Tech-Image CO., LTD

“Tech-Image” Video Endoscope System

Instructions for Use

Version 1.1

Apr. 26, 2026

Caution: Rx ONLY

Federal law restricts this device to sale by or on the order of a physician.

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1. Product Overview

1.1 Product Description

The **“Tech-Image” Video Endoscope System** is an integrated digital imaging platform designed for the real-time visualization of internal anatomical structures. The system consists of the CYTS-02 Video Display Device, a reusable 13.3-inch Full-HD LCD console, and the TISE Series Single-use Video Endoscopes. Utilizing advanced 'Chip-on-Tip' CMOS technology and integrated LED illumination, the system captures high-resolution imaging data and supports external video output via a dedicated HDMI port. The TISE endoscopes are available in various configurations—including different diameters, viewing angles, and working lengths—to accommodate the specific requirements of the indicated surgical procedures. When used in conjunction with their corresponding sterile cannula accessories, the system facilitates precise access through a surgical opening. This single-use architecture ensures that the device is provided sterile for each procedure and eliminates the risk of cross-contamination, ensuring consistent optical performance and patient safety.

1.2 Intended Use and Indications for Use

Intended Use Statement

The **“Tech-Image” Video Endoscope System** is intended to be used as a single-use endoscopic video camera by qualified physicians to provide real-time illumination and visualization of internal anatomical structures during various general surgical and minimally invasive endoscopic procedures in diagnostic and therapeutic interventions.

Indications for Use

The **“Tech-Image” Video Endoscope System** is intended to be used as a single-use endoscopic video camera to provide visualization of the interior of the body’s internal anatomy during various diagnostic and surgical endoscopic procedures. These applications include, but are not limited to: general surgery and minimally invasive surgery (e.g., orthopedic, spine, laparoscopic, and plastic surgical procedures).

1.3 Expected Clinical Benefits

The “Tech-Image” Video Endoscope System is an adjunctive visualization device that enables endoscopic imaging of natural body passages, thereby enhancing the effectiveness and efficiency of diagnostic and surgical procedures.

1.4 Precautions before operation

Instructions for Use

⚠ This device is for prescription use only (**Rx ONLY**) and must be used by or under the supervision of trained healthcare professionals experienced in endoscopic techniques and procedures.

⚠ The device is intended for use in hospitals or clinical environments only, and for adult patients.

⚠ Operation must follow established clinical procedures to avoid contamination prior to insertion.

⚠ Endoscopic images must not be used as the sole basis for pathological diagnosis. Physicians must interpret findings in conjunction with clinical information and other diagnostic methods.

⚠ Before use, please ensure that the system's packaging and equipment are intact and refer to the user manual to ensure proper function and safe operation. If any defect or malfunction is detected, please contact the manufacturer's authorized service provider. Do not attempt to repair the device yourself.

Contraindications

⚠ This product is a medical device intended for medical use only. It must not be used for any non-medical purposes.

⚠ This product is contraindicated for patients with acute genital tract infections, pelvic infections, or patients who are unable to comply with operating instructions.

⚠ Do not use this system in the presence of flammable gases.

⚠ Patients for whom use of an endoscopic system is contraindicated must not be treated with this device

⚠ Do not use this device in a magnetic resonance imaging (MRI) environment. Doing so may result in patient injury and image artifacts.

Handling Instruction

⚠ Avoid excessive vibration, impact, or pressure to prevent damage.

⚠ Avoid direct contact between the distal tip and foreign objects to

prevent contamination or image degradation.

⚠ To prevent potential malfunction, avoid:

- ✓ Dropping the endoscope onto hard surfaces;
- ✓ Applying excessive pressure to the distal tip;
- ✓ Contact between the distal lens and foreign objects.

1.5 Warning and Precautions

Warnings

⚠ The endoscope is a single-use device. Follow applicable medical device handling procedures prior to use to prevent contamination before insertion.

⚠ Endoscopic images must not be used as the sole basis for pathological diagnosis. Physicians must interpret and confirm findings using other diagnostic methods and the patient's clinical condition.

⚠ Do not activate endoscopic accessories until the distal end of the accessory is clearly visible on the monitor and extends sufficiently beyond the distal tip of the endoscope. Failure to do so may result in patient injury or damage to the endoscope.

⚠ Do not use this product if the device or its packaging is damaged in any way, or if the endoscope fails the pre-use inspection (refer to this user manual).

⚠ Do not attempt to clean, disinfect, or reuse the endoscope. This is a single-use device. Reuse may result in contamination and infection.

⚠ Do not use the endoscope while administering oxygen or highly flammable anesthetic gases to the patient. This may result in patient injury.

⚠ Do not use the endoscope in an MRI environment.

⚠ Do not use the endoscope during defibrillation.

⚠ This device is intended for use only by trained and qualified healthcare professionals experienced in clinical endoscopic techniques and procedures.

⚠ Do not apply excessive force when advancing, manipulating, or withdrawing the endoscope.

⚠ Continuously monitor the patient's condition throughout the procedure.

⚠ Always observe the real-time endoscopic image on the monitor while advancing or withdrawing the endoscope. Failure to do so may result in patient injury.

⚠ Do not use the endoscope if the sterile barrier or packaging is damaged.

⚠ The distal tip of the endoscope may increase in temperature due to heat generated by the light source. Avoid prolonged contact between the distal tip and patient tissue, as extended contact may result in tissue injury.

⚠ Do not advance or withdraw the endoscope while accessories protrude from the distal end of the working channel, as this may cause patient injury.

⚠ Electronic equipment and the endoscopic system may interfere with each other's normal operation. If the system is used adjacent to or stacked with other equipment, verify proper operation of all devices prior to use. Mitigation measures such as reorienting or relocating equipment or shielding the room may be necessary.

⚠ Carefully verify whether the image displayed on the monitor is a live image or a recorded image, and confirm that the image orientation is correct.

⚠ If any defect or malfunction is detected, immediately discontinue use and withdraw the endoscope. Do not attempt to repair the device. Contact the manufacturer or distributor for assistance.

⚠ Before using the endoscope in conjunction with high-frequency electrosurgical equipment, ensure that appropriate preoperative preparation has been completed, including removal of flammable gases and implementation of preventive measures. Electrosurgical parameter settings for endoscopic procedures may differ from conventional electrosurgery and may significantly affect surrounding tissues. Parameters must be determined by experienced and trained clinicians

based on the clinical situation. To prevent burns, tissue perforation, or device damage, activate high-frequency current only after the electrode is clearly visible within the endoscopic field of view, and avoid contact between the electrode and the endoscope.

⚠ When using the endoscope or its accessories in conjunction with laser equipment, appropriate eye protection must be worn to prevent ocular injury. To avoid laser-related tissue injury or damage to the endoscope, activate the laser only when the distal tip of the laser fiber is clearly visible within the field of view. Do not contact the laser fiber during laser activation.

⚠ Not all instruments that meet the minimum working channel diameter are compatible with the endoscope. Compatibility of accessories must be verified prior to the procedure.

⚠ When using electrically powered endoscopic accessories, patient leakage current may increase. Only electrically powered endoscopic accessories classified as Type CF or Type BF applied parts may be used with the endoscope to minimize total patient leakage current.

⚠ Excessive gas insufflation (e.g., air or inert gases) prior to high-frequency or laser-assisted procedures may result in gas embolism. Exercise caution to minimize patient risk.

Electromagnetic Compatibility (EMC)

When installing and operating this device, observe the following guidelines:

⚠ During operation, the endoscope and all supplied accessories shall be kept at a minimum distance of 30 cm (12 inches) from other electronic equipment, including other medical devices in operation, to reduce the risk of electromagnetic interference.

⚠ Do not place this device adjacent to, on top of, or below other electronic equipment, as this may result in electromagnetic interference that could affect normal operation of the device.

⚠ Do not use this system simultaneously with portable or mobile radio frequency (RF) communication equipment, as such equipment may interfere with the proper operation of the device.

⚠ Use only power supplies and accessories specified by the manufacturer. Use of unapproved power supplies or accessories may result in electromagnetic interference and adversely affect the performance and safety of the endoscope.

Precautions

1. Ensure that an appropriate backup system is readily available for immediate use in the event of device failure, in order to avoid interruption of the procedure.
2. When using sharp instruments such as needles through the endoscope, exercise caution to avoid damage to the insertion portion or distal end.
3. When the endoscope is used in conjunction with electrically powered devices, take care to avoid damage to the insertion portion or distal end.
4. Handle the distal end with care and avoid impact with other objects, as this may result in device damage. The lens surface of the distal end is fragile and may be damaged, resulting in image distortion.
5. Keep the endoscope handle dry during preparation, use, and storage.
6. Do not use knives or other sharp tools to open sterile packaging or cartons.

1.6 General Information

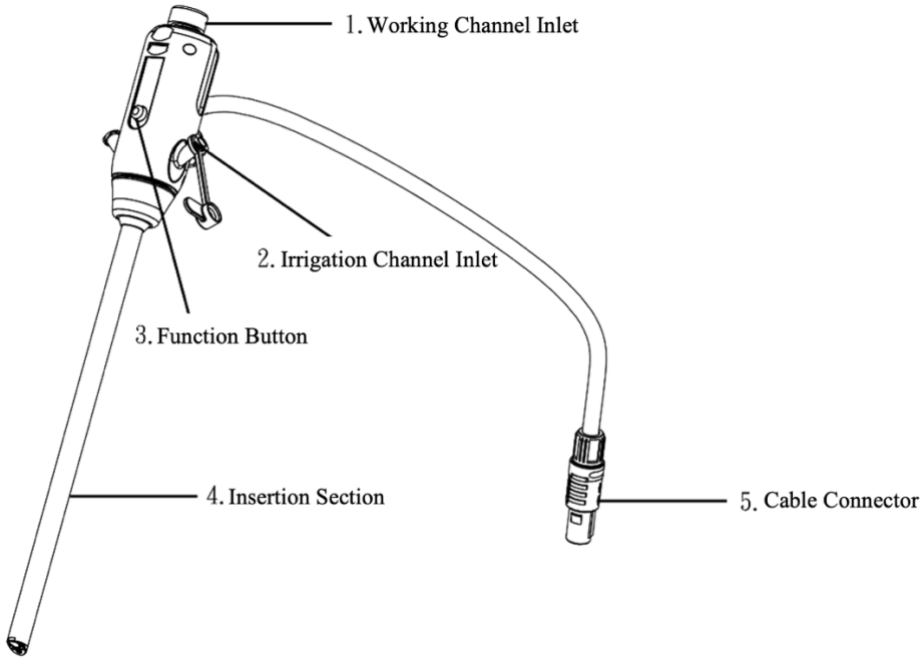
This device has been tested and complies with the following standards for electrical safety and electromagnetic compatibility:

i. IEC 60601-1-2:2014 + A1:2020
ii. EN 60601-1-2:2015 + A1:2021

This product is designed to meet the basic safety and essential performance requirements for medical electrical equipment and is intended for use in healthcare facility environments. When using this device, users must adhere to established clinical procedures and safety guidelines to ensure the safety of both patients and operators.

2. System Description

2.1 System Components



No.	Component Name	Description
1	Working Channel Inlet	Used for insertion of endoscopic accessory instruments.
2	Irrigation Channel Inlet	Used for fluid infusion and irrigation.
3	Function Button	Button functions: Short press: Capture image Long press: Start video recording (press again to stop recording)
4	Insertion Portion	The portion inserted into the patient for diagnostic or surgical procedures.
5	Cable Connector	Used to connect to the image display unit for transmission of image signals.

2.2 Device Compatibility

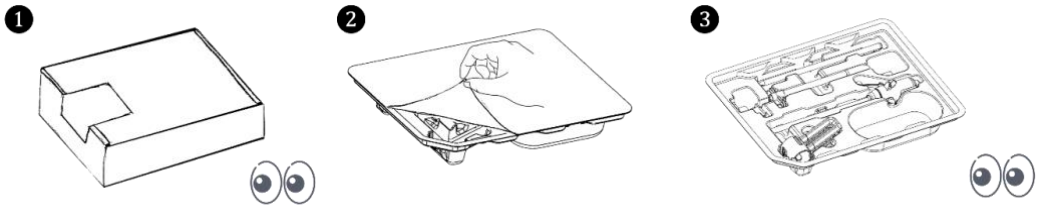
This endoscope is specifically designed for use in conjunction with compatible image display equipment to ensure proper system operation and optimal image performance.。



3. Instructions for Use of the "Tech-Image" Video Endoscope System

3.1 Pre-Use Inspection

1. Inspect the outer carton, the endoscope, and the image display unit to confirm they are intact. Verify that the seals are not damaged before opening the packaging.
2. Open the sterile package from the lower-left corner to allow safe removal of the endoscope and to minimize the risk of contamination.
3. Carefully inspect the device surface for any foreign matter, defects, or abnormalities (e.g., sharp edges, rough surfaces, or protrusions). Do not use the device if any defect is observed, as device defects may pose a potential risk of patient injury.

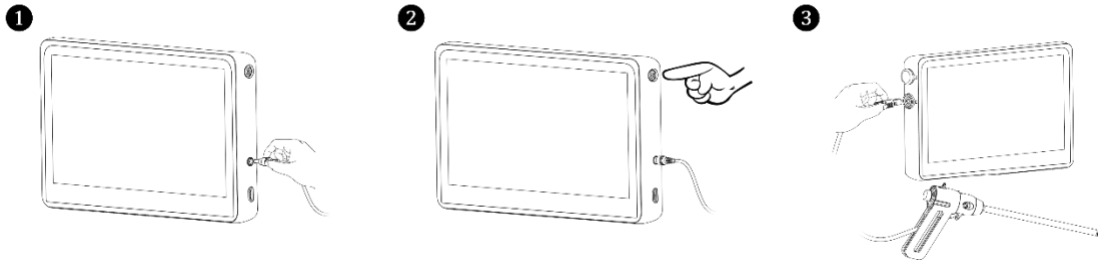


3.2 Image Inspection

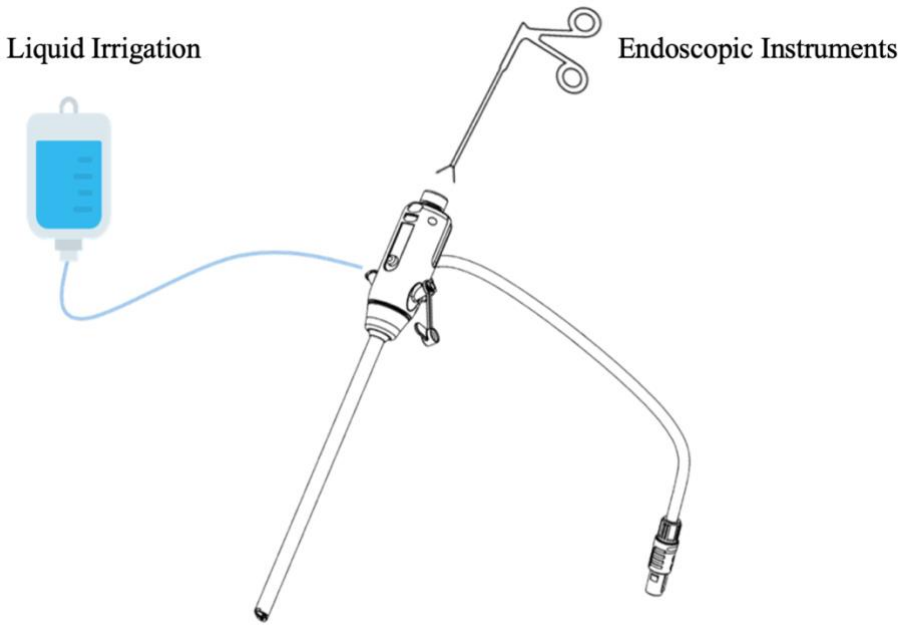
1. Connect the power supply to the power input port located on the right side of the device and ensure the connection is secure.
2. Press the power switch located at the upper right corner of the device

to turn on the image display unit.

3. Connect the endoscope to the image display unit and confirm that the connection is smooth and secure, with no resistance or looseness.
4. Aim the distal end of the endoscope at any target object and verify that the image is displayed properly on the monitor to confirm normal endoscope operation.
5. If the displayed image appears unclear, gently clean the distal lens of the endoscope, taking care not to damage the lens surface.



3.3 Working Channel and Irrigation Channel



Endoscopic instruments may be inserted through the working channel inlet located on the upper portion of the device. Lateral irrigation connectors (Luer lock) are provided on both sides of the device. The appropriate connector may be selected based on procedural requirements for connection to an irrigation or infusion system.

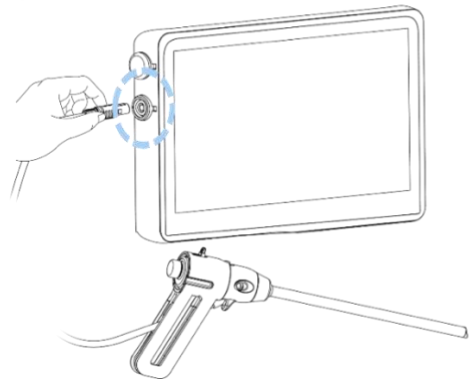
3.4 “Tech-Image” Display Unit

Connecting the Endoscope Cable to the Image Display Unit

As shown in Figure ❶, connect the endoscope cable to the endoscope connection port located on the left side of the image display unit. If the endoscope is not properly connected, no image will be displayed.

Once the endoscope is correctly connected, the monitor will display a real-time image, as shown in Figure ❷.

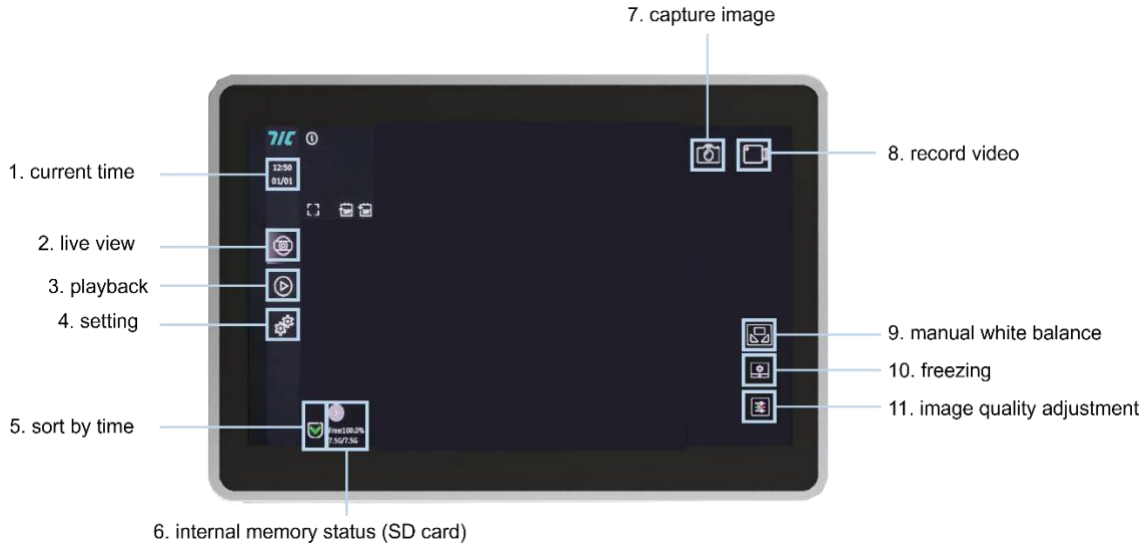
❶



❷



Main Page

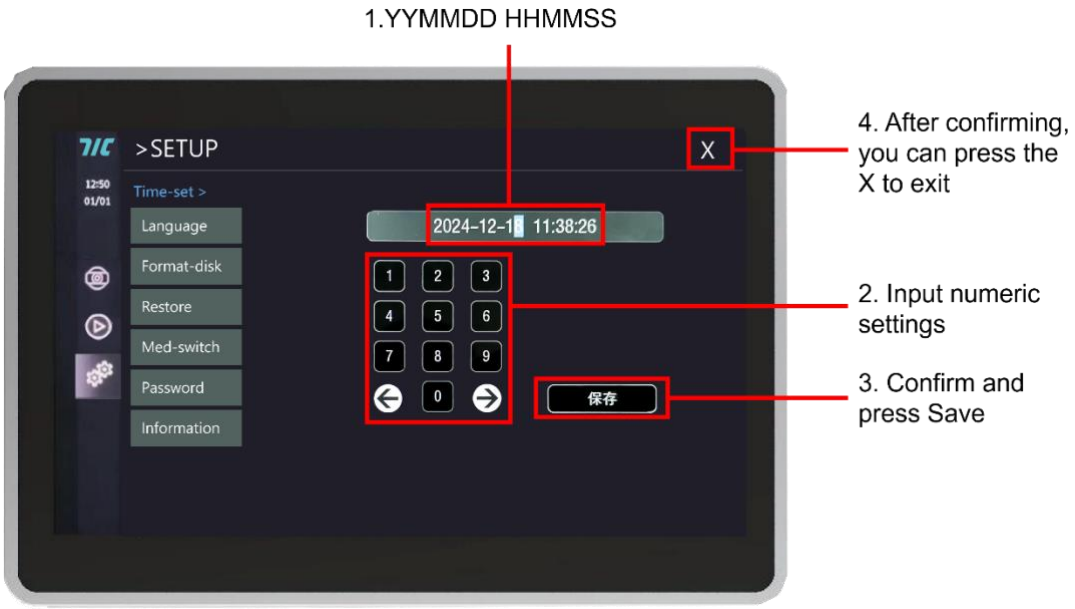


No.	Function	Description
1	Current Time	The initial date and time settings must be configured by the user.
2	Live view	Used to view the live endoscopic image.

3	Playback	Used to review captured images or recorded videos.
4	Settings	Used to configure system parameters.
5	Sort by time	Adjust and rearrange the display order of images or videos based on their capture time.
6	Internal memory Status	Used to view the status of internal storage devices.
7	Capture Image	Used to capture still images from the real-time video.
8	Record Video	Used to record video of the real-time image.
9	Manual White Balance	Used to compensate for changes in lighting conditions to ensure accurate color reproduction.
10	Freezing	Used to freeze the current image on the display.
11	Image Quality Adjustment	Used to fine-tune image brightness, contrast, sharpness, and color to achieve optimal display quality.

Settings

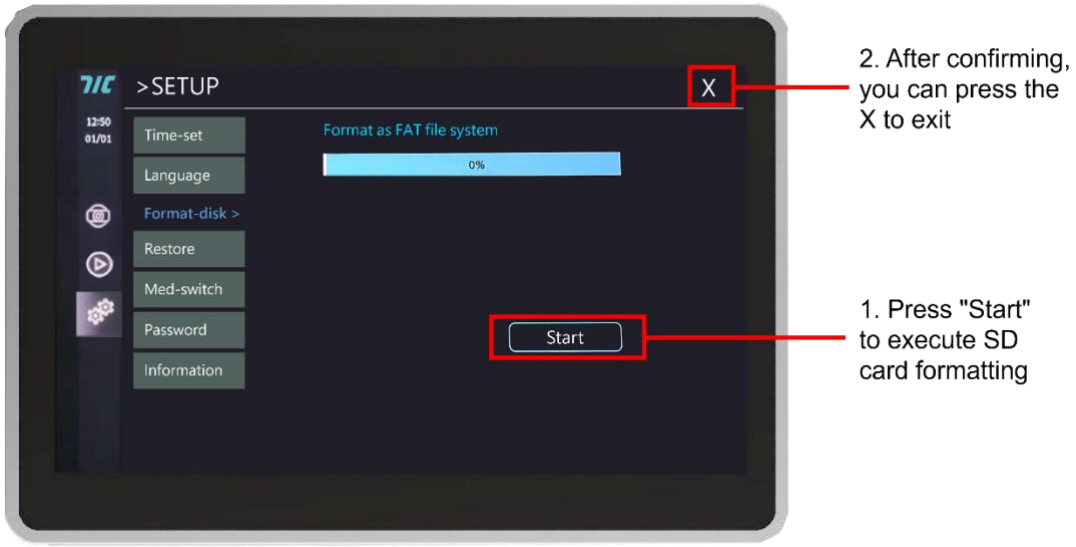
Time Setting



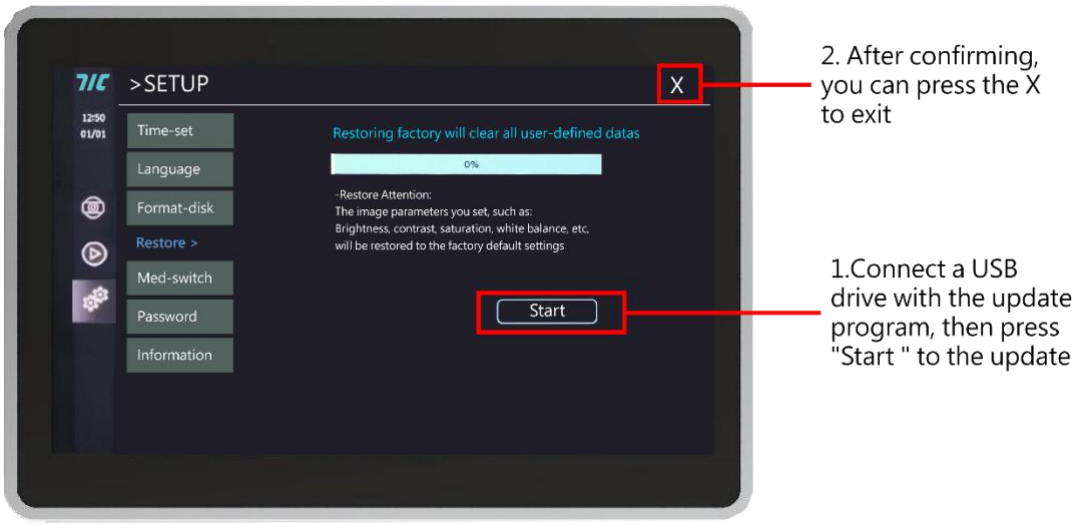
Language Setting



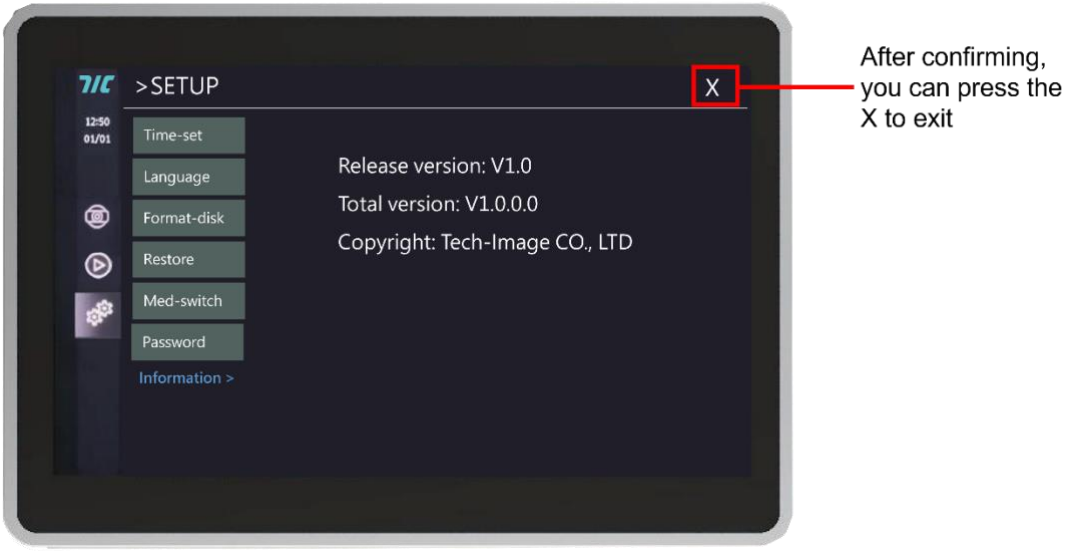
Format SD Card



Restore Factory Default Setting



System Configuration



Video Recording

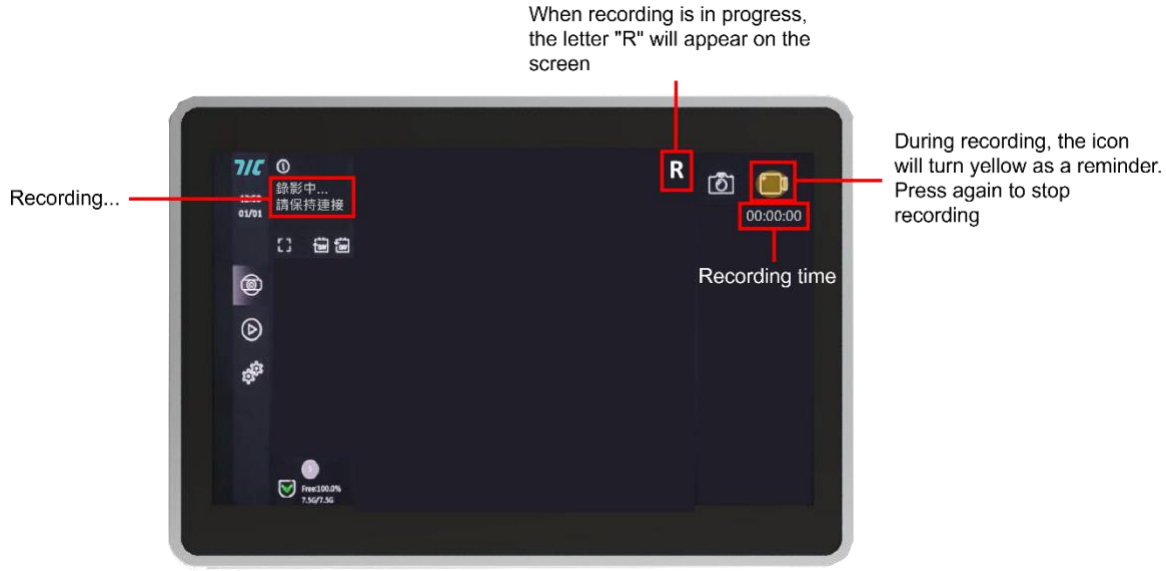
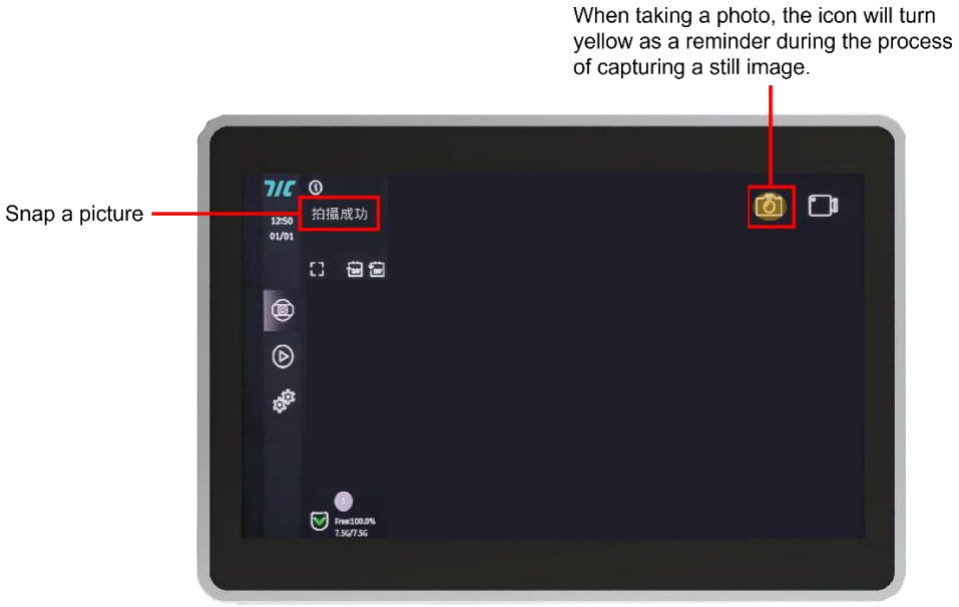
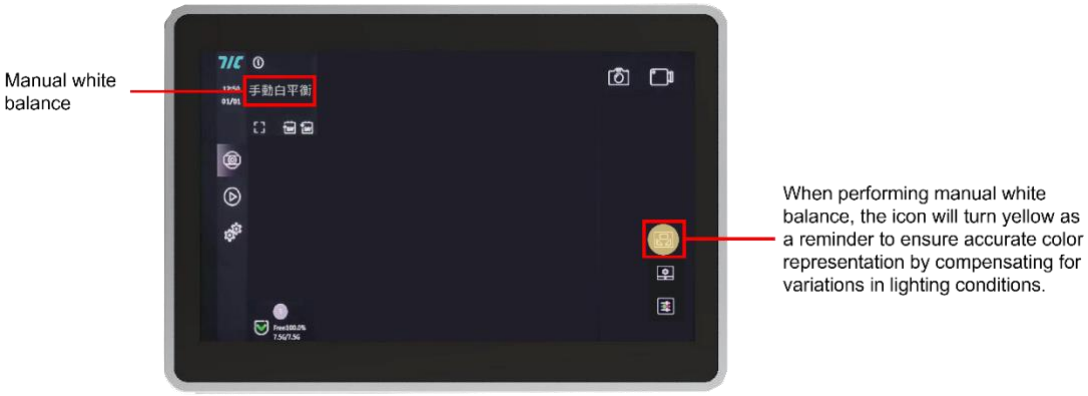


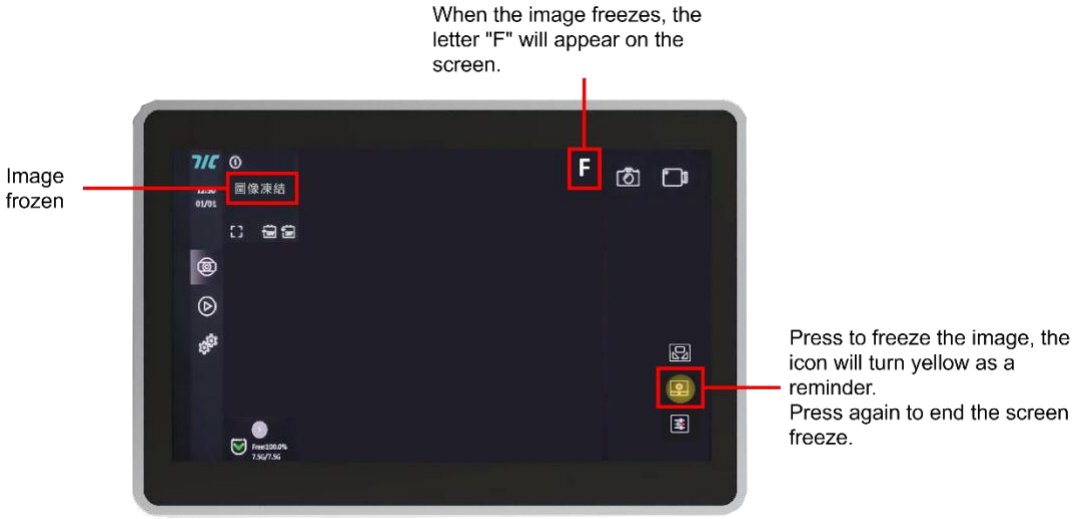
Image Capture



Manual White Balance



Freeze Image



Before each use, or after changing display modes or system settings, the operator shall verify that the image observed through the endoscope is a live (real-time) image and not a stored image, and that the image orientation is correct.

Image Quality Adjustment

Press the  icon to open the Image Settings Window.



3.5 Post-Processing

Visual Inspection

Visually inspect the endoscope, particularly the distal lens and insertion portion, for any signs of damage. Damage to these components may compromise patient safety during the procedure.

Disconnecting the Endoscope from the Image Display Unit

Disconnect the endoscope from the image display unit, turn off the image display unit, and unplug the power supply from the electrical outlet.

Disposal

As a single-use medical device, the endoscope shall be considered contaminated after use and must be disposed of in accordance with local regulations and guidelines for the disposal of contaminated medical devices and electronic components. Reuse of the endoscope is not recommended.

Reprocessing

All external and accessible surfaces of the image display unit (CYTS-

02), power cords, and power adapters shall be cleaned and disinfected using a soft cloth moistened with 75% alcohol. Gently wipe the housing and control panel surfaces.

4. Technical Specifications

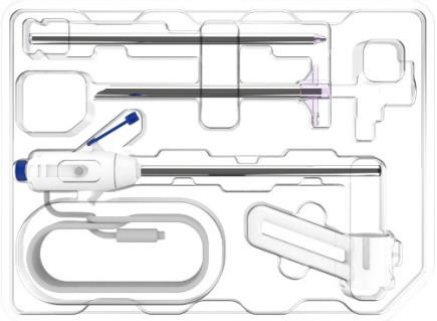
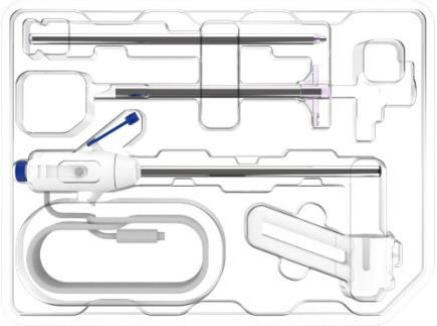
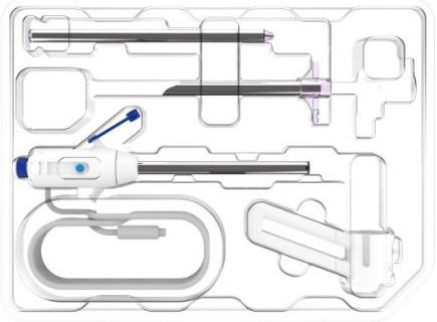
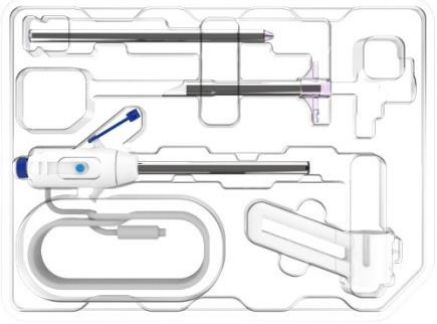
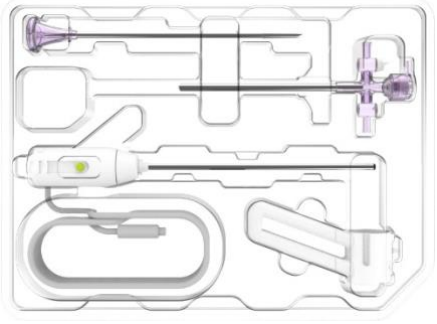
4.1 Main Products and Accessories

<table>
<tr><th colspan="4">“Tech-Image” Single-Use Video Endoscope (TISE Series)</th></tr>
<tr><td colspan="2">Model</td><td>TISE01</td><td>TISE02</td><td>TISE03</td></tr>
<tr><td colspan="2">Outer Diameter (mm)</td><td>8.6</td><td>10.0</td><td>4.7</td></tr>
<tr><td rowspan="3">Optical</td><td>Direction of View (DoV)</td><td>30°</td><td>15°</td><td>0°</td></tr>
<tr><td>Field of View (FoV)</td><td>130°</td><td>130°</td><td>130°</td></tr>
<tr><td>Working Distance (mm)</td><td>181</td><td>130</td><td>170</td></tr>
<tr><td></td><td>Effective Depth of Field (mm)</td><td>5~50</td><td>5~50</td><td>5~50</td></tr>
<tr><td colspan="2">Working Length (mm)</td><td>273</td><td>218</td><td>N/A</td></tr>
<tr><td colspan="2">Working Channel Diameter (mm)</td><td>4.3</td><td>5.8</td><td>N/A</td></tr>
<tr><td colspan="2">Illustration</td><td colspan="3">
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</table>

“Tech-Image” Single-Use Video Endoscope Cannula		
Model	Outer Diameter (mm)	Working Length (mm)
TISE01S1	9.6	178
TISE01S2	11.0	178
TISE01T1	8.5	225
TISE02S1	11.0	125
TISE02S2	13.5	125
TISE02T1	10.0	185

TISE03S1	5.6	174
TISE03T1	4.8	177
Illustration		

Sterilization Method	Ethylene Oxide (EO) Sterilization
Storage Environment	Ambient temperature: -20 to +60°C
Transportation Environment	Ambient temperature: -20 to +60°C
Operating Environment	Ambient temperature: +10 to +40°C
Atmospheric Pressure	700~1060 hPa
Relative Humidity	30% RH ~ 80% RH

“Tech-Image” Single-Use Video Endoscope & Cannula Combinations	
Model	Illustration
TISECK001 (TISE01+TISE01S1+TISE01T1)	
TISECK002 (TISE01+TISE01S2+TISE01T1)	
TISECK003 (TISE02+TISE02S1+TISE02T1)	
TISECK004 (TISE02+TISE02S2+TISE02T1)	
TISECK005 (TISE03+TISE03S1+TISE03T1)	

<table>
<tr><th colspan="4"><u>"Tech-Image" Video Display Device</u></th></tr>
<tr><td>Model</td><td colspan="3">CYTS-02</td></tr>
<tr><td>Display Panel</td><td colspan="3">13.3-inch LCD digital display</td></tr>
<tr><td>Resolution</td><td colspan="3">1920x1080</td></tr>
<tr><td>Image Format</td><td colspan="3">JPEG</td></tr>
<tr><td>Video Format</td><td colspan="3">MP4</td></tr>
<tr><td>Frame Rate</td><td colspan="3">60 fps</td></tr>
<tr><td>Language Options</td><td colspan="3">English, Traditional Chinese</td></tr>
<tr><td>Product Dimensions</td><td colspan="3">320mm x 220mm x 43.5mm</td></tr>
<tr><td>Product Weight</td><td colspan="3">2.14kg</td></tr>
<tr><td>Wired Connection Interface</td><td colspan="3">HDMI 1.4</td></tr>
<tr><td>Expected Service Life</td><td colspan="3">3 years</td></tr>
<tr><td rowspan="5">Input / Output Ports</td><td>#</td><td>Component</td><td>Description</td></tr>
<tr><td>1</td><td>Endoscope Connector</td><td>Receives signals from the “Tech-Image” video endoscope.</td></tr>
<tr><td>2</td><td>Power Button</td><td>Used to turn the image display unit on or off.</td></tr>
<tr><td>3</td><td>DC Power Input</td><td>Used to connect the DC power adapter.</td></tr>
<tr><td>4</td><td>HDMI Output Port</td><td>Used to connect an external display device.</td></tr>
<tr><td>Illustration</td><td colspan="3">
</td></tr>
</table>

Storage Environment	Ambient temperature: -20 to +60°C
Transportation Environment	Ambient temperature: -20 to +60°C
Operating Environment	Ambient temperature: +10 to +40°C
Atmospheric Pressure	700~1060 hPa
Relative Humidity	30% RH ~ 80% RH
CYTS-02 Adapter	
Brand	MEAN WELL
Model	GSM25B12-P1J
Input Rating	AC 100-240V, 50/60Hz, 0.7~0.35A
Output Rating	12V/2.08A
Illustration	

4.2 Applicable Standards

The functions of the endoscope (TISE Series) comply with the following standards:

1. ISO 8600-1 — Endoscopes — Medical endoscopes and endoscopic accessories — Part 1: General requirements.
2. ISO 8600-3 — Endoscopes — Medical endoscopes and endoscopic accessories — Part 3: Determination of field of view and direction of view of endoscopes with optics.
3. ISO 8600-4 — Endoscopes — Medical endoscopes and endoscopic accessories — Part 4: Determination of maximum width of the insertion portion.
4. IEC 60601-1 — Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
5. IEC 60601-2-18 — Medical electrical equipment — Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.
6. IEC 60601-1-2 — Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic disturbances — Requirements and tests.

The functions of the image display unit (CYTS-02) comply with the following

standards:

1. IEC 60601-1 (EN 60601-1) — Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
2. IEC 60601-1-2 (EN 60601-1-2) — Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic disturbances — Requirements and tests.

4.3 Electromagnetic Compatibility (EMC)

IEC 60601-1-2:2014+A1:2020/ EN 60601-1-2:2015 + A1:2021

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
This system is intended for use in the electromagnetic environment specified below. The customer or user of this system should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF Emissions (CISPR 11)	Group 1	The system uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause interference with nearby electronic equipment.
RF Emissions (CISPR 11)	Class A	The system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage Fluctuations / Flicker Emissions (IEC 61000-3-3)	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
This system is intended for use in the electromagnetic environment specified below. The customer or user of this system should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV Contact ±2, 4, 8, 15 kV Air	±8 kV Contact ±2, 4, 8, 15 kV Air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient / Burst IEC 61000-4-4	±2 kV for input/output lines	±2 kV input/output lines	Mains power quality should be that of a typical commercial or hospital environment.

Surge IEC 61000-4-5	±0.5, 1 kV line-to-line (L to N)	±0.5, 1 kV line-to-line (L to N)	
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	✓ 0% UT for 0.5 cycle (single phase) ✓ 0% UT for 1 cycle ✓ 70% UT for 25/30 cycles (50/60 Hz) ✓ 0% UT for 250/300 cycles (50/60 Hz)	✓ 0% UT for 0.5 cycle (single phase) ✓ 0% UT for 1 cycle ✓ 70% UT for 25/30 cycles (50/60 Hz) ✓ 0% UT for 250/300 cycles (50/60 Hz)	Mains power quality should be that of a typical commercial or hospital environment. If continued operation is required during power interruptions, it is recommended that the device be powered from an uninterruptible power supply (UPS).
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m (50 or 60 Hz)	30 A/m at 50 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity (RF)			
This system is intended for use in the electromagnetic environment specified below. The customer or user of this system should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF IEC 61000-4-6	Immunity level of 3 Vrms over the frequency range 0.15–80 MHz, and 6 V within ISM frequency bands	Disturbance voltage of 3 Vrms applied over 0.15–80 MHz, and 6 V applied within ISM frequency bands	Portable and mobile RF communications equipment should be used no closer to any part of this device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter。 $E=\frac{\sigma}{d}\sqrt{P}$
Radiated RF IEC 61000-4-3	Over the frequency range 80 MHz to 2.7 GHz, with 80% AM (1 kHz), tested under the following conditions: ✓ 385 MHz: 18 Hz pulse modulation,	Over the frequency range 80 MHz to 2.7 GHz, with 80% AM (1 kHz), tested as follows: : 385 MHz: 18 Hz pulse modulation, 27 V/m	P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and d is the recommended separation distance in meters (m).

	27 V/m ✓ 450 MHz: FM with ±5 kHz deviation, 1 kHz sine, 28 V/m ✓ 710, 745, 780 MHz: 217 Hz pulse modulation, 9 V/m ✓ 810, 870, 930 MHz: 18 Hz pulse modulation, 28 V/m ✓ 1720, 1845, 1970 MHz: 217 Hz pulse modulation, 28 V/m ✓ 2450 MHz: 217 Hz pulse modulation, 28 V/m ✓ 5240, 5500, 5785 MHz: 217 Hz pulse modulation, 9 V/m	450 MHz: FM with ±5 kHz deviation, 1 kHz sine, 28 V/m 710, 745, 780 MHz: 217 Hz pulse modulation, 9 V/m 810, 870, 930 MHz: 18 Hz pulse modulation, 28 V/m 1720, 1845, 1970 MHz: 217 Hz pulse modulation, 28 V/m 2450 MHz: 217 Hz pulse modulation, 28 V/m 5240, 5500, 5785 MHz: 217 Hz pulse modulation, 9 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a] , should be less than the compliance level in each frequency range [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
[a] Field strengths from fixed RF transmitters (such as base stations for radio (cellular/cordless) telephones, land mobile radios, amateur radios, AM and FM radio broadcast, and TV broadcast) cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength at the location where this device is used exceeds the applicable RF compliance level of 3 V/m, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

5. Patient Information

Patients should be provided with appropriate information based on the applicable post-procedure instructions, contraindications, warnings, precautions, or potential adverse events described in this Instructions for Use (IFU).

6. Explanation of Symbols

	Consult Instructions for Use before use
	Warning: result in damage to the device or property, malfunction, or hazard.
	Type BF Applied Part
	Dispose of separately / separate collection
	Medical Device
	Manufacturer
	Date of Manufacture
	Expiration Date / Use-by Date
	Reference Number
	Sterilized using Ethylene Oxide (EO)
	Single Use Only / Do Not Reuse
	Prescription Only

7. Troubleshooting

If a malfunction occurs, refer to the troubleshooting guide below. If the issue cannot be resolved, please contact the authorized medical device distributor or the manufacturer using the contact information provided for service and support.

Problem Description	**Corrective Action**
The user interface is displayed on the image display unit, but no image or a frozen image is shown	1. Ensure that the endoscope is properly connected to a compatible image display unit. 2. Restart the image display unit. 3. If the image issue persists after performing the above steps, replace the endoscope with a new one.
Poor image quality	1. Ensure that the distal lens is free from blood, saliva, or other obstructions. 2. If the image remains unclear after performing the above step, carefully clean the lens.
No fluid flow or reduced flow through the irrigation channel	1. Clean the irrigation channel using a cleaning brush, or flush the irrigation channel with sterile water or normal saline. 2. Ensure that the irrigation system is properly connected and functioning correctly.
Difficulty inserting instruments into the working channel	1. Check the working channel for foreign objects or blockages and remove them as necessary. 2. Use instruments of appropriate size and confirmed compatibility to avoid insertion issues.
Blurred or distorted image	1. Adjust image settings using the image quality adjustment function. 2. Restart the image display unit. 3. Verify that no other devices in the vicinity may be interfering with system operation. 4. Confirm that the distal lens of the endoscope is clean and free of foreign material. 5. If necessary, replace the endoscope.
The image display unit is powered on but touch operation is not responsive	1. Clean the surface of the image display unit using a soft cloth. 2. Restart the image display unit.

Notices

If software updates are required, users shall contact the distributor authorized by Tech-Image CO., LTD., the legal manufacturer. The manufacturer will use dedicated upgrade tools to assist with the software update process and will perform applicable verification checks to confirm proper software operation.
In the event of software-related issues, this user manual provides clear handling instructions to ensure that users can effectively and safely resolve the issue by following the recommended procedures.

8. Cybersecurity Information and Precautions

The Tech-Image Video Endoscope System incorporates certain cybersecurity controls designed to protect system integrity and stored clinical data, even though the device has no network connectivity.

1. Network Connectivity and Attack Surface

The Tech-Image Video Endoscope System does not have any wired or wireless network interfaces (no Ethernet, Wi-Fi, Bluetooth, or cellular connectivity). The device is not intended to be connected to any hospital network or the public internet. This limited connectivity reduces the potential attack surface to local physical access to the device.

2. USB Port and Firmware Updates

A USB interface is present on the system but is intended exclusively for use by authorized service personnel for firmware updates and maintenance. The USB port is not accessible to end users during normal clinical use and requires the use of service tools to physically access the connector. Only manufacturer-provided, authenticated firmware packages shall be used for updates, and users shall not connect any unauthorized USB storage devices or peripherals to the system.

All software/firmware updates must be performed by or under the direction of the authorized service personnel in accordance with the service procedures provided by Tech-Image CO., LTD., the legal manufacturer. End users should not attempt to modify, replace, or install any software or firmware on the device.

3. Internal Storage (SD Card) and Data Management

The system uses an internal SD card as non-removable internal storage for recording and storing procedure images and videos. The SD card is not intended to be removed or accessed by users. Recorded data can only be erased by reformatting the

internal storage via the device user interface or service procedures; physical removal of the SD card is not part of normal use and must not be attempted by users.

Users are responsible for ensuring that stored clinical data are managed in accordance with institutional policies and applicable privacy regulations, including secure erasure of data (e.g., reformatting internal storage) before device decommissioning, transfer, or reassignment, as instructed by the manufacturer.

4. User Responsibilities and Physical Security

Because cybersecurity risks for this device are primarily associated with physical access, the device should be installed and operated in controlled clinical environments with restricted access to prevent unauthorized physical interaction with the system. Users should:

- Prevent unauthorized individuals from accessing the device, especially when it is unattended.
- Not attempt to open the device housing, access internal components, or bypass physical protections.
- Contact authorized service personnel if any signs of tampering, damage, or unauthorized access are suspected.

5. Cybersecurity Information Portal

The legal manufacturer, Tech-Image CO., LTD., maintains a dedicated Cybersecurity Portal for the Tech-Image Video Endoscope System at:
https://cs-portal.wemed-biotech.com/tech-image-video-endoscope-system

This portal provides up-to-date cybersecurity-related information for the device, including (as applicable) known vulnerabilities, security advisories, recommended mitigations, and software/firmware update information. Users and institutional IT/biomedical engineering personnel are encouraged to periodically review this portal for the latest security information relevant to the device.

6. Incident Reporting

If users suspect a cybersecurity-related issue (e.g., suspected tampering, unexpected behavior that may indicate unauthorized modification of the system, or concerns related to stored data), they should:

- Remove the device from clinical use if necessary to ensure patient safety.
- Contact technical support using the contact information provided in the IFU or on the Cybersecurity Portal.
- Follow institutional procedures for reporting potential cybersecurity or data protection incidents.

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