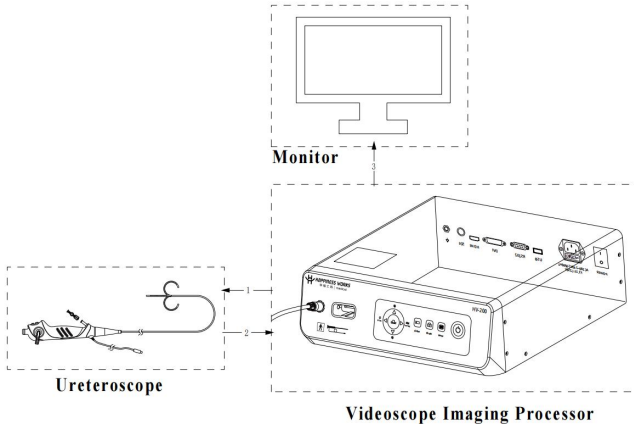


Figure 2 System Configuration

WARNING

● The Videoscope Imaging Processor (HV-200) is exclusively designed for use with endoscopes supplied by Happiness Works.

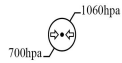
● Recommended monitor or display: Model E240C from Nanjing Jusha Commercial & Trading Co., Ltd. (UMDNS Code: 17960)

● Supported USB Flash Drives: Only CE-certified flash drives in FAT32 or ex FAT formats are compatible.

1.3 The Relevant Identification

Table 3: Symbols Explanation

Symbol	Symbol title	Symbol	Symbol title
ZebraScope	Product trademark		This way UP
	Medical device		DO NOT ROLL
	Catalogue number		Fragile, handle with care
	Batch code		Keep dry
	Manufacturer		Keep away from sunlight
	Date of manufacture		Stacking limit by number
	Use-by date		Fuse
	Follow instructions for use		Stand-by

	BF type application part		Endoscope connection
	Authorized representative in the European Community/ European		Storage/ Transportation temperature limitation
	Do not use if package is damaged and consult		Storage/ Transportation humidity limitation
	General warning sign		Storage/ Transportation atmospheric pressure
	Non-ionizing electromagnetic radiation		Separate collection

Chapter 2 Installation

2.1 Precautions Before Installation

● Surface Requirements: Install the Videoscope Imaging Processor and peripheral equipment on a stable, flat surface.
● Power Cord Safety: Ensure that the power cord is not twisted, crushed, or subjected to excessive tension.
● Grounding: For safety, it is essential that the equipment is properly grounded.
● Power Specifications: Confirm that all power requirements indicated on the nameplate located on the back panel are fulfilled.
● Dust Control: Install the Videoscope Imaging Processor in a dust-free environment. Accumulation of dust on or within the device can lead to malfunctions, including smoke or fire hazards.
● Mechanical Shock Prevention: Prevent the Videoscope Imaging 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.
● Non-Sterile Shipment: 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 or use the Videoscope Imaging 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 Videoscope Imaging Processor is exclusively compatible with endoscopes manufactured by Happiness Works. For detailed information regarding compatibility and usage, please consult with Happiness Works directly.

2.2 Connecting the endoscope

(1) Connect the Ureteroscope to the Videoscope Imaging Processor: Ensure that the endoscope is properly connected to the Videoscope Imaging Processor. For detailed information regarding the endoscope, please refer to the User Manual specific to the endoscope model.

(2) Insert the Video Signal Cable: Plug the video signal cable into the appropriate socket on the front control panel of the Videoscope Imaging Processor. Depending on the type of endoscope you are using, connect it to either the Lemo or Golden Finger socket, as illustrated in Figure 3.



or


Figure 3 Connect the Ureteroscope Video Signal Cable Plug to the Videoscope Imaging Processor

CAUTION

● Before insertion, ensure that the convex grooves on the video signal cable plug of the endoscope are properly aligned with the corresponding grooves on the Golden Finger Socket (or Lemo Socket) of the Videoscope Imaging Processor. Misalignment will prevent the video signal cable plug from being inserted into the Processor's input interface. Forcing the insertion or improper handling may result in damage to both the endoscope and the Videoscope Imaging Processor.

● Do not insert a wet, contaminated, or damaged endoscope 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

To connect the monitor, use an SDI, HDMI, or DVI video cable to link it 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.

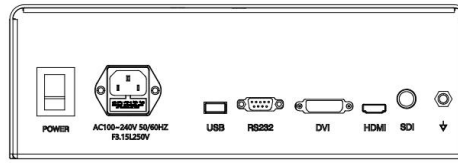


Figure 4 Back Panel of the Videoscope Imaging Processor

● SDI Output Port: Connect to the monitor using an SDI video cable.
● HDMI Output Port: Connect to the monitor using an HDMI video cable.
● DVI Output Port: Connect to the monitor using a DVI video cable.
● USB Port: Connect to a USB flash drive.
● 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.
● RS232 Port: The RS232 cable is designated for use exclusively with the Videoscope Imaging Processor in conjunction with the Single Use Digital Flexible Ureteroscope w/ Pressure Monitoring and Renal Pressure Monitoring Processor.

2.4 Method and Function of Equipotential Conductor

Usage Method of the Equipotential 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 Equipotential 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.

Chapter 3 Pre-Use Inspection

Before operating the Videoscope Imaging 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 examination, verify that:

- The Videoscope Imaging Processor is powered off.
- The Videoscope Imaging Processor is securely positioned on a stable, flat surface.
- Endoscope is correctly connected to the Processor.

WARNING

- Insulation Requirement: Ensure insulation (BF type electronic medical equipment) is in place to prevent contact with the endoscope. When in use with patients, avoid exposure of the endoscope to other devices. Operators should always wear rubber gloves to prevent direct contact.
- Device Compatibility: If using the endoscope in conjunction with other devices, verify that all equipment is functioning properly. Other devices must not compromise the operation or safety of the endoscope or the Videoscope Imaging Processor. If any component of the endoscope or Videoscope Imaging Processor is not operating correctly, do not proceed with the surgery.
- Malfunction Protocol: In the event of a endoscope malfunction, ensure a backup endoscope and Videoscope Imaging Processor are available prior to surgery to mitigate safety risks.
- Modification Prohibition: Do not modify this equipment without prior authorization from Happiness Works.
- High-Frequency Surgical Equipment: This product is not compatible with high-frequency surgical equipment.
- Image Verification: Before use, or after changing modes/settings, the operator must confirm that real-time images are being displayed through the endoscope and that the image orientation is correct.
- 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.
- Cable and Connector Inspection: Examine all cables and cords for damage, including cuts in insulation, fraying, broken wires, or contaminated/bent connector pins. Ensure that all connected equipment complies with applicable electrical safety standards. Confirm proper system functionality before use and replace any damaged components.
- 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.

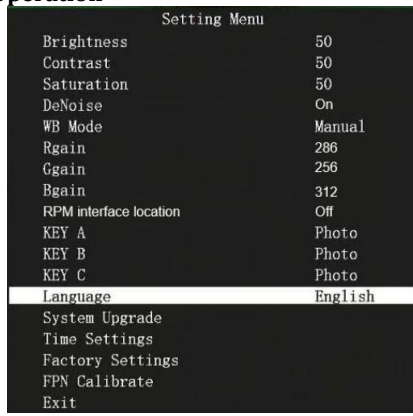
Chapter 4 Operational Steps

4.1 Operational Procedures

To ensure safe and effective use of the Videoscope Imaging 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 Videoscope Imaging Processor to the hospital's electrical outlet and power on all peripheral equipment.
3. Activate the 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 endoscope manual to connect the endoscope.
4. Adjust White Balance: Regulate the white balance settings according to the guidelines provided in the endoscope manual.
5. Conduct Inspections: Perform any necessary inspections to ensure proper operation.
6. Terminate Examination: Complete the examination process as required.
7. To turn off the Videoscope Imaging Processor: Press the "Control Switch" button first, followed by the "Rocker Switch" button. Disconnect the power cord.
8. Remove the endoscope: Carefully detach the endoscope after use.
9. Maintenance and Storage: Perform appropriate maintenance and store the Videoscope Imaging Processor and peripheral equipment correctly after use.

4.2 Menu Operation



Function	Operating method
Brightness	1. Press the 【(☰)】 key to access the 【Setting Menu】 interface. 2. Press 【▽】 and 【△】 keys to navigate the cursor to the "Brightness" position. 3. Press 【◁】【▷】 to adjust the value. 4. Press the 【(☰)】 key to return to the image display interface.
Contrast	Refers to the operating method of Brightness adjustment
Saturation	Refers to the operating method of Brightness adjustment
DeNoise	1. Press the 【(☰)】 key to access the 【Setting Menu】 interface. 2. Press 【▽】 and 【△】 keys to navigate the cursor to the "DeNoise" position. 3. Press 【◁】【▷】 to adjust "On" or "Off". 4. Press the 【(☰)】 key to return to the image display interface.
WB Mode	Refers to the operating method of DeNoise setting
Rgain	Refers to the operating method of Brightness adjustment.
Ggain	
Bgain	
RPM interface	Refers to the operating method of DeNoise setting.

location	
KEY A	Refers to the operating method of Brightness adjustment.
KEY B	Refers to the operating method of Brightness adjustment.
KEY C	Refers to the operating method of Brightness adjustment.
Language	Refers to the operating method of Brightness adjustment. (If necessary, you can change the language to your preferred option in step 3 and then press the 【】 key to save or press the 【】 key to exit.)
System Upgrade	1. Press the 【】 key to access the 【Setting Menu】 interface. 2. Press 【▽】 and 【△】 keys to navigate the cursor to the “System Upgrade” position. 3. Press the 【】 key to open the upgrade selection interface. 4. Press the 【◁】 and 【▷】 keys to choose between “Confirm” and “Cancel”. 5. Press the 【】 key to confirm the selection. 6. Press the 【】 key to return to the image display interface.
Time Settings	1. Press the 【】 key to access the 【Setting Menu】 interface. 2. Press 【▽】 and 【△】 keys to navigate the cursor to the “Time Settings” position. 3. Press the 【】 key to enter the “Time Settings” interface. 4. Press the 【◁】 and 【▷】 keys to select the options for “year”, “month”, and “day”. Adjust the numeric values using the 【▽】 and 【△】 keys. 5. Press the 【】 key to confirm the selected value. 6. Press the 【】 key to return to the image display interface.
Factory Settings	Refers to the operating method of System Upgrade.
FPN Calibrate	Refers to the operating method of System Upgrade.
Exit	1. Press the 【】 key to access the 【Setting Menu】 interface. 2. Press the 【】 key to return to the image display interface.

WARNING

● Ensure that patients do not come into contact the Processor.
● To prevent damage to the LCD display and function keys, 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 endoscope or the Videoscope Imaging Processor during the procedure, resulting in the loss or degradation of the visualization image, return the deflection section of the endoscope to a neutral position, and then carefully withdraw the endoscope 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 is lost during operation and remains absent after restarting the Videoscope Imaging Processor, promptly replace the endoscope with a new one.
● To minimize the risk of electric shock, ensure that this equipment is properly grounded.
● Avoid placing the equipment in locations where disconnection may be difficult.
● Before use, refer to the operating manuals for all electromedical energy sources utilized with endoscopic instruments for relevant instructions, warnings, and precautions.
● Do not use accessories that do not meet the compatibility requirements specified in the Instructions for Use, as this may cause damage to the endoscope, the Processor, or any connected accessories.

Chapter 5 Post-Processing

Post-Processing Procedure for the Videoscope Imaging Processor:
(1) Turn off the Videoscope Imaging Processor.
(2) Disconnect the endoscope from the Videoscope Imaging Processor.
(3) 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 Videoscope Imaging 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 Videoscope Imaging 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 Videoscope Imaging 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. To safely power down the system, press the "Control switch" button first and followed by the “Rocker Switch” button. Do not disconnect the Processor by unplugging it directly from the hospital's electrical outlet before shutting it down via the "Control switch" and “Rocker Switch” button. 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. Device and accessories should be safely disposed of in accordance with hospital, administrative, and/or local government policy and with the Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU.

WARNING

● Using a Processor contaminated with patient fluids can expose the operator or secondarily, the patient through clinician contact, to bio-hazardous materials. To prevent exposure to potentially bio-hazardous materials, clean and disinfect the Processor during and between uses using the cleaning procedure described in the “5.1 Cleaning Instructions” section.

5.3 Storage

CAUTION

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

● Do not store the Videoscope Imaging Processor in a vertical position, as this increases the risk of failure.
● Do not store the Videoscope Imaging Processor outside its specified 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 Videoscope Imaging 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 the storage environment adheres to the specifications outlined in **Chapter 6: Environmental Requirements**.
● Ensure the storage area is protected from potential water leaks or splashes.

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°C~50°C (-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 Videoscope Imaging 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 Videoscope Imaging Processor for Maintenance:
● Ensure that appropriate protective packaging is used to prevent further damage to the Videoscope Imaging Processor during transportation. (Using the product's original packaging is recommended.)
● Please describe the details of the fault, the serial number of the Videoscope Imaging Processor, your name and contact information, and the address of the sender.
● All accessories related to the failure of the Videoscope Imaging Processor should be also sent with the Videoscope Imaging 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 Videoscope Imaging 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 endoscope and contact Happiness Works for consultation and maintenance.

● The Videoscope Imaging Processor requires the endoscope to process and display images simultaneously. To troubleshoot image-related issues, please refer to the troubleshooting section of the endoscope manual.

8.1 Unable to Start the Videoscope Imaging Processor

Issue: Power cords are not properly connected.

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

Issue: Fuse test failure.

Solution: Return the Videoscope Imaging Processor for maintenance.

8.2 No Image 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: Data cables are not properly connected.

Solution: Ensure all data cables are correctly connected.

Issue: endoscope is not properly connected.

Solution: Ensure the endoscope is correctly connected.

8.3 Abnormal Operation of Key Functions

Issue: The Videoscope Imaging Processor may be damaged.

Solution: Return the Videoscope Imaging 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 must comply with all applicable 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.

Chapter 11 Security Classification

● Electric Shock Prevention Classification: Class I;

● Degree of Electric Shock Protection: BF-type;

● Ingress Protection Rating: IPX0;

●Safety in Presence of Flammable Anesthetic Gas mixed with air or with oxygen or nitrous oxide: Not applicable;

● Operation Mode Classification: Continuous operation

● Rated Voltage and Frequency: AC 100-240V 50/60Hz.

● Protection Against Defibrillation Discharge Effects: No

● Signal Output/Input Capability: Yes;

● Installation Type: Portable equipment

● Normal Operating Conditions: The output voltage is less than DC 10V, which is within the safe voltage range.

WARNING

● The endoscope must be used in conjunction with Videoscope Imaging Processor.
● 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 interfering radiation and immunity standards and have passed EMC testing as part of Digital Endoscope System:

Table 3: Cable Overview

Cables	Length (m)
HDMI to HDMI cable	1.5
SDI to SDI cable	1.5
HDMI - DVI cable	3.0
Power cord	1.5

CAUTION

● Buyers and users of the Videoscope Imaging Processor and endoscope 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 Videoscope Imaging Processor and endoscope.
● Portable and mobile RF communication devices may interfere with the proper functioning of the Videoscope Imaging Processor and endoscope. Please operate these devices under the recommended electromagnetic conditions.

WARNING

● It is advisable to avoid using the Videoscope Imaging Processor and endoscope 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 (30 cm) 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.

Videoscope Imaging Processor 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 Videoscope Imaging Processor is very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	Videoscope Imaging Processor 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 60601-1-2 Test level**	**Compliance level**
Electrostatic discharge (ESD)	± 8 kV contact ± 2 kV, ± 4 kV, ± 8	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air

IEC 61000-4-2	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 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle 70 % UT; 25/ 30 cycles 0 % UT; 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 % U_T; 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	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 Specification Parameters

Power supply requirement	Voltage	AC 100~240V
	Frequency	50/60Hz
	Input Power	50VA
	Input Current	2.0A
Operation environment	Ambient Temperature	10℃~40℃ (50~104°F)
	Relative Humidity	20%～85%
	Atmosphere	700hPa～1060hPa
Storage environment	Ambient Temperature	-40℃~50℃ (-40~122°F)
	Relative Humidity	10%～93%
	Atmosphere	700hPa～1060hPa
Function button	Brightness	Manual multilevel brightness adjustment
	White Balance	Auto white balance
	Freeze	Image freezing
	Zoom	Image magnification
	Photo	Photo taking
	Video	Video recording
Image output	HDMI	Video resolution no less than 1920*1080
	SDI	
	DVI	
Electromagnetic Compatibility	Designed in accordance with	IEC 60601-1:2020 IEC 60601-1-2:2020
Electrical safety		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