Operator’s Manual

HD3/HD3-S/HD3-T/HD3-N
EC3/EC3-S/EC3-T/EC3-N
Endoscope Camera System

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For this Operator's Manual, the issued date is 2021-4 (Version: 9.0).

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- the electrical installation of the relevant room complies with the applicable national and local requirements, and
- the device is used in accordance with the instructions for use.

NOTE

- **This device must be operated by skilled/trained clinical professionals.**

⚠ WARNING

- **It is important for the hospital or organization that employs this device to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or personal injury.**

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- **Malfunction or damage caused by improper operation or repair by unqualified or unauthorized service people.**
- **Malfunction of the device or part whose serial number is not legible enough.**
- **Others not caused by device or part itself.**

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Return Procedure

In the event that it becomes necessary to return this device or part of this device to Mindray, the following procedure should be followed:

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Freight policy: The customer is responsible for freight charges when this device is shipped to Mindray for service (this includes customs charges).

Return address: Please send the part(s) or device to the address offered by the Customer Service Department.

Contact Information

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Tel:	0049-40-2513175
Fax:	0049-40-255726

Notification of Adverse Events

As a health care provider, you may report the occurrence of certain events to NANJING MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD., and possibly to the competent authority of the Member state in which the user and / or patient is established.

These events, include device-related death and serious injury or illness. In addition, as part of our Quality Assurance Program, NANJING MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. requests to be notified of device failures or malfunctions. This information is required to ensure that NANJING MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. provides only the highest quality products.

Table of Contents

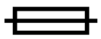
1 Safety Instructions

1.1 Definition of Symbols

In the Manual, "⚠ **Danger**", "⚠ **Warning**", "⚠ **Caution**", "**Note**", and "Description" are used to indicate safety-related and other important matters, with the specific meanings described as below. Please clearly understand and remember the meaning of these terms before reading the Manual.

Symbols and Terms	Definitions
⚠**Danger**	**Indicates that an urgent dangerous situation will occur and cause death or severe injury if not avoided.**
⚠**Warning**	**Indicates that a potential dangerous situation will occur and cause death or severe injury if not avoided.**
⚠**Caution**	**Indicates that a potential dangerous situation will occur and cause minor or moderate injury if not avoided.**
Note	Indicates a possible dangerous situation and will cause property loss if not avoided.
Instructions	Will remind you how to effectively use this system's important information.

1.2 Safety Symbols

Symbols	Detailed Explanation
MD	Medical Device
	TYPE BF APPLIED PART
	Date of manufacture
SN	Serial number
IPX7	Protected against the effects of temporary immersion in water per IEC 60529
	Equipotentiality
	Protective earth (ground)
	Fuse
CE	The product bears CE mark indicating its conformity with the provisions of the REGULATION (EU) 2017/745 on medical devices and fulfills the general safety and performance requirements of Annex I of this regulation. Note: The product complies with the Council Directive 2011/65/EU.
	Refer to instruction manual/ booklet
	Dispose of in accordance to your country’s requirements
	Caution
	Alternating current
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	USB connector
	Standby

1.3 Safety Warning

To ensure the safety of patients and operators, please strictly obey the following safety precautions when using the system.

⚠**Danger:**	**Never use the system where flammable gases (such as anesthetic gases, hydrogen gas, etc.) or flammable liquids (like ethyl alcohol, etc.) are present, otherwise an explosion may occur.** **During inspection, do not unplug the power supply or press the power switch button.**

⚠**Warning:**

1. **The power plug of the system must be connected to an outlet which conforms to power requirements and must meet the requirements on rated power on the identification plate of the system. Using an adapter or a multi-functional socket may influence grounding and make the current leak beyond the required safe current levels.**
2. **To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.**
3. **For use of peripherals not powered by this system or not recognized by Mindray Medical International Ltd., the total leakage of current of the entire medical electrical system consisting of peripherals and the system must conform to electrical safety standards of medical equipment in the corresponding regions of use(for example, IEC 60601-1 defines that the current leakage of case must be less than 500 uA), and the operator is responsible for whether these standard requirements are met.**
4. **During system operation, ensure that the ground terminal of the system is earthed reliably and the grounding cable is connected when the system is off, otherwise an electric shock will be caused.**
5. **Please follow correct electrical connection methods of connecting the power supply to the ground, otherwise a shock hazard will occur. Do not connect the ground wire to any gas pipes or water pipes, for it will cause poor earthing or an explosion hazard will occur.**
6. **Before cleaning the machine, be sure to unplug the power cable, or electrical shock and equipment damage may occur.**

7. **Do not let any liquid splash on or let flow into the machine, or a shock hazard or device damage will occur. If a liquid is accidentally splashed on the machine, turn off the power at once and contact your service representative.**
8. **Do not let live parts (such as various signal input and output ports, etc.) of the system or any other devices contact with a patient. If the system or other equipment fails, patients would be at risk of an electric shock.**
9. **Do not use any cameras not provided by the Company, or damage to the machine and the camera will occur, and may even cause fire or other types of accidents to occur in extreme situations.**
10. **Do not bump and shake the host.**
11. **Do not open the case or panel, or it will cause short circuit or electric shock will occur.**
12. **Do not use the system simultaneously with electronic equipment like a high frequency electrotome, a high frequency therapy apparatus, or a defibrillator. Otherwise an electric shock to patients may occur.**
13. **Precautions during transportation: Please hold tightly both sides of the system to move it. If you hold other parts, system damage due to abnormal stresses will occur. Do not move the machine to the left or right, or the system will fall over.**
14. **All analog and digital devices connecting with the system must be certified in accordance with the designated IEC standards (such as IEC 60950 Information Technology Equipment Standards and IEC 60601-1 Medical Device Standards). All the configurations must be in accordance with the valid version of GB9706.15 system standards. The operator is responsible for connecting additional equipment to signal input/output ports and that the system complies with GB9706.15 standards. For any questions, please contact the supplier.**
15. **Do not turn off the system while the lens body remains in patient's body.**
16. **Do not modify this equipment without authorization of the manufacturer.**

17. **The operators of the equipment must not simultaneously contact patients and live parts of the system or other equipment (such as various signal input and output ports) connected to the system, otherwise a shock hazard to patients may occur.**
18. **When product failure occurs during use, stop operation immediately, unplug the power cord and take out the endoscope slowly from the patient's body and contact the manufacturer to assign the designated operators for repair.**
19. **Any endoscope used together with this system must have an insulated connection with the camera. Otherwise a shock hazard to patients may occur.**
20. **Please use an enclosure including endoscope, light source, light bundle etc. that designated by Mindray or contact Mindray's after-sales for consulting, to ensure they will work with the system.**

⚠**Caution:**

1. **Precautions related to clinical examination technology:**
   - **This system can only be operated by medical staff with qualified professional training.**
   - **This Manual does not introduce clinical examination technology. Choose the correct examination technology based on knowledge from professional training and clinical experience.**
2. **Precautions when moving the system:**
   - **During installation, ensure the system is horizontally installed and placed in a fixed position. Otherwise, the system may move and cause injury.**
   - **Do not sit on the system, for the system may move and fall down due to a loss of balance.**
   - **Before moving the system, ensure the devices around have been firmly affixed. Otherwise these devices may tilt and cause injury.**
3. **If the circuit protector is in working condition, it indicates that the system or peripheral equipment has failed; please contact your service representative and do not handle the problem by yourself.**
4. **This system and its accessories are not disinfected before delivery. After accessories are disinfected, clean all chemical reagents completely. The residues of chemical reagents will cause damage to both accessories and the human body.**
5. **Do not plug or unplug the system or its accessories (such as the printer and the video recorder, etc.) when the power is on, otherwise it will cause system damage or electric shock will occur.**
6. **During operation, inappropriate shut down may cause data corruption or system failure.**
7. **Do not use USB memory with unsafe data (such as flash drive, a mobile hard disk, etc.), or system damage will occur.**

8. **Do not use video equipment not specified in the Manual.**
9. **Only use the disinfectants that meet the requirements of local laws and regulations.**
10. **Always keep the lenses clean.**
11. **Do not pour or spray any liquid on the equipment or permit fluid to seep into connections or openings.**
12. **Read the Manual carefully before using the camera system to conduct clinical operations.**
13. **If the grid power is unstable and may affect normal operation of the system, use an uninterruptible power supply.**
14. **Do not exert too many vibrations on the machine (for example, when moving the equipment), or damage to components will occur.**
15. **Always keep the machine dry and do not move it from a cold place to a warmer place quickly, or condensation of water droplets which may result in a short circuit will occur.**

Notes:

1. Do not use the system in a strong electrical field or magnetic field (such as a transformer), or a negative impact on the system will occur.
2. Do not use the system near high frequency devices (such as mobile telephones), or a negative impact on system performance will occur and cause equipment failure.
3. When using or placing the system, ensure that the system is placed horizontally to avoid a loss of balance.
4. To avoid damage to the system, do not use the system under the following circumstances:
   - Under direct sunlight;
   - Where temperatures vary greatly;
   - In a dusty place;
   - Where this system may easy be vibrated;
   - Near a heat source;
   - In high humidity.
5. Do not restart immediately after the power is turned off, but after a period of time, or the system may not be started normally.
6. Avoid applying force on the control panel, or damage to the machine will occur.
7. Using the system in small spaces may cause a rise of the indoor temperature. Therefore, good indoor ventilation is necessary.
8. If it is necessary to abandon the system or any accessory, please contact your service representative. Do not dispose of the system without consulting the Company. The Company will not be responsible for any damage caused by not following the instructions.

9. When used over an extended period of time, the system’s safe electrical and mechanical performance will decline (such as the occurrence of current leakage, deformation, and wear of mechanical parts), the sensitivity and accuracy of images will deteriorate as well. Check the equipment regularly to ensure normal performance. It is suggested that a maintenance and repair agreement be signed to prevent the occurrence of any accidents.
10. Replaceable accessories inside the system can only be replaced by Mindray's maintenance engineers or technicians assigned by Mindray.
11. Do not turn off the system’s power during printing, saving, and calling data, or a failure of these processes and file information loss will occur.
12. Please verify that the system date and time settings are consistent with the currently inspected date and time.
13. Use a pluggable power cord as the point to separate the device from the power grid.

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2 System Overview

2.1 Intended Purpose

The system is used to enlarge the video of the operation area in a body during an endoscopic surgery.

Note:	According to the conclusion of clinical evaluation and residual risk evaluation, for the intended patients, there is no known side effects that can occur during or after the use of the medical device. And there is no need for the operator to make extra preparations. Thus, no residual risk associated with using the medical device should be disclosed due to the risk management report.

2.2 Intended Users

Generally, the user of the product shall be the medical workers who has taken training of endoscopic technique and thoroughly mastered the endoscopic operation technology.

2.3 Intended Patient Population

The system is not limited to a certain type (sex, age, weight etc.), it can be applicable for adults, pregnant women, pediatric patients and neonates, etc. The attending physician must decide whether the foreseen application is admissible based on the general condition of the patient.

2.4 Intended Medical Conditions

The system should be used in medical rooms which are equipped with electrical facilities in accordance with national regulations.

2.5 Contraindications

As of now, there is no contraindications directly related to this product, all the usage should follow the instruction of the responsible physician according to the situation of the patient.

2.6 Precautions before Use

When used over an extended period of time, the safe electrical and mechanical performance of the system will decline. To avoid unnecessary impact on diagnosis, treatment, and normal use of the product, regular inspection and maintenance must be performed. It is suggested to sign a maintenance and repair agreement to prevent the occurrence of accidents. Inspect the product before each use.

Do not modify the product in any way without authorization. The Company reserves the right to maintain, upgrade, and modify the product.

2.7 Packing List

No.	Name	Quantity	Remarks
1	Image processing host	1	Standard configuration
2	Camera Head	1	Standard configuration
3	Certificate	1	Standard configuration
4	Operator's Manual	1	Standard configuration
5	Power line	1	Standard configuration
6	Fuse	2	Standard configuration
7	DVI signal line	1	Standard configuration
8	HD-SDI signal line	1	Standard configuration
9	S-Video signal line	1	Standard configuration
10	Serial port line	1	Standard configuration

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3 System Functions and Parameters

3.1 Block Diagram of Overall Structure.

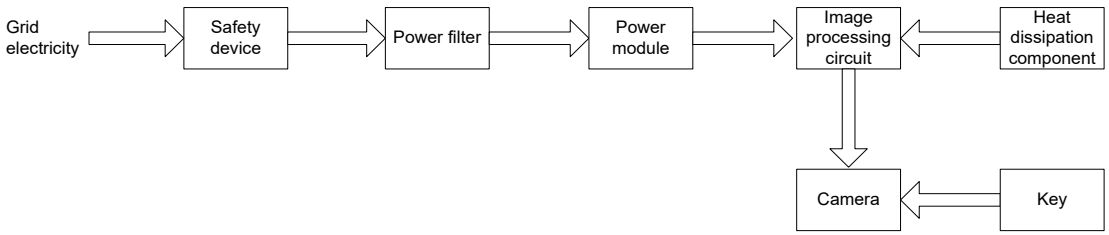

Figure 3-1 Block Diagram of Overall Structure

3.2 Front Panel

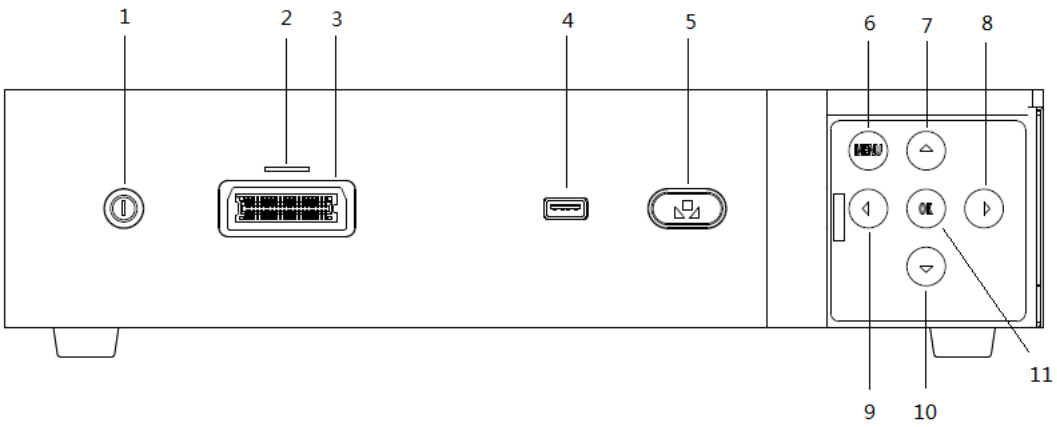

Figure 3-2 Image Processing Host-Front Panel

Descriptions of front panel:

1. Standby switch: Open and standby image processor
2. Indicator lamp of camera connection: Indicates weather or not camera is connected to image processor
3. Camera connection port: Connect to camera
4. USB connector: Connect to USB storage device,recommend 2.0 port of SSK USB device,and the capacity of SSK ≥ 8GB.
5. White balance button: Start white balance operation
6. Menu button: Enter system setting menu
7. "Up" navigation button: Move up in system setting menu
8. "Right" navigation button: Move right in system setting menu
9. "Left" navigation button: Move left in system setting menu
10. "Down" navigation button: Move down in system setting menu
11. "OK" button: Select "OK"

3.3 Rear Panel

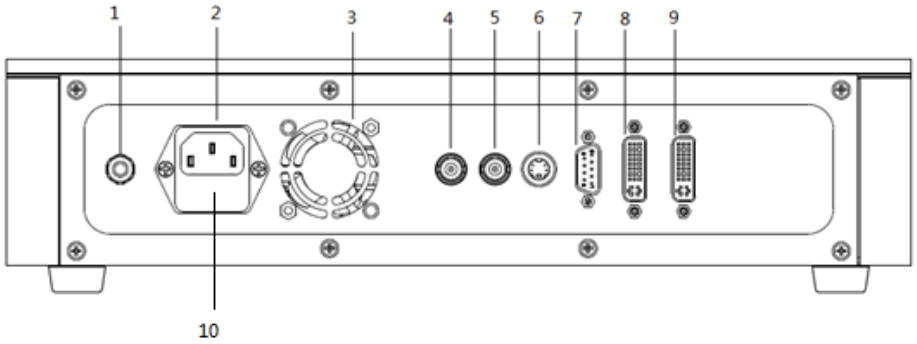

Figure 3-3 Image Processing Host - Real Panel

Description of rear panel:

1. Equipotential column
2. AC Input
3. Air outlet
4. HD-SDI out: Digital video output
5. HD-SDI out: Digital video output
6. S-Video out: Analog video output
7. Serial control interface: Connected to external devices.
8. DVI out: Digital video output
9. DVI out: Digital video output
10. Fuse cartridge

3.4 Camera Head

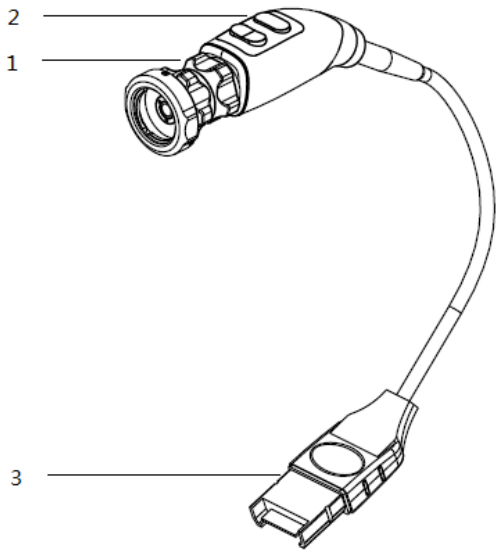

Figure 3-4 Camera Head

Camera description:

1. Endoscopic adapter: focusing and zooming knob
2. Camera handle: integrated photo/video button and white balance button.
3. Connector: Connect to picture processing host

3.5 Description of System Functions

As a kind of imaging device, the camera system is connected to the endoscope and a display for clinical use, and for endoscopic surgery, it is used to enlarge the video of the operation area in the body.

The main functions are as follows:

1. White balance

   The camera system possesses an automatic white-balance function. After the camera is focused on the white board, color balance can be established by pressing the "White Balance" button.

2. Optical zooming

   The camera is provided with optical focusing and optical zooming functions and is able to keep image clarity in the optical zooming process at all times.

3. Exposure control

   The camera system is provided with automatic and manual exposure control systems, which can be chosen by the operator as needed.

4. Digital signal transmission

   The camera system applies fully digital signal transmission.

5. Image capture and storage (optional)

   The camera system possesses image capture function and stores captured images through the USB connector.

6. Image storage (optional)

   The camera system possesses the function of storing images through the USB connector.

7. Image rollover

   The camera system possesses the function of flipping images in horizontal and vertical directions.

   - HD3/EC3 supports the function of flipping images in horizontal and vertical directions.
   - HD3-S/EC3-S supports the function of flipping images in horizontal directions.
   - HD3-T/EC3-T supports the function of flipping images in vertical directions.
   - HD3-N/EC3-N doesn't support the function of flipping images.

8. External control function

   The system is provided with the function for external equipment to control the camera system through the serial control interface.

9. System settings

   The camera system utilizes the following functions through system settings: surgical scene selection, image adjustment and exposure mode selection, image resolution adjustment, video signal settings and language selection.

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4 Installation and Use

4.1 Installation

4.1.1 Placement

Before placing the system, please carefully read and comprehend the safety precautions to ensure the safety of operators and equipment.

1. Turn off the system power supply and unplug the power.
2. Disconnect all non-onboard peripheral equipment, and place all cables properly to prevent tripping over them.
3. Fix the system to the preset position.

⚠**Caution:**	**1. Provide enough space behind and at the bottom of the machine, or machine failure due to temperature rise inside the machine may occur.** **2. Attention: Do not move the system on slopes with a gradient over 10° otherwise the system will fall over.**

4.1.2 Connect Camera Head to Picture Processing Host

Insert the terminal block of the camera into the host connector and gently pull the cable to check whether or not it is inserted tightly.

4.1.3 Connection with Endoscope

1. Rotate the handle front knob and place the eyepiece end of the endoscope into the card slot.
2. Loosen the front knob of the handle and gently pull the endoscope to check whether or not it has been clamped in place.

4.1.4 Connection with the Power Grid

1. Plug the power supply cable into the power socket at the bottom of machine's backside.
2. Plug the power supply cable into a power outlet. Ensure that the grounding terminal is connected with a ground protection wire inside the socket.

Notes: Connected cables must maintain proper looseness to prevent the plug from disconnecting with the socket after the system is moved slightly. If the plug of the host power supply wire is disconnected accidentally, test data will be lost.


It is an equipotential terminal and is used to balance the electric potential of the protective grounding between the system and other electrical equipment. Please refer to graphic "3.3" for equipotential terminal in the system.

⚠Warning:

1. **Connect the equipotential wire before inserting the power supply plug into socket. Similarly, to avoid electrical shock, pull the system plug away from the socket before unplugging the equipotential wire.**
2. **When other equipment is connected to the system, equipotential cables must be used to connect to each equipotential terminal, or an electrical shock will occur.**
3. **When connecting or disconnecting protective grounding wires, turn off the equipment power supply. Or an electrical shock will occur.**
4. **If the circuit breaker and fuse of for a socket are the same as that used in this system and are used to control the current of equipment such as a life support system, do not connect the system to such socket. Because once the system operates abnormally, overcurrent is generated, or there is transient current when starting up, the circuit breaker and the fuse of the power supply system will be in protective mode.**

4.1.5 Check before Startup

⚠Caution: **Make routine maintenance and inspection to ensure that the system operates safely and effectively. In case any abnormality is detected, turn off the system immediately and contact your service representative. Using the system with abnormal operation may cause injury to patients and damage to equipment.**

- Check before startup

  Before startup, please inspect or operate carefully according to the following requirements:

No.	Inspection items
1	Temperature, humidity, and atmospheric pressure must meet the conditions required for use. Refer to "Appendix A.3 Environmental Specifications" for detailed requirements.
2	No condensation phenomena can exist.

No.	Inspection items
3	The system and peripheral equipment must not be deformed, damaged, or contaminated. If contaminated, cleaning must be conducted as per the specifications in section "5.2 Cleaning ".
4	The wire and material interfaces must not be loosened or have any loose screws.
5	Cables must not be broken (power supply cable, etc) and its joint connections must be tight.
6	The connected endoscopic lens must not be broken or contaminated. If contaminated, cleaning and disinfection must be performed as required.
7	Do not place any objects on the host.
8	Inspect all ports of host and ensure that no abnormal phenomenon exists (such as damage or blockage caused by other objects). There must not be any obstacles present near the moving area and ventilation opening.
10	Clean place and environment.
11	Make sure that the connecting finger is free of contamination or not deformed so that it can be properly connected to the host.

- Check during and after startup

  After plugged in, press power switch to start the camera system.

  Check whether the equipment has started normally and conduct the following items after the startup check:

No.	Inspection items
1	No unusual noise, strange odors or overheat shall exist.
3	No significant unusual noises can exist.

⚠Warning:

1. **Using unusual heating lenses may burn patients.**
2. **If any abnormality occurs, it indicates that machine has a fault; turn off the machine immediately and contact your service representative.**
3. **Prepare a backup host before an operation in case that equipment failure may affect the operation.**

4.2 Use

1. Opening the camera system

   Verify that the power supply is connected correctly and that ventilation openings of the chassis are unobstructed.

   1) Verify the endoscope is well connected correctly with the camera.
   2) Press the power button to start up the host and fan.

2. Function operation

   1) White balance

      Focus the camera on a white object and press the "WB" button (the button is set on both the image processing host and the camera) to adjust the white balance. After completion, the image color display will become normal and the screen will prompt that the white balance has been completed. If the image color display is abnormal or the screen prompts that the white balance has failed, readjust the white balance.

      To reduce the WB times, you should make the camera aim at a purely white object, and make the white color full in screen. When you operate WB, do not move the camera and keep it fixed.

   2) Image capture and storage (optional)

      Before using the image capture and storage functions, insert the USB storage device into the front panel. Press the "Video" button on the camera to start image storage and press again to finish recording the image to storage.

   3) Image storage (optional function)

      Before using the image capture and storage functions, insert the USB storage device into the front panel. Press the "Video" button on the camera to start image storage and press again to finish the image recording storage.

   4) External control function

      Connect the image host with peripheral equipment (computer, laptop, or central control board) through a serial control interface to communicate with the image processing host through peripheral equipment and change the parameter settings of the camera host.

   5) System settings

      The following settings can be made via the navigation button of the camera host: surgical scene selection, image adjustment and exposure mode selection, image resolution adjustment, video signal settings, image adjustment, and language selection.

      Note: System settings can only be operated by Mindray's maintenance engineers or technicians assigned by Mindray.

Figure 4-1 Picture Processing Host Menu

3. Fuse replacement

   Replace the fuse using the following steps when it is necessary to do so:

   1) Unplug the power supply of the rear panel and pull out the built-in fuse drawer from power supply socket.
   2) Replace the broken fuse with a new one.
   3) Push back the fuse drawer to its original position.

4. Turning off the camera system

   Turn off the camera system as per the following steps:

   1) Press the power button to shut down the camera system.

⚠**Caution:**	**Unplug the power supply cord from the socket to disconnect the power supply if needed.**

Notes:	Before using this system, switch on the function of flipping image.

4.3 Considerations for using the U disk

- As there are many fake and shoddy U disks, please buy U disk in regular channels (such as the official website of the U disk.
- Use FAT32 format, 2.0 protocol, the default configuration size of the U disk for image storage.
- The U disk used should be within the validity of the U disk.
- Before using the U disk, to ensure that the U disk function is normal, no hidden viruses and damage, it is recommended to backup data, and then the U disk format, delete the U disk irrelevant data, so as not to affect the normal image storage function.

The U disk that has been tested is shown below:

Manufacturer	**Model**	**Capacity（GB）**
Kingston	DT101G2	16
SSK	SFD042	16
TOSHIBA	Enshu	16
PNY	虎克	16
SONY	USM16GR	16
Teclast	CF16GBNUU-P2	16
Apacer	AH333	16
EAGET	CM981	16

5 Maintenance

5.1 Maintenance Principles

⚠**Warning**:	**1. Used equipment may be contaminated by blood or body fluids, please follow the disinfection control and safety rules during operation.** **2. Moving parts and detachable parts pose the risk of pinching and crushing fingers, so be careful when moving or replacing system components.**

Do not use faulty equipment and only let the service representatives authorized by the Company finish necessary maintenance work as much as possible, or only let qualified professionals complete the replacement and maintenance of components listed in the Manual.
Test the equipment after maintenance to ensure that it is functioning normally and conforms to specifications.

Note:	Ensure that the power grid has been plugged in before cleaning.

5.2 Cleaning

1. The camera system surface can be cleaned with cleansers generally used to clean electrical equipment (such as clean water, detergent, and soapy water) additionally, do so in strict accordance with the manufacturer's instructions.
2. Use a piece of soft gauze dipped with cleanser and squeezed dry to gently wipe the external surfaces of the camera system.
3. Do not directly contact the camera system with excessive moisture or droplets of water.
4. Do not use cleansers which are banned for use on plastics, such as ammonium hydroxide, acetone, etc.
5. Prevent the cleansers or liquids from entering into the camera system.
6. Cleaning should be conducted weekly.

5.3 Disinfection

1. The camera system surface can be disinfected with disinfectants which can be used for electrical equipment disinfection, such as ethyl alcohol (70%), isopropyl alcohol (70%), sodium hypochlorite (10%) or hydrogen peroxide (3%) in strict accordance with the manufacturer's instructions.
2. Use a piece of soft gauze dipped with disinfectant and squeezed dry to gently wipe the external surface of the camera system.
3. Do not directly contact the camera system with excessive moisture or droplets of water.
4. Prevent the disinfectants or liquids from entering into the camera system.

5.4 Inspection and Maintenance

1. Carry out preventive inspection for operability of the product and accessories monthly. Refer to "4 Installation and Use" for operation steps.
2. The comprehensive preventive inspection for electrical safety must be conducted by professionals annually and if service is needed, please contact Mindray's after-sales.
3. It is recommended that comprehensive maintenance be conducted by professionals annually and if service is needed, please contact Mindray's after-sales.

5.5 Repair

1. When the device needs to be repaired, pad the equipment with the original packing insulation and place it into the original packing container and send it to the manufacturer or authorized repair station together with the faulty or damaged pieces of equipment, meanwhile inform the repairman of the name and telephone number of all workers familiar with the equipment.
2. Minor problems during equipment use can be fixed by operators or assistants by referring to the troubleshooting guide (please refer to trouble analysis and troubleshooting) All other repair work can only be conducted by operators authorized by the manufacturer. All service parts must be original parts provided by manufacturer. The Company will not be responsible for any device damage or injury caused by repairs not conducted by the above-mentioned operators.

5.6 Fault Analysis and Troubleshooting

For common minor faults and solutions for the equipment, the operator can troubleshoot them or contact the maintenance staff designated by Mindray.

Common faults	Analysis and solutions
Startup failure	Check whether the power supply connection is inserted normally and is loose, there are power outages, or an unstable connection. Replug the power line in and press the power indicator lamp again.
No image is outputted	Check whether the camera is connected correctly to the image processing host, is loosely connected, and other unstable conditions. Check whether the image processing host is correctly connected to the display video. Turn on and off the camera system, and contact the maintenance staff if there is still no output image.
Abnormal sound during operation	Check whether the image processing host is placed horizontally, and whether any objects have been placed on the host. If something unusual suddenly occurs, please turn off the power supply and contact the maintenance staff.
Blurred screen	Verify that the DVI cable is properly connected. If the problem persists, contact the maintenance staff.
HEAD ERROR（#03）	Check the HEAD connect the HOST, re-connect the HOST. If it can't be solved, please contact service.
REC ERR（#05） File system.	Unconnected or unrecognized USB disk. Please use these USB disks recommended by MINDRAY
SS ERR（#05） File system.	Unconnected or unrecognized USB disk. Please use these USB disks recommended by MINDRAY
REC ERR（11） Other error.	Unrecognized USB disk. Please use these USB disks recommended by MINDRAY
SS ERR（11） Other error.	Unrecognized USB disk. Please use these USB disks recommended by MINDRAY
SS ERR（04） No media.	Unrecognized USB disk. Please use these USB disks recommended by MINDRAY
REC ERR（04） No media.	Unrecognized USB disk. Please use these USB disks recommended by MINDRAY

6 Precautions

⚠**Warning**:

1. **This product can only be used by doctors or other operators who have received professional training and have been authorized to operate this product. Any unauthorized persons or those without training cannot use the product. Operate the equipment in strict accordance with the Manual.**
2. **Before use, inspect the equipment, connecting lines, and accessories to ensure that they can run normally and safely.**
3. **Maintenance or upgrading of the equipment can only be conducted by maintenance workers trained and authorized by the Company.**
4. **Do not use the product where flammable and explosive gases are present.**
5. **If the product falls or collides with something and the operator is not sure whether its functions and safety have been effected, stop using it immediately and send back to the designated after-sales service center for inspection and maintenance.**

Notes:

1. The standardly equipped image processing host and camera of the camera system have been inspected, so normal imaging can be guaranteed. Do not use the camera of other manufacturers or models together with this image processing host; the Company will be not be responsible for any damage to the camera system therefrom.
2. All devices connected to the product must be classified as medical instruments and equipment and conform to corresponding Standards of Terminal Product (such as IEC 60950 or IEC 60065) and Standards of Medical System GB 9706.15.
3. The product conforms to the standards of YY 0505 - 2012 *Medical Electrical Equipment Part 1 - 2: General Requirements for Safety Collateral Standards: Electromagnetic Compatibility Requirements and Testing*.

When operating the product, pay attention to the following points to ensure the safety of both patients and doctors. The product is used to provide cold light illumination for an endoscope and may only be used by trained doctors in medical institutions. Do not use the product for other purposes (beyond the product application scope) or in other places.

1. Do not install and use the product in an environment that has a high temperature, is wet, in direct sunlight, contains dust, acid and alkali corrosion, etc. or product performance will be effected.
2. Do not install and use the product in an environment with flammable and explosive gases and chemicals.
3. Do not install, use, or transport the product in a tilted manner, and do not bang and shake the product.
4. Ensure that all supply networks and connecting interfaces are consistent with the technical parameters on the nameplate of the rear panel.

5. Do not use a sharp object to press the control button on the front panel or the button may be damaged.
6. Use the product as per the operating instructions and in an operating environment described in the Manual, or a decline and failure of the safe electrical performance will occur.
7. To avoid fire and electrical shock, do not turn on and expose the equipment to the rain and/or a damp environment.
8. Do not get or splash water on the interfaces and air vents of the equipment.
9. Do not modify or change the product without permission, and repair it only through a designated after-sales maintenance service.
10. Do not wind, squeeze, or strain the power line.
11. When using an isolation transformer, ensure that the safety grade of the transformer is not lower than that of the equipment.

A Product Specifications

A.1 Basic Parameters and Performance

No.	Item name		Technical parameters
1	Rated voltage		100 - 240V ~
2	Rated frequency		50/60 Hz
3	Input current		0.6 A - 0.3 A
4	Performance index	Image transfer pixels	1920*1080
5		Optical zoom ratio	2.14, ± 10 %
6		Physical pixels	1920*1080
7		Video pixels	1920*1080
8		Signal to noise ratio	Greater than 62 dB, - 20%
9		Horizontal resolution	1000 lines, - 20%
10	Fuse size		T1.6AH250V
11	Device interfaces		Camera connection port: 1 USB connector: 1, USB2.0 protocol Power socket: 1, connecting the AC Mains SDI out: 2 S-Video out: 1 Serial control interface: 1 DVI out: 2

A.2 Safety Specifications

No.	Product classification foundation	Product type
1	Protection against electric shock type	Class I equipment powered by external power supply
2	Protection against electrical shock level	BF application
3	Liquid inlet protection class	CameraIPX7 Image processing host a piece of ordinary equipment (enclosed equipment without liquid inlet protection)
4	Cleansing and disinfection methods	Use cleaning and disinfection equipment recommend by the manufacturer.
5	Take extra care while using with flammable anesthetic gases mixed with air, oxygen, or nitrous oxide	This equipment cannot be used with flammable anesthetic gases mixed with the air, oxygen, or nitrous oxide.
6	Working mode	Continuous operation
7	If the equipment is provided with applied parts that protect from defibrillation charge effects	No applied part for protection from defibrillation charge effects is provided.
8	Signal output/input section	The equipment is provided with a signal output/input section
9	Permanently installed equipment or non-permanently installed equipment	Non-permanently installed equipment
10	GB 4824-2013	Group 1 Class B

A.3 Environmental Specifications

Item	Group	Operation and use
Climate and Environment	Group II	Use in general environments
Mechanical environment	Group II	General vibration and impact are allowed.

A.4 Storage and Operation

Item	Temperature (°C)	Relative humidity (Non - Condensing)	Atmospheric pressure (hPa)
Working	10 - 40	30% - 85%	700 - 1060
Transportation/Storage	-20 - 55	10% - 95%	700 - 1060

B EMC

The device complies with the EMC standard IEC 60601-1-2: 2014.

WARNING:

1. **Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.**
2. **The non-ME EQUIPMENT (e.g. ITE) that is a part of an ME SYSTEM may be disrupted by the electromagnetic interference of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the non-ME EQUIPMENT or shielding the location.**
3. **Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.**
4. **Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.**
5. **This device is intended for use in professional healthcare environment. If it is used in special environment, such as magnetic resonance imaging environment, the equipment/system may be disrupted by the operation of nearby equipment.**

TABLE 1

GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC EMISSIONS		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.		
EMISSIONS TEST	**COMPLIANCE**	**ELECTROMAGNETIC ENVIROMENT—GUIDANCE**
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device 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
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Compliance	

NOTE:
1. The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
2. Other devices may interfere with this system even though they meet the requirements of **CISPR**.
3. The EMISSIONS characteristics of this device make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this device might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the device.
4. If the essential performance is lost or degraded, it may be necessary to take mitigation measures, such as re-orienting or relocating the ME EQUIPMENT or ME SYSTEM, shielding the location or stopping using the ME EQUIPMENT or ME SYSTEM and contact the service personnel.

If the device is operated within the electromagnetic environment listed in Table 2 and Table 3, the device will remain safe and will provide the following basic performances:

- White balance
- *imaging*

TABLE 2

GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure 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; ±15 kV air	±8 kV contact; ±15kV 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 power supply lines; ±1 kV for input/output lines	±2 kV for power supply lines; ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
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	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, Short interruptions and voltage variation on power supply input voltage IEC 61000-4-11	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle 70% U_T for 25/30 cycle at 0° 0 % U_T; 250/300 cycle	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle 70% U_T for 25/30 cycle at 0° 0 % U_T; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If you require continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 HZ) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the A.C. mains voltage prior to application of the test level.			

TABLE 3

<table>
<tr><th colspan="4">GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY</th></tr>
<tr><td colspan="4">The device is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.</td></tr>
<tr><th>IMMUNITY TEST</th><th>IEC 60601 TEST LEVEL</th><th>COMPLIANCE LEVEL</th><th>ELECTROMAGNETIC ENVIRONMENT-GUIDANCE</th></tr>
<tr><td>Conduced RF
IEC 61000-4-6</td><td>3 Vrms
0,15 MHz – 80 MHz
6 Vrms in ISM and amateur
radio bands between
0,15 MHz and 80 MHz</td><td>3 Vrms
0,15 MHz – 80 MHz
6 Vrms in ISM and amateur
radio bands between
0,15 MHz and 80 MHz</td><td rowspan="5">Portable and mobile RF communications equipment should be used no closer to any part of system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
d = 1.2 x $\sqrt{P}$
d = 0.35 x $\sqrt{P}$ 80 MHz to 800 MHz
d = 0.7 x $\sqrt{P}$ 800 MHz to 2.7GHz
Where, 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).
Field strengths[a] from fixed RF transmitters, as determined by an electromagnetic site survey, 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:  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>10 V/m
80MHz - 2.7GHz</td><td>10 V/m
80MHz - 2.7GHz</td></tr>
<tr><td rowspan="3">Proximity fields from RF wireless communications equipment
IEC 61000-4-3</td><td>27 V/m
380–390 MHz</td><td>27 V/m</td></tr>
<tr><td>28 V/m
430–470 MHz, 800–960 MHz, 1700–1990 MHz, 2400–2570 MHz</td><td>28 V/m</td></tr>
<tr><td>9 V/m
704–787 MHz, 5100–5800 MHz</td><td>9 V/m</td></tr>
<tr><td colspan="4">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.</td></tr>
<tr><td colspan="4">a Field strengths from fixed transmitters, such as base stations for radio (cellular /cordless) telephones and land mobile radios, amateur radio, 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 in the location in which system is used exceeds the applicable RF compliance level above, system 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 150kHz to 80MHz, field strengths should be less than 3V/m.</td></tr>
</table>

TABLE 4

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATION DEVICE AND THE ME EQUIPMENT OR ME SYSTEM			
The device is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and system as recommended below, according to the maximum output power of the communication equipment.			
Rated Maximum Output power of Transmitter (W)	**Separation Distance According to Frequency of Transmitter (m)**		
	150kHz -80MHz $d=1.2\sqrt{P}$	80MHz-800MHz $d=0.35\sqrt{P}$	800MHz-2.7GHz $d=0.7\sqrt{P}$
0.01	0.12	0.035	0.07
0.1	0.38	0.11	0.22
1	1.2	0.35	0.7
10	3.8	1.1	2.2
100	12	3.5	7
For transmitters at a maximum output power not listed above, the recommended separation distanced in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. If system image distortion occurs, it may be necessary to position system further from sources of conducted RF noise or to install external power source filter to minimize RF noise to an acceptable level. Note 1 At 80 MHz and 800 MHz, the separation distance for 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.			

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C Unit and Symbol

C.1 Unit List

Unit	Meaning
º	angle
A	ampere
ºC	centigrade
cm	centimeter
g	gram
h	hour
Hz	hertz
hPa	hectopascal
k	kilo-
kg	kilogram
kPa	kilopascal
L	litre
lp/mm	lines pair per millimeter
lx	Illuminance
m	meter
min	minute
ml	milliliter
mm	millimeter
mmHg	millimeter of mercury
s	second
V	volt
VA	Volt ampere
Ω	ohm
μA	microampere
μV	microvolt
W	watt

C.2 Symbol List

Symbol	Meaning
-	minus
%	percent
/	Per; divide; or
～	to
^	power
＋	plus
＝	equal to
＜	less than
＞	greater than
≤	less than or equal to
≥	greater than or equal to
±	plus or minus
×	multiply
©	copyright

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