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## Chapter 1. Overview

### 1.1 Device Description and Features

The 4K Medical Endoscope Camera System is designed to provide illumination, image acquisition, processing, and display during endoscopic procedures.

The system consists of the following components:

- Light source
- Camera head compatible with approved endoscopes
- Image processing unit
- Display monitor

This system is intended for use in in-office diagnostic and visualization procedures only.

### 1.2 Warnings

- To reduce the risk of fire or electric shock, do not expose the device to rain or moisture.
- This device is supplied non-sterile. Use of a non-sterile device may result in infection. The device must be reprocessed in accordance with the provided instructions prior to initial use and after each subsequent use.
- High-intensity light output may cause permanent eye damage or tissue injury. Do not look directly into the light output. Always use the minimum light intensity required for adequate visualization.
- Do not connect peripheral devices that exceed the specified voltage or electrical ratings.
- Use only manufacturer-approved power cables and accessories.
- Do not pull, bend, or otherwise damage cables. Damaged cables must be replaced immediately.
- Do not service, open, or modify the device. All repairs must be performed by authorized service personnel.
- Do not block ventilation openings. Inadequate ventilation may result in overheating and device failure.
- Do not operate or store the device in the following environments:
  - Flammable or explosive atmospheres
  - Areas exposed to liquids or excessive moisture
  - Direct sunlight or radiant heat sources
  - High temperature or unstable power conditions
  - High humidity or dusty environments
  - Strong electromagnetic or magnetic fields

### 1.3 Intended Use/Indications for Use

The 4K Medical Endoscope Camera System is intended to provide illumination and visualization of internal structures during endoscopic procedures. The system captures and displays real-time images when used with compatible, legally marketed endoscopes. The device is intended for use by qualified healthcare professionals in appropriate clinical environments.

### Clinical Applications

The system is intended for use in visualization and documentation across a range of endoscopic procedures, including but not limited to:

- General surgical procedures requiring endoscopic visualization

- ENT procedures (e.g., nasal endoscopy, sinus procedures, laryngoscopy)
- Arthroscopic procedures of joints and articular cavities
- Gastrointestinal endoscopic visualization
- Urological endoscopic examinations
- Gynecological endoscopic procedures
- Pulmonary endoscopy
- Neurosurgical endoscopic visualization
- Plastic and reconstructive surgical procedures

## **Clinical Settings**

This device is suitable for use in the following environments:

- Hospital operating rooms and surgical centers
- Outpatient clinical environments
- Physician offices equipped for endoscopic procedures
- Medical training and education facilities

### **1.4 System Components and Features**

The system includes the following features:

- High-definition digital camera with enhanced imaging capabilities
- LED light source providing illumination of the surgical field
- Video recording functionality with time stamping for procedure documentation
- Multiple connectivity options for integration with compatible medical equipment
- User interface designed to support efficient clinical workflow

### **1.5 Compatibility And Versatility**

This system is designed for use with a wide range of commercially available endoscopes, including:

- Rigid endoscopes of various lengths and diameters
- Flexible endoscopes across multiple specialties
- Standard endoscopic equipment from major manufacturers

### **1.6 Contraindications**

No device-specific contraindications are currently known. The physician responsible must determine whether the intended procedure is appropriate based on the patient's clinical condition.

### **1.7 Patient Population**

**Age:** There are no restrictions regarding patient age groups.

**Weight – Warning: Sensitivity to Heat Transmission in Smaller Patients**

For smaller patients, particularly those weighing less than 5 kg (11 lbs), heat generated by the light source transmitted through the endoscope may be more pronounced and could potentially cause discomfort or thermal injury.

- Use the lowest light intensity necessary for adequate visualization
- Monitor the temperature of the endoscope tip during prolonged procedures
- If the temperature exceeds 41°C, immediately reduce the light intensity or discontinue use until the device has cooled

**Health Status:** Endoscopic procedures should only be performed on patients who, in the judgment of the operating physician, are able to tolerate the procedure without undue risk.

## 1.8 Operator

This device is intended for use by licensed physicians or healthcare professionals who are trained in endoscopic procedures.

## 1.9 Normal Operating Conditions

- Ambient Temperature: 5°C to 35°C (41°F to 95°F)
- Relative Humidity: ≤ 80%
- Atmospheric Pressure: 86 kPa to 106 kPa
- Power Requirements: ~230 V, 50 Hz

Note: The device should be kept away from strong electromagnetic or magnetic interference during operation.

## 1.10 Storage and Transport Conditions

Temperature: -10°C - 60°C (14°F to 140°F)

Relative humidity: 20-95%

## 1.12 Operating Conditions

Temperature: 5°C to 35°C (41°F to 95°F)

Relative humidity: 20-95%

### 1.1 Environmental Protection

Waste related to the device and its accessories, both during use and at the end of their service life, must be disposed of in accordance with applicable local, regional, and national regulations.

### 1.2 Device Lifespan

The expected service life of the device is 5 years from the date of manufacture, as indicated on the product labeling.

## Chapter 2. Device Characteristics

### 2.1 Device Composition

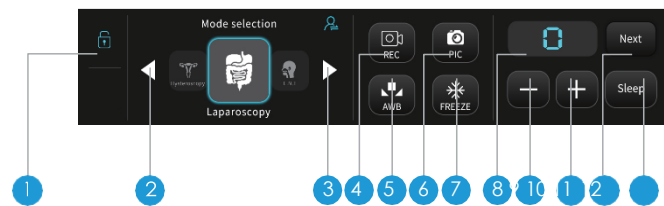
The 4K Medical Endoscope Camera System consists of the following components:

- Control unit (host)
- Camera head
- Cold light source
- Display monitor
- Optical interface
- Connection cables

### 2.2 405-466CS

Model	Control host	Camera	Cold light source	Display
405-466CS	YES	YES	YES	27 inches

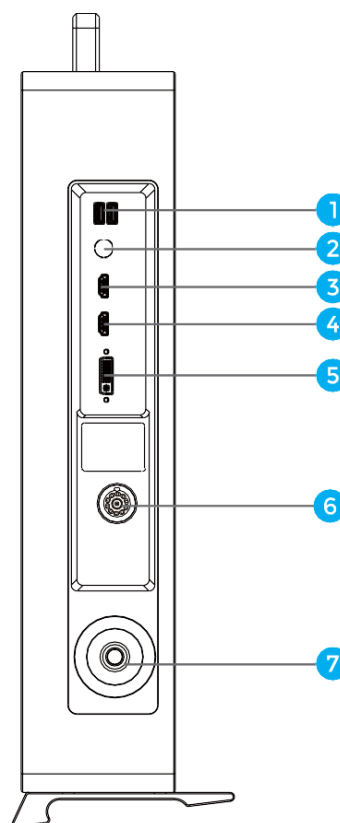
**Figure 2.3: Front panel**



- |                       |                                  |
|-----------------------|----------------------------------|
| 1. Lock Screen        | 7. Freeze                        |
| 2. Mode Select Left   | 8. Light Indicator               |
| 3. Mode Select Right  | 9. Next Page                     |
| 4. Record             | 10. Light Intensity Decrease (-) |
| 5. Auto White Balance | 11. Light Intensity Increase (+) |
| 6. Photo Capture      | 12. Light Sleep                  |

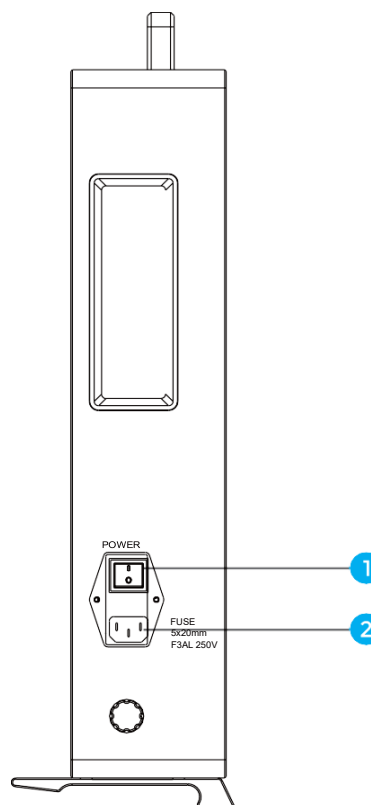
**Figure 2.4: Right side panel**

- 1. USB Ports
  - USB 1: Keyboard connection
  - USB 2: USB storage device (memory stick)
- 2. SDI signal output
- 3. HDMI 1 signal output
- 4. HDMI 2 signal output
- 5. DVI signal output
- 6. Camera Interface Port
- 7. LED Light Output Port

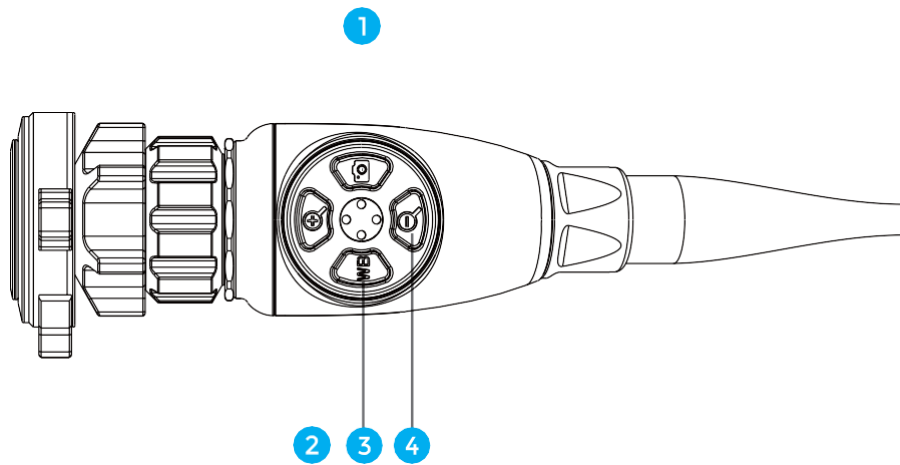


**Figure 2.5: Left side panel**

- 1. Power Switch
- 2. Power Input (AC)

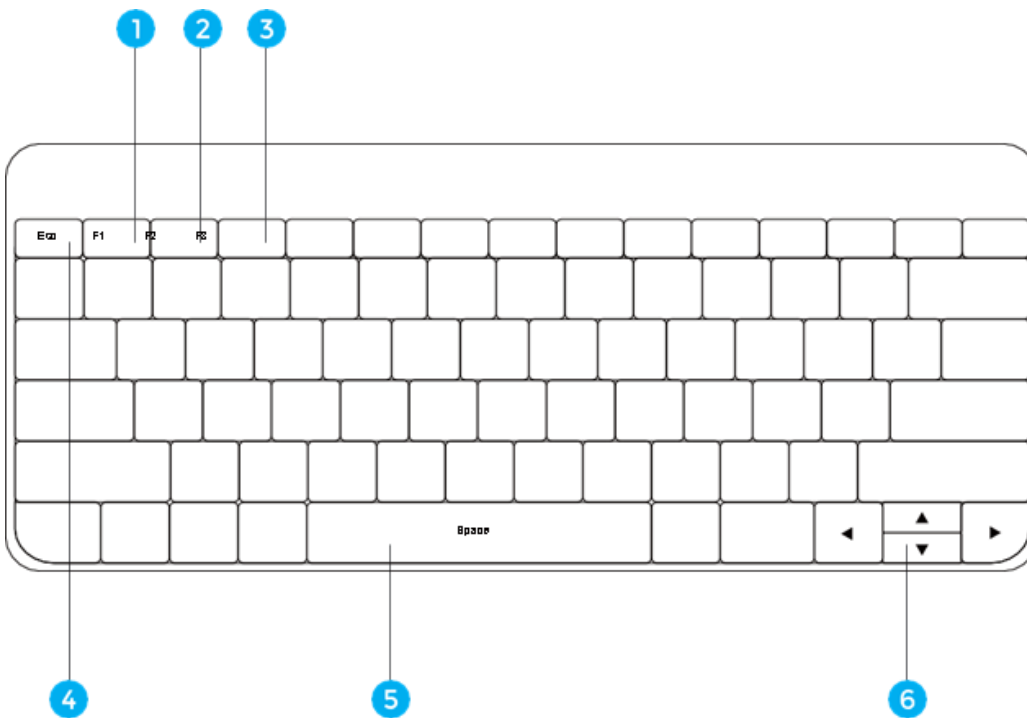


**Figure 2.6: Endoscopy Camera**



- 1. Image Capture
- 2. Zoom In
- 3. White Balance
- 4. Zoom Out

**Figure 2.7: Optional keyboard use**



- |                      |                         |
|----------------------|-------------------------|
| 1. Recording         | 4. Back                 |
| 2. Photo Capture     | 5. Enter                |
| 3. File Name Editing | 6. Navigation (Up/Down) |

## Chapter 3. Technical Features

### 1.1 Safety Features

- Applied Part Classification: Type BF applied part (camera head)
- Power Supply: 110–240 V~, 50/60 Hz
- Input Power: ≤ 300 VA
- Protection Against Explosion: This device is not suitable for use in the presence of flammable anesthetic mixtures with air, oxygen, or nitrous oxide (Non-AP/APG)
- Protection Against Fluid Ingress: Not protected against fluid ingress (IP rating not specified)
- Mode of Operation: Continuous operation

### 1.2 Key Technical Features

- Image Sensor Resolution: 3840 × 2160 (approx. 8.4 megapixels)
- Image Sensor Size: 1/1.8 inch
- Optical Interface Compatibility: F16, F18, F20, F24, F28, F32
- Brightness Adjustment: Continuously adjustable via control knob
- Minimum Illumination: 0.5 lux
- Resolution: 1800 TVL
- Signal-to-Noise Ratio: ≥ 50 dB
- White Balance: Automatic / Manual
- Video Outputs:– 3G-SDI– DVI– 2 × HDMI

## Chapter 4. Installation Instructions


### 4.1 Installation

After unpacking the device, verify that all components are present and match the packing list.

- Place the device on a stable, level surface away from flammable or corrosive materials.
- Align the red dot on the camera head connector with the red dot on the corresponding input port.
- Connect the light source cable securely to the designated output port.
- Connect the display monitor using the appropriate video output (HDMI, DVI, or SDI).
- Insert the power cable into the AC power input.
- Connect the device to a grounded electrical outlet (110–240 V~).
- Turn the power switch to the “I” (ON) position.
- Verify that the system powers on and that the display shows the camera image and system interface.

## Chapter 5. Instruction Manual

### 5.1 Instruction

1. If the image is not clear, adjust the focus on the camera head or on the endoscope. If the endoscope has been previously used, ensure it has been properly cleaned prior to use.
2. Ensure the power plug is securely connected before turning on the device.
3. Keep the device away from sources of electromagnetic interference.
4.  FIRE HAZARD: If the device is powered on, keep the distal end of the endoscope or light source away from paper, drapes, or other flammable materials.
5. After use, turn off the system by switching the power from position "I" ( ON)
6. to "O" (OFF).
7. Disconnect the power cable and remove all connected accessories, including the endoscope and cables.
8. When disconnecting cables, grasp the connector close to the device and pull straight out. Do not pull on the cable itself.
9. Store the device in a clean, dry, and flat environment.

### 5.2 White Balance

The system performs automatic white balance under normal operation. To perform manual white balance:

1. Aim the camera at a white surface.
2. Press the White Balance (WB) button on the camera head.

### 5.3 Picture Taking and Video Recording

#### •Image Capture:

Press and release the Image Capture button on the camera head. The indicator "PIC" will appear on the display.

#### •Video Recording:

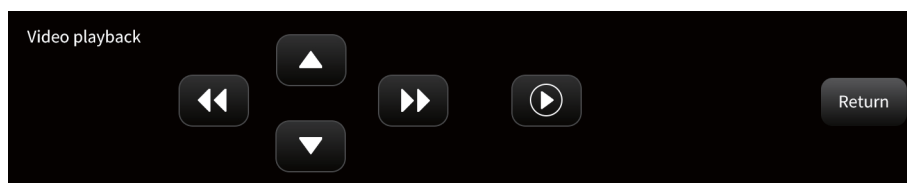
Press the Record button on the display or control panel. Recording files are automatically saved with date and time stamps.

If required, file names may be modified using a connected external keyboard (see Section 2.7).

### 5.4 Video Playback WARNING

To view recorded videos:

1. Press and hold the Playback/Record button for approximately 3 seconds
2. Use the Up/Down navigation controls to select a file based on date and time
3. Press the Playback/Record button to start playback.
4. Press the same button again to exit playback mode.



Ensure a USB drive formatted to exFAT is inserted into the USB port before powering on the device. All image and video data are recorded directly to the USB drive. No data are stored on the device. To view recorded videos:

1. Press the Playback button.
2. Use the Up/Down controls to navigate through recorded files.
3. Files are automatically named based on the date and time of recording.
4. Once a file is selected, press the Play button to begin playback.

During playback, on-screen controls allow you to:

- Fast forward
- Rewind
- Step forward / step backward
- Pause
- Play

To exit playback mode, press the Playback button again.

## 5.5 Flexible vs Rigid Scope Mode

By default, the device operates in Rigid Scope (E.N.T.) Mode, optimized for otolaryngology (ENT) procedures using rigid endoscopes (e.g., sinusscopes, laryngoscopes).

When using flexible endoscopes (e.g., nasopharyngoscopes or flexible laryngoscopes), image quality may be improved by switching to Flexible Scope (FLEXISCOPE) Mode.

**CAUTION:** Do not change imaging modes during active procedures unless clinically necessary.

### To Change Imaging Mode:

1. Press and hold the UP button on the device monitor for approximately 2–3 seconds until an audible tone is heard.
2. The current imaging mode will be displayed on the screen.
3. Press and hold the UP button again to toggle between:
  - i. E.N.T. (Rigid Mode)
  - ii. FLEXISCOPE (Flexible Mode)

## Chapter 6. OSD (On-Screen Display) Settings

The OSD (On-Screen Display) menu allows users to adjust image parameters, optimize visualization, and configure system settings for specific procedures.

To access the OSD menu, press the Menu button on the control panel.

### 6.1 Menu Structure Scene (Preset Modes)

Select a preset mode based on the clinical application:

- Arthroscopy
- Fiber (Flexible Endoscopy)
- PTED
- Cystoscopy
- Ureteroscopy
- User Mode
- Laparoscopy
- E.N.T.
- Gynecology

### 6.2 Image Adjustment Settings

The following parameters can be adjusted manually:

- **AWB** (Auto White Balance) – Adjusts color balance automatically
- **Color** – Controls overall color intensity
- **Brightness** – Adjusts image luminance
- **Saturation** – Controls color vividness
- **Contrast** – Adjusts difference between light and dark areas

- **Sharpness** – Enhances edge definition
  - **Gain** – Amplifies signal in low-light conditions
  - **3DNR** (3D Noise Reduction) – Reduces image noise
  - **Gamma** – Adjusts image tone curve
  - **DRC** (Dynamic Range Control) – Enhances detail in bright and dark areas
  - **Meter Mode** – Selects exposure measurement method (e.g., Mid Metering)
- ### 6.3 Playback and System Settings
- **Playback** – Access recorded images and videos
  - **System** – Access system configuration settings
  - **Exit** – Exit the OSD menu

## 6.4 System Settings

The following parameters are available:

- Language – Select system display language(English, Chinese, Russian, Spanish)
- Video Output Resolution – Set output resolution(e.g., 3840 × 2160P)
- Video Mode (Frequency) – Set output frequency(e.g., 60 Hz or 50 Hz)
- Time – Set system date and time
- Clock – Enable or disable on-screen clock display
- Version – Displays firmware/software version information
- Reset – Restore system settings to default values
- Advanced Settings – Access additional system configuration
- Key Settings – Configure button or control behavior
- Recording Settings – Configure recording parameters
- Network (Net) – Configure network settings (if applicable)
- Storage Info – View connected storage device status
- Return – Exit the System menu

### 6.6.2 Frequency (FREQ)

The frequency setting helps prevent image flickering caused by electrical interference.

Available Options:

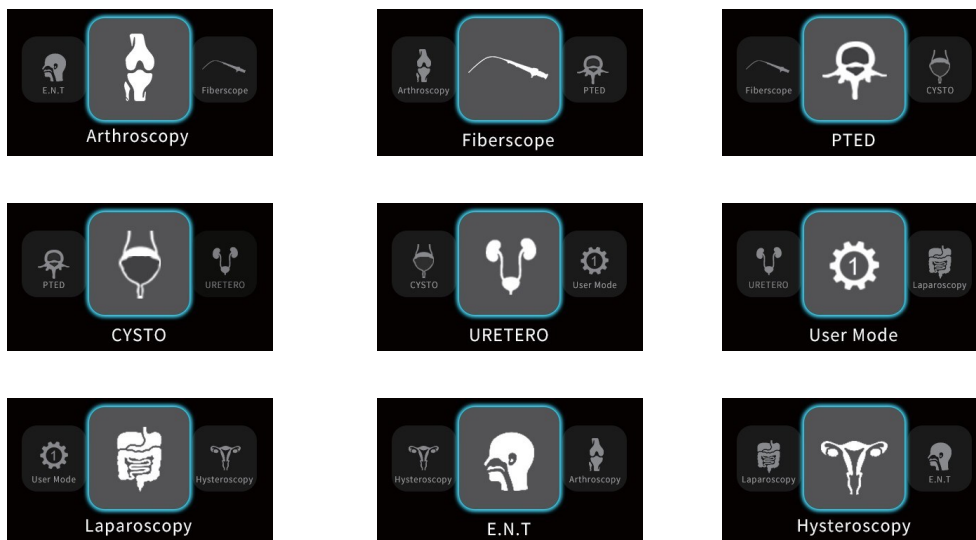
- 60 Hz
- 50 Hz Recommendation:
- 

Set the frequency to match the local power supply:

60 Hz – United States and regions with 60 Hz power 50 Hz – Europe and regions with 50 Hz power

⚠ Important Improper frequency settings may result in visible flickering during image capture or display.

### 6.2 Scene Mode



#### Recommendation:

Select the imaging mode based on the procedure type. For example, use Laparoscopy mode for abdominal procedures. Use Custom/User modes when specific image settings are required.

### Chapter 7 – Troubleshooting

To identify and resolve common issues, refer to the table below. If the issue persists, contact authorized service personnel.

#### Troubleshooting Table

Issue	Possible Cause	Solution
<b>No image displayed</b>	Power cable not properly connected	Ensure the power cable is securely connected to the power outlet
	Camera cable not properly connected to the light source	Reconnect the camera cable securely
<b>Device overheating</b>	Fan failure or insufficient ventilation	Ensure ventilation openings are not blocked. Maintain at least 5 cm clearance around the device. Verify that cooling fans are operating properly
<b>Image is blurry</b>	Camera surface contaminated (residue or biological material)	Remove the endoscope and check image clarity. Clean and disinfect the camera surface as required
	Incorrect focal length or lens position	Adjust the focal length to achieve a clear image
	Incorrect imaging mode selected	Select the appropriate mode for the procedure (see Section 5.5)
<b>Image color is incorrect</b>	White balance not set correctly	Set white balance to automatic mode or perform manual white balance
	Incorrect white balance	Perform white balance using a clean white

Issue	Possible Cause	Solution
	procedure	surface. Ensure no colored objects are visible. Press the <b>WB</b> button on the camera head and confirm completion
	Incorrect color settings	Reset image settings to default or adjust color parameters as needed
	Internal component degradation	Contact authorized service personnel
<b>Power LED is not illuminated</b>	Power plug or fuse malfunction	Check the power connection and inspect the fuse
<b>Excessive light reflection (glare)</b>	Light source intensity too high	Reduce the light intensity using the illumination control

## Chapter 8 – Cleaning and Disinfection

### 8.1 Precautions

- Disconnect the device from the power supply before cleaning or disinfection.
- Perform cleaning in a well-lit environment to ensure all contaminants are visible.
- Do not use benzene, thinners, or other volatile solvents, as they may damage device surfaces.
- Do not spray liquids directly onto the device. Apply cleaning agents to a cloth or wipe.
- Avoid excess moisture. Prevent liquid from entering seams, connectors, or openings.

### 8.2 Cleaning and Disinfection Procedures

#### 8.2.1 External Device Housing

1. Remove dust using a soft, dry cloth.
2. For visible contamination, use a cloth lightly dampened with a neutral detergent.
3. Wipe dry with a clean cloth.
4. Disinfect using a soft cloth or surgical gauze moistened with:
  - **Isopropyl alcohol (50–70% v/v)** or
  - **70–75% ethanol (medical alcohol)**

#### 8.2.2 Camera Head

1. Remove visible debris using a soft brush or lint-free cloth.
2. Clean using a soft cloth or surgical gauze moistened with:
  - **Isopropyl alcohol (50–70% v/v)** or
  - **70–75% ethanol**
3. Clean the lens using **lint-free lens paper**.
4. Ensure no residue remains on the optical surface.

#### 8.2.3 Cables

1. Wipe cables using a soft cloth or surgical gauze.
2. If necessary, use a cloth lightly dampened with a neutral detergent.
3. Wipe dry thoroughly to remove all moisture.

### 8.2.4 Display (Monitor)

1. Remove dust using a dust blower or soft cloth.
2. Clean the screen using a soft, lint-free cloth lightly dampened with an LCD-approved cleaner.
3. Wipe gently from the center outward.
4. Dry the surface using a clean, dry cloth.

---

#### **⚠ Important**

- Do not use non-approved cleaning agents, as some chemicals may damage display coatings.
- Do not allow liquids to contact internal components.

## **Chapter 9 – Maintenance**

To ensure safe and reliable operation, inspect the device before each use.

If any issues are identified that cannot be resolved, contact authorized service personnel.

---

### 9.1 Daily Inspection and Maintenance

#### **Cable:**

- Inspect cables for damage, cracks, or exposed wiring.
  - Do not use damaged cables.
  - Store cables loosely coiled (minimum diameter approximately 10 cm) to prevent kinking.
- 

#### **Main Unit (Host):**

- Ensure rear panel connectors are clean and free of dust or debris.
  - Verify that all external screws are secure.
- 

#### **Power-On Check:**

- Power on the device and confirm normal operation.
  - Verify that all front panel buttons function correctly.
- 

### 9.2 Periodic Inspection and Maintenance

#### **Monthly Inspection:**

- Check for loose screws or damaged components.
  - Ensure connectors and vents are free of dust or foreign material.
- 

#### **Annual Inspection:**

- Perform a comprehensive functional check of the device.
- Verify image quality, system performance, and control functionality.

## **Chapter 10 – After-Sales Service**

Devices sold by the company are covered by a warranty period as specified on the invoice. During the warranty period, the company will provide repair services for failures resulting from manufacturing defects.

After the warranty period, **lifetime paid repair services** are available.

For device components purchased separately and installed by the customer or a third party, on-site service may not be available during the warranty period. For quality-related issues, **mail-in repair service** will be provided.

For products purchased through authorized distributors, please contact the distributor first.

## 10.1 Warranty Exclusions

The warranty does not cover failures resulting from:

- Unauthorized disassembly or modification of the device
- Accidental damage (e.g., impact, dropping)
- Improper use or operation not in accordance with this manual
- Failure to perform required maintenance
- Use outside specified environmental conditions
- Repairs performed without authorization
- Use of non-approved accessories or components
- Improper cleaning or disinfection procedures
- Operation by untrained personnel
- Force majeure events (e.g., natural disasters)

---

## 10.2 Warranty Limitations

- Consumables are not covered under warranty
  - Complimentary items (giveaways) are not covered
  - Devices beyond their specified service life are not covered
  - Warranty service requires proof of purchase or warranty documentation
- 

## Chapter 11 – Limited Liability

To the maximum extent permitted by applicable law, the company shall not be liable for:

- Third-party claims, except in cases of personal injury, death, or damage to tangible property where required by law
- Loss, corruption, or inaccessibility of data
- Indirect, incidental, special, or consequential damages, including loss of profits or business interruption, even if advised of the possibility of such damages
- Malfunctions resulting from the use of non-approved software or hardware
- Failure to operate the device in accordance with this manual
- Use of the device outside specified operating conditions
- Damage caused by force majeure events

## Appendix A – Electromagnetic Environment

### ⚠ WARNING

The device may be affected by electromagnetic interference (EMI). During installation and use, ensure the device is kept away from sources of strong electromagnetic emissions, including:

- Radio transmitters and communication towers
- High-frequency electrical equipment
- Magnetic resonance imaging (MRI) systems

This device may also generate electromagnetic interference that could affect nearby equipment. The device complies with applicable electromagnetic compatibility (EMC) standards. Guidance regarding its electromagnetic environment is provided in **Tables 1–4**.

### ⚠ Warnings – Electromagnetic Compatibility (EMC)

#### ⚠ WARNING

Portable and mobile RF communication equipment may affect the performance of this device.

#### ⚠ WARNING

Do not touch connector pins marked with the electrostatic discharge (ESD) symbol.

#### ⚠ WARNING

This device should not be used adjacent to or stacked with other equipment.

If such use is necessary, the device must be observed to verify normal operation in the intended configuration.

**⚠ WARNING**

Use of accessories other than those specified in this manual may result in degraded electromagnetic performance.  
The user is responsible for ensuring compliance if non-approved accessories are used.

**Essential Performance – EMC Information****Table 1 – Guidance and Manufacturer’s Declaration: Electromagnetic Emissions**

The device is intended for use in the electromagnetic environment specified below.  
The user should ensure that it is used in such an environment.

**Electromagnetic Emissions**

<b>Emission Test</b>	<b>Compliance</b>	<b>Electromagnetic Environment – Guidance</b>
<b>RF Emissions (GB 4824)</b>	Group 1	The device 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
<b>RF Emissions (GB 4824)</b>	Class A	The device is suitable for use in all establishments other than domestic environments and those directly connected to the public low-voltage power supply network
<b>Harmonic Emissions (GB 17625.1)</b>	Not applicable	—
<b>Voltage Fluctuations / Flicker (GB 17625.2)</b>	Not applicable	—

**Table 2 – Recommended Separation Distances****Recommended separation distance between portable and mobile RF communication equipment and the Endoscopy Camera System**

The device is intended for use in an electromagnetic environment in which RF disturbances are controlled.

The user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device, as recommended below, based on the maximum output power of the transmitter.

**Recommended Separation Distances**

<b>Rated Maximum Output Power (W)</b>	<b>150 kHz – 80 MHz <math>d = 1.2\sqrt{P}</math></b>	<b>80 MHz – 800 MHz <math>d = 1.2\sqrt{P}</math></b>	<b>800 MHz – 2.5 GHz <math>d = 2.3\sqrt{P}</math></b>
0.01	0.12 m	0.12 m	0.23 m
0.1	0.38 m	0.38 m	0.73 m
1	1.2 m	1.2 m	2.3 m
10	3.8 m	3.8 m	7.3 m
100	12 m	12 m	23 m

**Additional Guidance**

For transmitters with maximum output power not listed above, the recommended separation distance ( $d$ , in meters) can be calculated using the formula applicable to the transmitter frequency, where  $P$  is the maximum output power of the transmitter in watts (W).

**Notes**

**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.

**Table 3 – Electromagnetic Immunity****Guidance and Manufacturer’s Declaration – Electromagnetic Immunity**

The device is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.

**Table 3 – Electromagnetic Immunity****Guidance and Manufacturer’s Declaration – Electromagnetic Immunity**

The device is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.

**Electromagnetic Immunity Table**

<b>Immunity Test</b>	<b>IEC 60601 Test Level</b>	<b>Compliance Level</b>	<b>Electromagnetic Environment – Guidance</b>
<b>Electrostatic Discharge (ESD)</b> GB/T 17626.2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be ≥30%
<b>Electrical Fast Transient / Burst</b> GB/T 17626.4	±2 kV (power supply lines) ±1 kV (input/output lines)	±2 kV (power supply lines) Not applicable (I/O lines)	Mains power quality should be that of a typical commercial or hospital environment
<b>Surge</b> GB/T 17626.5	±1 kV line-to-line ±2 kV line-to-ground <5% UT (>95% dip) for 0.5 cycle 40% UT (60% dip) for 5 cycles	±1 kV line-to-line ±2 kV line-to-ground Same as IEC test level	Mains power quality should be that of a typical commercial or hospital environment. If continuous operation is required during power interruptions, use an uninterruptible power supply (UPS) or battery backup
<b>Voltage Dips, Short Interruptions, and Voltage Variations</b> GB/T 17626.11	70% UT (30% dip) for 25 cycles <5% UT (>95% dip) for 5 s	Same as IEC test level	Mains power quality should be that of a typical commercial or hospital environment. If continuous operation is required during power interruptions, use an uninterruptible power supply (UPS) or battery backup
<b>Power Frequency Magnetic Field (50 Hz)</b> GB/T 17626.8	3 A/m	3 A/m	Magnetic field levels should be consistent with those of a typical commercial or hospital environment

**Note**

**UT** refers to the AC mains voltage prior to application of the test level.

**Table 4 – Electromagnetic Immunity (RF)****Guidance and Manufacturer’s Declaration – Electromagnetic Immunity**

The device is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.

## Electromagnetic Immunity Table

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
<b>Conducted RF</b> GB/T 17626.6	3 Vrms 150 kHz – 3 Vrms 80 MHz		Portable and mobile RF communications equipment should not be used closer to any part of the device, including cables, than the recommended separation distance calculated from the applicable frequency formula
<b>Radiated RF</b> GB/T 17626.3	3 V/m 80 MHz – 3 V/m 2.5 GHz		Maintain recommended separation distances based on transmitter power and frequency

## Recommended Separation Distance

The separation distance ( $d$ , in meters) is calculated as follows:

- **150 kHz – 80 MHz:**  
 $d = 1.2 \sqrt{P}$
- **80 MHz – 800 MHz:**  
 $d = 1.2 \sqrt{P}$
- **800 MHz – 2.5 GHz:**  
 $d = 2.3 \sqrt{P}$

Where:

**P** = maximum output power of the transmitter (W)

**d** = recommended separation distance (m)

## Additional Guidance

The field strength from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol: 

## Notes

**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 the human body.

## a) Fixed RF Transmitters

Fixed transmitters, such as base stations for wireless (cellular/cordless) telephones, land mobile radios, amateur radios, AM and FM radio broadcasts, and television broadcasts, 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 of use exceeds the applicable RF compliance level, 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) Field Strength Limitation

Over the frequency range **150 kHz to 80 MHz**, the field strength should be less than **3 V/m**