U1/U1-T/U1-S/U1-N

Endoscope Camera System

Operator's Manual

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

WARNING

- **Only skilled/trained clinical professionals should operate this equipment.**
- **It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or personal injury.**

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Preface

Manual Purpose

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any questions, please contact Mindray.

This manual is an integral part of the product. It should always be kept close to the equipment so that it can be obtained conveniently when needed.

Intended Audience

This manual is geared for clinical professionals who are expected to have a working knowledge of medical procedures, practices, and terminology as required for monitoring of critically ill patients.

Illustrations

All illustrations in this manual serve as examples only. They may not necessarily reflect the setup or data displayed on your equipment.

Conventions

- *Italic text* is used in this manual to quote the referenced chapters or sections.
- **Bold text** is used to indicate the screen texts and names of hard keys.
- → is used to indicate operational procedures.

Contents

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1 Safety

1.1 Safety Information

WARNING

- **Indicate a potential hazard or unsafe practice that, if not avoided, could result in death or serious injury.**

CAUTION

- **Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.**

NOTE

- **Provides application tips or other useful information to ensure that you get the most from your product.**

1.1.1 Warnings

WARNING

- **Never use the equipment where flammable gases, such as anesthetic gases and hydrogen gas, or flammable liquids, like ethyl alcohol, are present, otherwise an explosion may occur.**
- **If the equipment is to be placed on a medical supply unit, make sure the load capacity of the supply unit is not lower than 40 kg.**
- **Make sure that no live parts, like various signal input/output ports, of the system or other equipment contact the patient. If such contact exists, the patient might get shocked if the system or other equipment goes wrong.**
- **Do not touch the patient and live parts simultaneously.**
- **To avoid risk of electric shock, make sure the connecting parts between the endoscope to be used with the system and the camera head are insulated.**
- **The equipment is intended to be connected to a separate power supply. Ensure that the rated output of the power supply matches the input of the equipment.**

The power supply and this equipment constitute an ME SYSTEM together, meeting the requirements of IEC 60601-1.

- **Do not disconnect the power cord or turn off the equipment during a surgery.**

1.1.2 Cautions

CAUTION

- **The equipment is not intended to be used within the Magnetic Resonance (MR) environment.**
- **The Endoscope Camera System and monitor are suitable for use within the patient environment. Devices connected to the equipment must meet the requirements of the applicable IEC standards (e.g. IEC 60950 safety standards for information technology equipment and IEC 60601-1 safety standards for medical electrical equipment). The system configuration must meet the requirements of the IEC 60601-1 medical electrical systems standard. Any personnel who connects devices to the equipment's signal input/output port is responsible for providing evidence that the safety certification of the devices has been performed in accordance with the IEC 60601-1. If you have any questions, please contact Mindray.**
- **The equipment can only be connected to mains power with protective earth. Do not use a power socket that is not grounded.**
- **Do not use multiple portable socket outlets, which might cause interference, electric shock or equipment damage.**
- **To avoid the interference of high frequency electrosurgical equipment (ESU), do not connect the equipment and ESU to the same power socket. Besides, keep the equipment away from ESU as much as possible.**
- **The equipment meets the requirements of type BF applications. Medical devices or accessories used with the equipment should at least meet the requirements for BF applications.**
- **The weight of objects stacked on the equipment should not exceed 20 kg.**
- **Use only endoscopes and light sources specified by Mindray. Using accessory or equipment that is not compatible with the equipment may cause injury to the patient, damage to the equipment or deterioration in performance. Contact us in case of any questions concerning equipment compatibility.**
- **Prior to putting the equipment into clinical operation and inspection, read this manual carefully and make sure all contents are fully understood, to ensure the correct operation of the equipment and safety of the patients and operators.**
- **This equipment must be operated by skilled/trained clinical professionals.**
- **The system is only supplementary in clinical examinations. The doctors shall carry out diagnosis and treatments based on the clinical manifestations of patients.**

- **This manual does not contain contents relating to clinical examination technologies. Examination approach should be selected based on medical knowledge and clinical experiences.**
- **Before the endoscopic surgery or examination, a backup camera system should be prepared for possible system failure that might interrupt the surgery or examination.**
- **Do not unplug the equipment or accessories without cutting the power supply. Otherwise, the system might be damaged.**
- **Do not bend, pull, tangle or squeeze the cables, or the cable or equipment might be damaged.**
- **Do not press the connectors with excessive strength, or the connectors might be damaged.**
- **Do not block the ventilation outlet, or the equipment may overheat, which might trigger system self-protection or cause equipment damage or fire.**
- **Do not spray any liquid to the equipment or let any liquid enter the inside, or there will be risks of electric shock or equipment damage. If liquids are spilled on the equipment, disconnect the power supply, dry the equipment and contact your service personnel.**
- **Dispose of the package material as per the applicable waste control regulations. Keep the packing material out of children's reach.**
- **At the end of its service life, the equipment, as well as its accessories, must be disposed of in compliance with the local or hospital's guidelines regulating the disposal of such products, to avoid contaminating or infecting the environment, other persons or equipment.**

1.1.3 Notes

NOTE

- **Keep this manual in the vicinity of the equipment so that it can be obtained conveniently when needed.**
- **Put the equipment in a location where you can easily view and operate the equipment.**
- **The equipment uses a mains plug as isolation means to the mains power. Locate the equipment in a place that is convenient to operate the mains plug.**
- **The software was developed in compliance with IEC 62304. The possibility of hazards arising from software errors is minimized.**
- **This manual describes all features and options. Your equipment may not have all of them.**

- **The software equipment copyright is solely owned by Mindray. No organization or individual shall resort to modifying, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.**

1.2 Equipment Symbols

Symbol	Description	Symbol	Description
	Refer to instruction manual/ booklet		Manufacturer
	Stand-by		Date of manufacture
	TYPE BF APPLIED PART		General warning sign
	Serial number		USB connector
	Alternating current		Fuse
	Equipotentiality		Computer network
	Endoscope	IPX7	Protected against the effects of temporary immersion in water
	Stacking limit by number		Keep away from rain
	This way up		Fragile; handle with care
	Humidity limitation		Atmospheric pressure limitation
	Temperature limit	MD	Medical Device

Symbol	Description	Symbol	Description
EC REP	Authorized representative in the European Community		Dispose of in accordance to your country's requirements
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.		

NOTE

- **Some symbols listed above may not appear on your equipment.**

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2 The Basics

2.1 Intended Use

The U1 series endoscope camera system is intended to be used with optical endoscopes for endoscopic diagnosis and observation.

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 Qualification Requirements for Operator

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

2.3 Intended Patient Type

U1 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 U1 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 Applied Part

The applied part of the equipment is endoscope.

2.7 Differences Among the Models

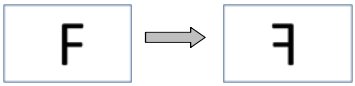
The differences among the models are shown below:

Model	Flip (Horizontal)	Flip (Vertical)
U1	√	√
U1-T	√	×
U1-S	×	√
U1-N	×	×

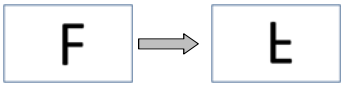
NOTE

- **"√" indicates "configured" while "×" indicates "not configured".**

The horizontal and vertical flips are shown below:



Flip (Horizontal)

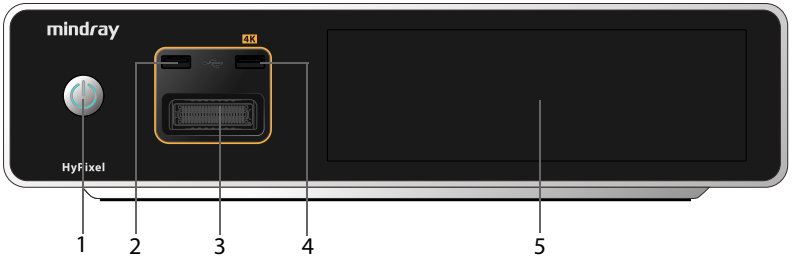


Flip (Vertical)

2.8 System Components

The Endoscope Camera System consists of a Camera control unit (hereinafter referred to as the CCU) and a camera head.

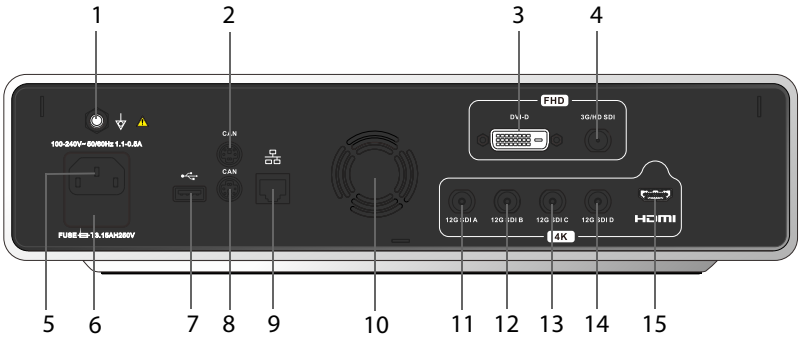
2.8.1 Front View of the CCU



(1)	Power switch: turns on or off the CCU

(2)	USB1 connector: connects a USB (Universal Serial Bus) drive for image and video storage
(3)	Camera connector: connects the camera head
(4)	USB2 connector: connects a USB drive for image and video storage
(5)	Touchscreen: used to display the status of the equipment and change settings

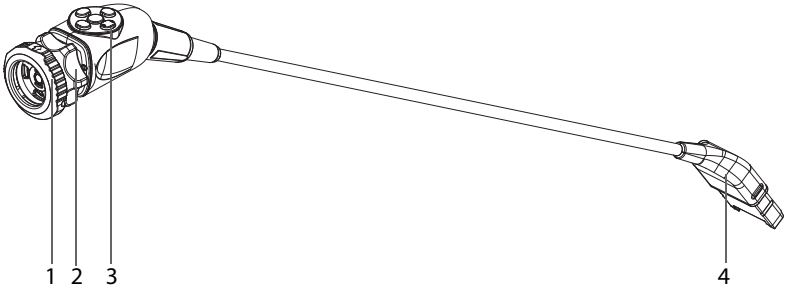
2.8.2 Rear View of the CCU



(1)	Equipotential grounding terminal: when using the equipment together with other devices, connect their equipotential grounding terminals together to eliminate the potential difference between them
(2)	CAN (Controller Area Network) connector: connects external devices, like light source
(3)	DVI (Digital Visual Interface) out: connects high definition video devices, such as monitor
(4)	3G-SDI (Serial Digital Interface) out: connects high definition video devices, such as monitor
(5)	AC (Alternating Current) power input: connects the AC Mains
(6)	Fuse holder: a compartment that keeps the fuse
(7)	USB connector: connects a USB drive for system upgrade
(8)	CAN connector: connects external devices, like light source
(9)	Network connector: reserved
(10)	Ventilation outlet: used for heat dissipation
(11)	12G-SDI out: connects 4K video devices, such as monitor
(12)	12G-SDI out: connects 4K video devices, such as monitor

(13)	12G-SDI out: connects 4K video devices, such as monitor
(14)	12G-SDI out: connects 4K video devices, such as monitor
(15)	HDMI (High Definition Multimedia Interface) out: connects 4K video devices, such monitor

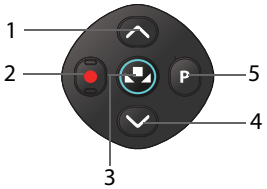
2.8.3 Camera Head



(1)	Endoscope coupler: connects and secures the endoscope
(2)	Focusing ring: rotate the ring to focus the camera head
(3)	Camera head buttons: there are five functional buttons
(4)	CCU connector: connects the CCU

2.9 Camera Head Buttons

There are five buttons on the camera head, and some can be set to perform different functions. More descriptions are shown below:



(1)	: used to zoom in on the image by default. You can change the function to adjusting image brightness. For details, refer to ***4.11.3.1 Setting Camera Buttons***.
(2)	: press to start or stop video recording.
(3)	: point the endoscope to white gauze or any white reflective object, and press this button to perform white balance.
(4)	: used to zoom out on the image by default. You can change the function to adjusting image brightness. For details, refer to ***4.11.3.1 Setting Camera Buttons***.
(5)	P: press to store the image currently displayed on the monitor

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3 Getting Started

3.1 Overview

This chapter describes the preparation and basic settings before putting the equipment into use.

3.2 Safety Information

WARNING

- **The Endoscope Camera System and monitor are suitable for use within the patient environment. Devices connected to the system should conform to the applicable IEC standards, (e.g. IEC 60950 safety standards for information technology equipment and IEC 60601-1 safety standards for medical electrical equipment) and the connection shall be performed as instructed in the effective versions of the IEC standards. Any personnel who connect devices to the equipment's signal input/output port are responsible for providing evidence that the safety certification of the devices has been performed in accordance to the IEC 60601-1. If you have any question, please contact us.**
- **If it is not evident from the equipment specifications whether a particular combination with other devices is hazardous, for example, due to summation of leakage currents, please consult the manufacturers or else an expert in the field, to ensure the necessary safety of patients and all devices concerned will not be impaired by the proposed combination.**

CAUTION

- **The equipment should be installed by authorized Mindray personnel.**
- **Install the equipment properly and make sure it is adequately protected from potential damage caused by falling, hitting, strong vibration or other external mechanical force.**
- **Make sure the equipment is horizontally installed at a fixed place to avoid possible movement and damage thus caused.**
- **Before moving the equipment, make sure all peripheral equipment connected has been secured, in case of equipment falling and damage.**
- **Magnetic and electrical fields are capable of interfering with the proper performance of the equipment. For this reason make sure that all external**

devices operated in the vicinity of the equipment comply with the relevant EMC requirements. Mobile phones, X-ray equipment or MRI devices are possible sources of interference as they may emit higher levels of electromagnetic radiation.

- **Do not use the system in strong electric or magnetic fields (where a transformer presents, for example), or near high-frequency devices (such as mobile phones). Performance degradation or system failure might occur.**
- **The equipment meets the requirements of type BF applications. Medical devices or accessories used with the equipment should at least meet the requirements for BF applications.**
- **To avoid safety risks and environment contamination, when disposing of the packaging material, be sure to observe the applicable waste control regulations and keep it out of children's reach.**
- **The equipment might be contaminated during storage and transport. Before use, verify whether the packages are intact. In case of any damage, do not apply it to patients.**
- **Make sure that the operating environment of the equipment meets the specific requirements. Otherwise unexpected consequences, e.g. damage to the equipment, could result.**
- **Keep the equipment dry. Do not move the equipment directly from a place of low temperature to a warm one, which may cause condensation or water drops and bring the risk of short circuit.**

NOTE

- **Risks might arise when the system is connected to other devices. Read the safety messages in the instructions for use accompanied with such devices carefully before operation.**
- **Put the equipment in a location where you can easily view and operate the equipment.**
- **Keep this manual in the vicinity of the equipment so that it can be obtained conveniently when needed.**
- **Save the packing case and packaging material for possible shipment or storage in the future.**

3.3 Unpacking and Checking

Before unpacking, examine the packing case carefully for signs of damage. If any damage is detected, contact the carrier immediately. Open the package and remove the equipment and accessories carefully. Check all materials against the packing list and check for any mechanical damage. Contact us in case of any problems.

3.4 Environmental Requirements

The operating environment of the equipment must meet the requirements specified in this manual.

The environment where the equipment is used should be reasonably free from noises, vibration, dust, corrosive, flammable and explosive substances. To maintain good ventilation, sufficient space, i.e. at least 2 inches (5 cm), shall be left for each side of the equipment.

When the equipment is moved from one place to another, condensation may occur as a result of temperature or humidity difference. In this case, wait until the condensation disappears before starting the system.

3.5 Installation

The system can be installed:

- on a flat surface;
- on a medical supply unit; or,
- on a trolley.

NOTE

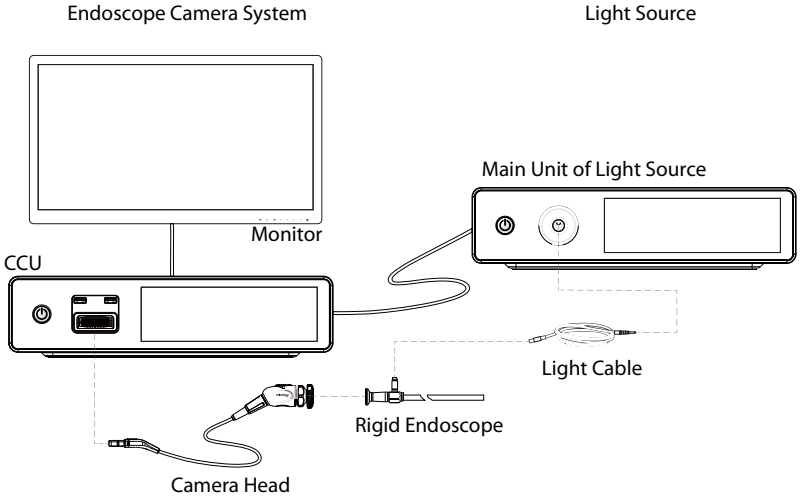
- **If the equipment is to be used with a trolley, there will be risks of falling or collision during movement. For more safety instructions, refer to the instructions for use accompanied with the trolley.**

3.6 Preparation

Read this operator's manual carefully before using this equipment. Familiarize yourself with its function and operation, and observe the warnings and cautions included in the manual.

3.6.1 System Connection

The equipment can be connected with endoscopes, light sources and monitors to provide images needed for surgical operations and clinical examinations. The connection is shown as below:



3.6.1.1 Connecting the CCU and Monitor

Connect a monitor to a correct video output connector on the back of the CCU with a video cable. Select a video cable that matches the video output connector. More than one monitors can be connected simultaneously to the CCU.

3.6.1.2 Connecting the CCU and Light Source

Connect a light source to the CAN connector on the back of the CCU.

3.6.1.3 Connecting the CCU and Camera Head

Plug the connector of the camera head to the camera head connector on the front panel of the CCU.

3.6.1.4 Connecting the Camera Head and Endoscope

To connect the camera head and endoscope:

1. Rotate the endoscope coupler as indicated by the arrow on it.
2. Align the eye piece of the endoscope with the endoscope coupler on the camera head.
3. Push the endoscope to the camera head and release the endoscope coupler.
4. Pull the endoscope slightly to check if the endoscope is secured.

To remove the endoscope:

1. Hold the camera head with one hand, and the endoscope with the other.
2. Rotate the endoscope coupler as indicated by the arrow on it. The endoscope falls off automatically.

CAUTION

- **Make sure the CCU is turned off before connecting or disconnecting the camera head. Otherwise, the image transducer might be damaged and the system may fail to display images.**
- **Do not bend, pull or squeeze the camera head or pull the camera head cable with excessive force in case the camera head breaks or the cable falls off.**

3.6.2 Connecting the AC Mains

The equipment is powered by AC power supply. Before connecting the equipment to the AC mains, check that the voltage and frequency ratings of the power line are the same as those indicated beside the AC power input.

To use the AC power source, follow this procedure:

1. Connect the female end of the power cord to the AC input on the back of the CCU.
2. Connect the other end of the power cord with a wall AC outlet.
3. The power indicator shall be on, which indicates the AC power is connected correctly.

WARNING

- **Always use the power cord delivered with the equipment.**
- **Ensure that the equipment is supplied with continuous electric power during work. Sudden power failure may cause data loss or system failure.**
- **If the power supply is unstable, the system might not work properly. It is recommended to use uninterrupted power supply.**
- **The equipment should only be connected to mains power with protective earth. Do not use a power socket that is not grounded.**
- **The equipment is intended to be connected to a separate power supply. Ensure that the rated output of the power supply matches the input of the equipment. The power supply and this equipment constitute an ME SYSTEM together, meeting the requirements of IEC 60601-1.**
- **Before connecting the equipment to the AC mains, check that the voltage and frequency ratings of the power supply are the same as those indicated on the equipment's label or in this manual.**

3.6.3 Connecting USB Drive

All images and videos are stored in the USB drive connected to the CCU. Before recording, plug a USB drive to the USB connector on the front panel. You can connect two USB drives simultaneously. The system detects the status of the USB drive automatically and displays on the touchscreen. Besides, if one USB drive is out of memory, images and videos will be stored to the other USB drive.

Select FAT32 or exFAT USB drives from a qualified manufacturer, such as SanDisk CZ880 (128GB) and Western Digital Element 4T mobile hard disk. It is recommended to format the USB drive before use.

For details about formatting a USB drive, refer to ***4.11.3.4 Formatting a USB Drive***.

CAUTION

- **Select USB drives from qualified manufacturers. Otherwise file corruption or system failure could result.**
- **Formatting a USB drive will clear all data stored in it. Make sure a backup of data you need is made.**

4 Operations and Settings

4.1 Overview

This chapter introduces the operations, screen display and settings of the equipment.

4.2 Safety Information

WARNING

- **Do not turn the equipment off when the endoscope is still inside the patient.**
- **In case of system failure in operation, stop the operation immediately, turn off the equipment, disconnect the power cord, and pull the endoscope out from the patient carefully.**

CAUTION

- **Before the endoscopic surgery or examination, a backup camera system should be prepared for possible system failure that might interrupt the surgery or examination.**
- **Before the surgery, it is required to perform white balance correctly to build color balance. Failing to do so would cause color distortion in image display.**
- **Before using ESU, it is required to make sure that the ESU is installed and connected in strict accordance with its instructions for use, and that the interference thus caused would not affect the examination and surgery. Using ESU without such confirmation might cause patient injury.**
- **If the image displayed on the monitor is blurred, the tip of endoscope might be contaminated by blood, mucus or tissue fragments. Pull the endoscope out from the patient carefully and remove the blood or mucus to get better lighting and thus ensure a safe examination. Or the front of the endoscope might overheat and burn the patient or operator.**
- **Do not connect or disconnect the camera head when the CCU is on, or the image transducer might be damaged.**
- **Do not block the ventilation outlet of the equipment, or it might overheat and cause fire or system failure.**

- **During the endoscopic examination and surgery, it is required to keep observing the images displayed in real time. Do not operate the endoscope when the image is frozen, or the patient might be injured.**
- **When using medicament sprays, make sure no drops could enter the inside of the equipment from the ventilation outlet, or fire or equipment damage might result.**
- **Cables connecting the ESU should be taken away from the system as much as possible, or the high frequency circuit would affect the performance of the touchscreen and image display.**

4.3 Check before Startup

Check the items listed below before starting the equipment:

- all devices and accessories connected with the equipment are compatible;
- the temperature, humidity, and atmospheric pressure meet the requirements, and installation site are clean;
- there is no condensation;
- there is no distortion, damage or contamination on the surface of the system and peripheral equipment connected to it;
- there is no rough surface, sharp edges or protrusions on the parts of the endoscope or other accessories that will be put inside the patient;
- light cable and other connections are intact and well routed;
- connectors or plugs are not loose, distorted, damaged, contaminated or blocked;
- there is no irrelevant objects on top of the equipment; the ventilation outlet is not covered by dust or other objects;
- there is no obstacle in the movement range of the system or near the ventilation outlet.

4.4 Starting the System

Follow the procedure below:

1. Turn the monitor on.
2. Press the power switch on the front panel of the CCU.

4.5 Check before Operation

It is required to check and ensure that the system works properly. After turning on the system, check the following items:

- there is no abnormal noise, smell or excessive heat;

- put a hand at the ventilation outlet and make sure there is air flowing out;
- the touchscreen displays and functions correctly;
- point the front of the endoscope to an object and check if the image is normally displayed on the monitor.

CAUTION

- **Put the system in use only when it is confirmed that the system works normally.**
- **In case of any failure, stop and remove equipment from use. Otherwise, injury to the patient or operator or damage to the equipment might result.**

4.6 Using the Touchscreen

The CCU is configured with a touchscreen on which you can operate and set the equipment.

4.6.1 Locking the Touchscreen

The touchscreen can be automatically locked to avoid inadvertent operations. When this function is enabled, the touchscreen will be locked automatically if no operation is detected in one minute.

Follow the procedure below to enable the lock screen function:

1. Select on the touchscreen to display the setup menu.
2. Select **System Setup**, slide the tabs on the top of the screen to the left until **Lock Screen** is displayed. Select **Lock Screen**.
3. Select **ON**.

The lock screen function will not be enabled if **OFF** is selected.

4.6.2 Unlocking the Touchscreen

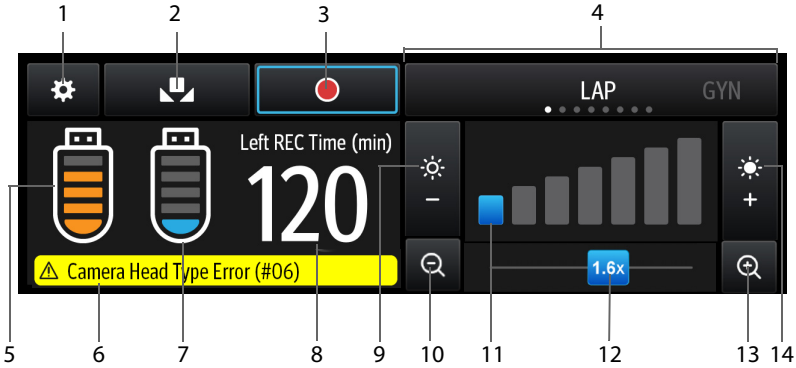
When the touchscreen is locked, is displayed on the top left. To unlock the touchscreen:

1. Tap anywhere on the touchscreen. An unlocking bar is displayed on the top left.

2. Press and slide it to the position on the right. The touchscreen is unlocked, and displays the main screen.

4.6.3 Touchscreen Display

Below is an introduction of contents displayed on the touchscreen:



(1)	: press to display the setup menu.
(2)	: point the endoscope to white gauze or any white object, and press the icon to perform white balance.
(3)	: press to start or stop video recording.
(4)	Scene: select the correct surgery scene. The current selection is highlighted.
(5)	USB1 status: indicates the current status of the USB drive connected to the USB port on the left:  the USB drive is empty / 20% of memory occupied / 40% of memory occupied / 60% of memory occupied / 80% of memory occupied / USB drive is nearly full / no USB drive is connected Note: Keep observing the **Left REC Time (min)** value and replace the USB drive if necessary.
(6)	Error message area: displays error messages.
(7)	USB2 status: indicates the current status of the USB drive connected to the USB port on the right:  the USB drive is empty / 20% of memory occupied / 40% of memory occupied / 60% of memory occupied / 80% of memory occupied / USB drive is nearly full / no USB drive is connected Note: Keep observing the **Left REC Time (min)** value and replace the USB drive if necessary.

(8)	**Left REC Time (min)**: indicates the estimated recording time (in minutes) the current connected USB drive supports.
(9)	 : press to decrease the brightness of the image displayed.
(10)	 : press to zoom out on the image displayed.
(11)	Brightness indicator: indicates the current brightness level.
(12)	Zoom ratio indicator: indicates the current zoom ratio.
(13)	 : press to zoom in on the image displayed.
(14)	 : press to increase the brightness of the image displayed

4.7 Selecting Surgery Scene

Slide the scene tabs on the main screen to the left or right to select a surgery scene. Below is a brief introduction of the options and their recommended applications.

Scene	Full description	Applicable for
LAP	Laparoscope	Laparoscope and thoracoscope operation
GYN	Gynaecology	Hysteroscope operation
URO	Urology	Cystoscope opeartion
FIBER 1	Fiberscope1	Ureteroscpe operation
FIBER 2	Fiberscope2	Cholangioscopy or other soft-fiber endoscope operation
ARTHRO	Arthroscope	Arthroscope operation
E.N.T	Ear.Nose.Throat	Otoscope, rhinoscope and laryngoscope operation

You can also select the surgery scene via the setup menu. For details, refer to ***4.11.1.5 Selecting Surgery Scene***.

4.8 Performing White Balance

The white balance function is used to calibrate the color of the image displayed on the monitor.

It has be to performed:

- before starting the surgery;
- after the light source is changed; and,

■ when the color of the image is anomalous.

Follow the procedure below to perform white balance:

1. Point the camera head or endoscope to white gauze or any white object at a distance of about 10 cm, and make sure your sight is filled with white. Do not shake the camera head or the endoscope in the process.
2. Adjust the brightness to an appropriate level and avoid overexposure.
3. Press on the camera head for 2 seconds to start white balance. You can also press the icon on the touchscreen of the CCU.
4. Check the prompt message on the monitor. If white balance is indicated to be failed, repeat the procedure.

4.9 Adjusting Image Brightness

Select the / icons on the main screen of the CCU to adjust the image brightness.

The brightness indicator in the middle indicates the current brightness level. You can also slide the indicator to the left or right to decrease or increase the brightness.

If the / buttons on the camera head are set to **Brightness +/-**, you can also press them to adjust the brightness.

4.10 Zoom In/Out

Select the / icons on the main screen of the CCU to adjust the zoom ratio. The slider in the middle indicates the current zoom ratio. You can also slide the indicator to the left or right to zoom out or in.

If the / buttons on the camera head are set to **Zoom Out/In**, you can also press them to adjust the size of the image displayed.

4.11 Changing Settings

Select on the touchscreen to display the setup menu, where you can change the image, function and system settings.

CAUTION

- **After changing settings, ensure the view displayed on the monitor provides a correct and live image.**

4.11.1 Changing Image Settings

Select on the touchscreen and **Image Setup** is displayed.

4.11.1.1 Setting Image Color

Follow the procedure below:

1. Select  on the touchscreen, and the **Color** screen of **Image Setup** is displayed.
2. Press the + or - icons to adjust the **Paint Red**, **Paint Blue** and **Saturation** settings. You can also press **Reset** to restore factory default setting.

4.11.1.2 Setting Image Detail

Follow the procedure below:

1. Select  to display the setup menu.
2. Select **Image Setup** → **Detail**.
3. Set **Sharpness** to **Normal** or **High**.
4. Press the + or - icons to adjust the **Structure** and **Edge**. You can also press **Reset** to restore factory default setting**.**

4.11.1.3 Setting Image Exposure

Follow the procedure below:

1. Select  to display the setup menu.
2. Select **Image Setup** → **Exposure**.
3. Set the **Detection Area**.
4. Press the + or - icons to adjust the **Shutter Limit** and **Brightness**. You can also press **Reset** to restore factory default setting.

You can also select the  icons on the main screen to adjust the image brightness.

For details, refer to ***4.9 Adjusting Image Brightness***.

4.11.1.4 Flipping Image

Follow the procedure below:

1. Select  to display the setup menu.
2. Select **Image Setup** → **Image Flip** to flip the image horizontally or vertically.

If the image is flipped, "VF" (Vertical) and/or "HF" (Horizontal) will be displayed on the monitor.

4.11.1.5 Selecting Surgery Scene

Slide the scene tabs on the touchscreen to the left or right to select the correct surgery scene. You can also select the surgery scene following the procedure below:

1. Select  to display the setup menu.

2. Select **Image Setup**, slide the tabs on the top of the screen to the left, and then select **Scene**.
3. Select the correct surgery scene.

For details about the options and their recommended applications, refer to ***4.7 Selecting Surgery Scene***.

4.11.1.6 Freezing an Image

Follow the procedure below:

1. Select  to display the setup menu.
2. Select **Image Setup**, slide the tabs on the top of the screen to the left, and then select **Freeze**.
   - Select **ON** to freeze the current image.
   - Select **OFF** to unfreeze.

If the image is frozen, "Freeze" will be displayed on the monitor.

4.11.1.7 Setting Image Zoom Threshold

You can set the image zoom threshold to control the maximum zoom in ratio. After setting, the zoom in ratio will not change when the threshold is reached.

Follow the procedure below:

1. Select  to display the setup menu.
2. Select **Image Setup** → **Zoom Threshold**.
3. Select a value as needed.

4.11.2 Customizing Surgery Scene

You can customize four surgery scenes that are frequently used. Follow the procedure below:

1. Select  to display the setup menu.
2. Select **User Setup**.
3. Select a scene and the **Image Setup** screen is displayed.
4. Set **Brightness**, **Paint Red**, and other parameters as needed.
5. Press **Save** to make the settings take effect. You can also press **Reset** to restore factory default settings.

After the settings are saved, you can select the customized scene in the **Scene** menu. For details, refer to ***4.11.1.5 Selecting Surgery Scene***.

4.11.3 Changing Function Setup

4.11.3.1 Setting Camera Buttons

Follow the procedure below to set the buttons on the camera head:

1. Select to display the setup menu.
2. Select **Function Setup** and the **Camera Button** screen is displayed by default. You can set the functions of the buttons as needed:
   - **Brightness +/-**: to increase/decrease the brightness.
   - **Zoom Out/In**: to zoom out/in on the image displayed.

4.11.3.2 Changing Recording Setting

Follow the procedure below:

1. Select to display the setup menu.
2. Select **Function Setup** → **REC Setup**:
   - Select **Section Size** to set the maximum size of each video recorded; and,
   - Select **Quality** to set the quality of each video recorded.

4.11.3.3 Setting the Light Source

If light source is correctly connected to the system and operating normally, you can change the brightness of light source on the CCU. Follow the procedure below:

1. Select to display the setup menu.
2. Select **Function Setup** → **Light Source**.
3. Select the + or - icons or slide the indicators in the middle to adjust the brightness of the light source.

4.11.3.4 Formatting a USB Drive

You can format a USB drive with the equipment. Follow the procedure below:

1. Select to display the setup menu.
2. Select **Function Setup** → **UDisk Format**.
3. Press **Format** under **USB1** or **USB2** to start formatting.

When formatting is finished, "**Format Finished!**" is displayed on the touchscreen.

Format will be disabled if no USB drive is connected to the USB1 or USB2 connector on the front panel or the USB drive connected is not compatible. Replace the USB drive if needed.

CAUTION

- **Formatting a USB drive will clear all data stored in it. Make sure a backup of data you need is made.**

NOTE

- **You can format one USB drive at a time.**

4.11.4 Changing System Setting

4.11.4.1 Changing Output Setting

Follow the procedure below:

1. Select  to display the setup menu.
2. Select **System Setup** and the **Output Setup** screen is displayed by default.
3. Set **4K SDI OUT** based on the current video connector:
   - **12G SDI**: when the monitor is connected to the CCU via one of the 12G-SDI outs;
   - **3G SDI×4**: when the monitor is connected to the CCU via the four 12G-SDI outs.

4.11.4.2 Setting Date and Time

Follow the procedure below:

1. Select  to display the setup menus.
2. Select **System Setup** → **Date&Time**:
3. Drag the digits on the left of **y** (year), **m** (month), **d** (date), **h** (hour), **m** (minute), and **s** (second) to the correct date and time, and then select **OK**.

NOTE

- **Before using the system, check that the system time is consistent with your local time.**

4.11.4.3 Setting System Language

Follow the procedure below:

1. Select  to display the setup menu.
2. Select **System Setup** → **Language**.

3. Tap the current language and all the languages the system currently provide are displayed. Select the target language.

4.11.4.4 Initializing the System

Follow the procedure below:

1. Select to display the setup menu.
2. Select **System Setup** → **Initialization**.
3. Select **Initialization** and continue the setting as instructed.

4.11.4.5 Setting Logo Display

The Mindray logo can be displayed on the monitor. Follow the procedure below to change the setting:

1. Select to display the setup menu.
2. Select **System Setup** → **Logo**.
   - Select **ON**: the Mindray logo is displayed on the top left of the monitor; and,
   - Select **OFF**: the Mindray logo will not be displayed on the monitor.

4.11.4.6 Checking Version Information

You can check the software version of the system. Follow the procedure below:

1. Select to display the setup menu.
2. Select **System Setup**, slide the tabs on the top of the screen to the left, and then select **Version**.
3. Select **More** to view the license and reference statement of open-source software.

4.11.5 Maintenance

This menu is password-protected and only available for service personnel authorized by Mindray.

4.12 Error Messages

Message	Possible Cause	Attemptable Solution
Camera Head Connection Error	The camera head is not correctly connected to the CCU. The connector is broken.	Connect the camera head to the correct connector on the CCU. Replace the camera head with a new one.
Camera Head Type Error	The camera head connected to the CCU is not compatible.	Use the camera head specified by Mindray.

Message	Possible Cause	Attemptable Solution
CCU Over Heat	The ventilation outlet is blocked. The room temperature exceeds the limit. The fan does not work normally.	Clear the blockage from the ventilation outlet. Reduce the room temperature. Remove the equipment from use and use the backup one.
CCU initialization is failed	The camera head is not connected.	Connect the camera head correctly and restart the CCU.
Fan Error,Replace the Equipment	The fan is blocked or damaged.	Check the ventilation outlet for anything that might interrupt the rotation of the fan. Clear the blockage, if any. Remove the system from use and use the backup one.
Snap Error	No USB drive is connected. The USB drive connected is out of memory.	Connect an available USB drive. Replace the USB drive with a new one. Format the USB drive. Make sure a backup is made before formatting.
Recording Error	No USB drive is connected. The USB drive connected is out of memory. Equipment failure occurs.	Connect an available USB drive. Replace the USB drive with a new one. Format the USB drive. Make sure a backup is made before formatting. Remove the equipment from use and use the backup one.
Format Error, Please Change USB Disk !	The USB drive is not compatible. The USB drive is damaged.	Replace the USB drive with a new one.

NOTE

- **Keep observing the error messages and take actions as instructed above. If the equipment starts to beep, you need to check the message immediately and take corrective actions.**

4.13 Removing the System from Use

After the surgery or if system failure occurs, remove the system from use as indicated below:

1. Pull the endoscope out from the patient.
2. Check if there is a "REC" icon on the bottom left of the monitor. If so, press  and wait until this icon is no longer displayed.
3. Turn the equipment off.
4. Remove the endoscope from the camera head.

Perform cleaning, disinfection, sterilization, and other maintenance as required by the local or your hospital's regulation.

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5 Troubleshooting

This chapter lists the problems that are likely to occur and possible solutions. If the problem persists after corrective actions have been taken, contact your service personnel.

CAUTION

- **In case of any abnormality, remove the equipment from use immediately. Otherwise, injury to the patient or operator or damage to the equipment might result.**

Symptom	Possible Cause	Attemptable Solution
The equipment does not power up.	The equipment is not properly connected to the AC Mains.	Check the connection of the power cord. Replug the power connectors and restart the equipment.
There is abnormal sound during operation.	The equipment is not horizontally placed. Objects stacked on the equipment are too heavy.	Check if the equipment is properly placed on a horizontal surface. Do not stack on the equipment.
The monitor screen blurs.	The video cable is not correctly connected. The camera head cable is not correctly connected.	Check the connection of video cable. Reconnect the cable. Check the connection of camera head cable. Reconnect the cable.
White balance fails.	The white balance button is not correctly pressed.	Press the white balance button and check if white balance is correctly performed.
There is no image displayed on the monitor.	The monitor is not turned on. The monitor is not properly connected.	Check if the monitor is on. Check the connection between the camera head and CCU, and then the CCU and monitor. Turn off and then restart the system.
The color of the displayed image deviates.	White balance is not properly performed. The surgery mode is not correctly selected. The image setting is not appropriate.	Perform white balance correctly. Select the correct surgery mode. Check the image setting.

Symptom	Possible Cause	Attemptable Solution
The image displayed is blurred.	The camera head is not correctly focused. The front of endoscope is contaminated by blood, mucus or tissue fragments.	Rotate the focusing ring on the camera head to focus. Pull the endoscope out from the patient carefully and remove the blood or mucus.
The image displayed is too bright or dark.	The brightness and contrast of the monitor is inappropriate. The brightness setting of the CCU is inappropriate. The light cable is not correctly connected. The brightness and contrast of the monitor is not appropriate. The light cable is broken.	Adjust the brightness and contrast of the monitor following its instructions for use. Adjust the brightness of the CCU. Set the brightness of the light source following its instructions for use. Check the light cable. If case of damage, replace it with a new one.
The image is not displayed in the center.	The endoscope is not correctly connected.	Disassemble the endoscope from the camera head, and reassemble them.
Image is disturbed when using high-frequency surgical equipment.	The system is interfered by the high-frequency surgical equipment.	Take the cable that connects the high-frequency surgical equipment away from the system as much as possible.
Video recording fails.	The USB drive is broken. The USB drive is out of memory.	Check the status of USB drive on the screen of the CCU. Make sure it is ready for use.

6 Cleaning, Disinfection and Sterilization

6.1 Overview

This chapter describes the cleaning, disinfection and sterilization of the CCU and camera head.

The CCU and camera head are not intended to come into contact with the patient. Thus, they are not disinfected before leaving the factory. Clean and disinfect the equipment before the first use and after each use.

Do not sterilize the CCU. For sterilization of the camera head, refer to ***6.5 Sterilizing the Camera Head***.

For the cleaning and disinfection of accessories and connected equipment, refer to their instructions for use.

6.2 Safety Information

WARNING

- **It should be fully aware that there will be risks of infection when cleaning the equipment. Strictly follow the requirements in this chapter or the instructions of the cleaning, disinfection, and sterilization procedure of the hospital.**
- **Mindray makes no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For the method to control infection, consult your hospital's Infection Control Officer or Epidemiologist.**
- **Wear appropriate protective equipment, eye protection, gloves etc., during cleaning.**

CAUTION

- **Use only the substances and methods listed in this chapter for cleaning, disinfection or sterilization. Warranty does not cover damage caused by unapproved substances or methods.**
- **Dilute and use the detergents in strict accordance with the instructions of their manufacturers.**
- **Do not use mixed detergents for cleaning, disinfection or sterilization. Otherwise, damage or injury could result.**

- **Turn off the equipment and disconnect the power cord before cleaning. Otherwise, electric shock or damage to equipment could result.**
- **Never disassemble the equipment for cleaning processes. Contact Mindray for support whenever you need.**
- **Remove any fragments of body tissue on the equipment, if any, to avoid possible cross infection.**
- **Never use hard or abrasive materials to wipe the equipment. It may cause damage to the surface of the equipment.**
- **Do not use rust remover to clean the equipment. It may cause damage to the surface of the equipment.**
- **Any contact of cleansers or disinfectants with connectors or metal parts may cause corrosion. Avoid such parts during cleaning and disinfection.**
- **Do not pour any liquid directly on the equipment or let any liquid enter the interior.**
- **If liquid is spilled on the equipment, disconnect the power supply, dry the equipment and contact your service personnel.**
- **Check the equipment after cleaning and disinfection. If there is any sign of aging or damage, remove it from use immediately.**
- **Dry the equipment completely after cleaning and disinfection, especially before next use. Or, there might be risks of electric shock.**
- **Make sure there is no liquid residues at the electrical connectors of the equipment or accessories before use.**
- **Never immerse the equipment or accessories in liquids.**

6.3 Cleaning the CCU and Camera Head

Before cleaning, consult the local or your hospital's regulations for cleaning of medical equipment. To clean the equipment, follow this procedure:

1. Turn the equipment off and disconnect the power cord.
2. Clean the surface of the equipment with neutral liquid soap. For detailed operation instructions, refer to the instructions for use of the cleanser.
3. Remove the cleanser residue from the surface and dry the equipment.

Below is a cleanser of which the efficacy has been tested:

Product Name	Manufacturer
Herbal liquid soap	Shandong Annjet High-Tech Disinfection Co., Ltd.

CAUTION

- **Always keep the camera lens clean.**
- **To avoid poor connection caused by accumulated dirt on the connectors, it is recommended to clean the connectors of the equipment periodically based on the actual use. Wipe such connectors first with medical absorbent cotton dampened with rubbing alcohol and then a dry and clean gauze.**
- **Do not let any liquid enter the inside of the equipment.**

6.4 Disinfecting the CCU and Camera Head

Disinfect the equipment as required in the local or your hospital's servicing schedule. Clean the equipment before disinfection. Dilute and use the disinfectants in strict accordance with the instructions of their manufacturer. Use only the approved disinfectants listed below:

Product Name	Manufacturer	Camera Head	CCU
HEALTH ESSENCE Disinfecting Effervescent Tablets	Beijing ChangJiangMai Medical Science Technology Co. Ltd.	Applicable	Applicable
HEALTH ESSENCE Surface Disinfectant	Beijing ChangJiangMai Medical Science Technology Co. Ltd.	Applicable	Applicable
Health Essence Bis-QACs Disinfectant	Beijing ChangJiangMai Medical Science Technology Co. Ltd.	Applicable	Applicable
DIAN'ERKANG® Surface Wipes	Shanghai Likang Disinfectant Hi-Tech Co., Ltd.	Applicable	Applicable
DIAN'ERKANG® Surface Disinfectant	Shanghai Likang Disinfectant Hi-Tech Co., Ltd.	Applicable	Applicable
Ethanol, 75%	Wuhan Xuehuan Sterilization Goods Co., Ltd.	Applicable	Applicable

NOTE

- **If required by the local or the hospital's regulations, ultraviolet light can be used for disinfection but only of the CCU. Do not disinfect the camera head with ultraviolet light, long time exposure to which may cause damage to the parts and components of the camera head.**
- **Remove the detergent residue from the surface and dry the equipment.**

6.5 Sterilizing the Camera Head

Sterilize the camera head as required in the local or your hospital's servicing schedule. Low-temperature hydrogen-peroxide plasma sterilization can be used. Follow the instructions for use of the sterilizer and ensure the efficacy of the sterilization procedure.

Follow the procedure below:

1. Clean and disinfect the camera head as instructed in the previous sections.
2. Place the camera head in a sterilization tray or container of appropriate size.
3. Double wrap the sterilization tray or container with sterile sheet or any other packing material that is applicable for hydrogen-peroxide plasma sterilization.
4. Place the sterilization tray or container into the sterilizer, and make sure it is adequately exposed in the hydrogen-peroxide plasma but does not contact the inner sides of the sterilizer. The camera head has been tested with the following sterilizer:

Manufacturer	Product Type	Cycle Mode
LAOKEN Medical Technology Co., Ltd.	LK/MJQ-100	Standard

5. Set the sterilizer to standard cycle and sterilize the camera head following the instructions for use of the sterilizer.

After sterilization, cool the equipment down to room temperature before use. If not, the lens might fog or the camera head be damaged.

It has been tested that the camera head functions well after 200 cycles of hydrogen-peroxide plasma sterilization.

CAUTION

- **Without compromising the efficacy of sterilization, select a method that would least corrode the camera head.**
- **Make sure the camera head works normally before use. In case of any damage, remove it from use immediately, or patient or operator injury might result.**
- **Do not sterilize the CCU.**

NOTE

- **After long time of sterilization, the color of part of the camera head might fade. It is natural and will not affect the sealability or performance of the camera head.**

6.6 Consequences Caused by Inappropriate Cleaning, Disinfection and Sterilization

Using detergents or methods other than those recommended might cause the following consequences:

- color change on the surface of the equipment
- corrosion of metal parts
- cracks or distortion of cables, connectors and the housing of the equipment
- reduced service life of cables
- degradation of performance
- equipment malfunction

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7 Maintenance

7.1 Introduction

The performance of the equipment might degrade over time. To ensure the normal functioning, it is required to perform periodical maintenance and service.

7.2 Safety Information

CAUTION

- **The responsible individual hospital or institution using the equipment should implement a recommended maintenance schedule. Otherwise, undue equipment failure or possible health hazards might result.**
- **No modification of this equipment is allowed. All safety checks or maintenance involving any disassembly of the equipment should be performed by professional service personnel. Otherwise, undue equipment failure and possible health hazards could result.**
- **This equipment contains no user serviceable parts. In case of any equipment failure, contact your service personnel or Mindray.**
- **The service personnel must be properly qualified and thoroughly familiar with the operation of the equipment.**

NOTE

- **If needed, contact the manufacturer for circuit diagrams, component part lists, descriptions, calibration instructions, or other information concerning the repair of the equipment.**

7.3 Maintenance Schedule

Follow the maintenance schedule or local regulations to perform the maintenance. Make sure to clean and disinfect the equipment before taking any test or maintenance.

It is recommended that comprehensive maintenance be performed annually by qualified service personnel. Contact Mindray if you need such service.

7.3.1 Inspection

An appearance inspection should be performed every week. In case of any damage or abnormity, remove the equipment from use immediately and contact the hospital's equipment manager or your service personnel.

Follow these guidelines when inspecting the equipment and make sure that:

- the environment and power supply meet the requirements, and that there is no condensation;
- there is not any stain on the outside of the equipment or crack or damage on the touchscreen or monitor, and that the labels are properly affixed, intact and legible;
- light cable and other connections are intact;
- cables are securely connected with the equipment;
- connectors or plugs are not loose, distorted, damaged, contaminated or blocked;
- there is no irrelevant objects on top of the equipment; the ventilation outlet is not covered by dust or other objects;
- the image displays normally on the monitor after the system is started.

7.3.2 Replacing the Fuse

If the fuse blows, follow the procedure below to replace a new one:

1. Turn the equipment off and disconnect the power cord from the AC mains.
2. Unplug the power cord from the AC input on the rear panel.
3. Pull the fuse holder out with a screwdriver.
4. Remove the blown fuse and replace it with a new one.
5. Push the fuse holder back.

CAUTION

- **Use only the fuse provided by Mindray.**

7.3.3 Electrical Safety Tests

It is recommended to perform electrical safety tests annually or as needed. The test items shall be conducted as required by IEC 60601-1. Electrical safety tests shall be conducted by qualified service personnel authorized by Mindray.

7.4 Disposal

At the end of its service life, the equipment, as well as the accessories, must be disposed of in compliance with the local or hospital's guidelines regulating the disposal of such products. Clean and disinfect the equipment and accessories before disposal.

8 Accessories

The accessories listed in this chapter comply with the requirements of IEC 60601-1-2 when in use with the system.

WARNING

- **Use accessories specified by Mindray. Using other accessories may cause damage to the system or failure to meet the claimed specifications.**
- **The accessories listed below must be used with this system. The operator shall read this manual and the instructions for use of the accessories or contact Mindray to check the compatibility between the system and the accessories. Or patient injury might result.**

CAUTION

- **The accessories may not meet the performance specifications if stored or used outside the specified temperature and humidity ranges. If the performance of the accessories is degraded due to aging or environmental conditions, contact your service personnel.**
- **Check if the accessories and their packages are intact. Do not use them if any damage is detected.**
- **Use the accessories before the expiry date.**

PN	Description
0020-20-12522	Power cord (CE)
009-009729-00	12G-SDI cable (1.5 m)
009-009730-00	12G-SDI cable (10 m, optional)
009-009731-00	HDMI cable (HDMI2.0, 1.5 m)
009-009732-00	DVI cable (1.5 m)
1000-21-00122	Grounding cable

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A Product Specifications

A.1 Safety Specifications

The device is classified, according to IEC 60601-1:

Type of protection against electrical shock	Class I, equipment energized from an external electrical power source
Degree of protection against electrical shock	Type BF
Protection against harmful ingress of water	Camera Head: IPX7
Recommended methods of disinfection and sterilization	As recommended by the manufacturer
Degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide	The equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
Mode of operation	Continuous
Protection against the effects of the discharge of a cardiac defibrillator	No applied part is provided for protection against the effects of the discharge of a cardiac defibrillator
Installation type	Non-permanently installed equipment

A.2 Environmental Specifications

Item	Temperature (°C)	Relative humidity (noncondensing)	Barometric (kPa)
Operating condition	0 - 35	30% - 85%	70.0 - 106.0
Storage condition	-20 - 60	30% - 85%	70.0 - 106.0
Transportation condition	-20 - 60	30% - 95%	70.0 - 106.0

CAUTION

- **Use the equipment only in environment that meets the specific requirements. Otherwise, the equipment may not meet the performance specifications or unexpected consequences, e.g. damage to the equipment, could result. If the performance of the equipment is degraded due to aging or environmental conditions, contact your service personnel.**

A.3 Power Supply Specifications

Voltage	100 -240V~ (±10%)
Rated frequency	50/60 Hz
Input current	1.1 - 0.5A
Fuse	FUSE Time-lag 250V 3.15AD5X20

A.4 Physical Specifications

Size (CCU)	Length (front to back): 380 ± 5 mm Width (left to right): 350 ± 5 mm Height (top to bottom): 80 ± 5 mm (excluding the rubber feet)
Size (Camera head, excluding the cable)	Length (front to back): ≤180 mm Width (left to right): ≤ 55 mm Height (top to bottom): ≤ 55 mm
Weight	Camera Control Unit: ≤ 20 kg Camera head: ≤ 280 g (excluding the cable)

A.5 Hardware Specifications

Display type (CCU)	Touchscreen
Display size (CCU)	7.84 inches

Device interfaces	USB connector: 3, USB2.0 protocol Network connector: 1, standard RJ45 CAN connector: 2, CAN protocol 3G-SDI out: 1, HD 12G-SDI out: 4, 4K HDMI out: 1, 4K DVI out: 1, HD Power socket: 1, connecting the AC Mains
Signal output	5 4K channels and 2 HD channels
Diameter of eye piece cup connector	φ31.75, ±0.10 mm

A.6 Monitor Specification

Interface type	12G-SDI or HDMI2.0 4K monitors selectable Compatible with DVI and 3G-SDI HD monitors
Resolution	3840 * 2160 pixels
Refresh rate	50/60 Hz

A.7 Product Performance

Effective pixel of camera head	4000K pixels with a -20% tolerance
Image transfer resolution	3840*2160 ultra high definition
Focal length	20 mm with a ±10% tolerance

A.8 Operating Environment

Hardware configuration	CPU: 1 GHz RAM: 4 Gb Flash: 16 GB
Software environment	LINUX

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B EMC

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

WARNING

- **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.**
- **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.**
- **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.**
- **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.**
- **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

- **The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.**
- **Other devices may interfere with this system even though they meet the requirements of CISPR.**
- **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.**
- **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:

- imaging
- operation status
- image quality
- accessories identification
- data storage

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

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**
Conduced RF IEC 61000-4-6	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz	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 80 $\sqrt{P}$ 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 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: 
Radiated RF EM fields IEC 61000-4-3	3 V/m 80 MHz-2.7GHz	3 V/m	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	27 V/m 380–390 MHz	27 V/m	
	28 V/m 430–470 MHz, 800–960 MHz, 1700–1990 MHz, 2400–2570 MHz	28 V/m	
	9 V/m 704–787 MHz, 5100–5800 MHz	9 V/m	

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 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 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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.

Note1: 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.

C Default Settings

C.1 Image Setup

Tab	Items/Options	Default Setting
Color	Paint Red	0
	Paint Blue	0
	Saturation	-18
Detail	Sharpness	High
	Structure	2
	Edge	0
Exposure	Detection Area	Wide
	Peak Ratio	18
Image Flip	Horizontal	/
	Vertical	
Scene	LAP, GYN, URO, FIBER 1, FIBER 2, ARTHRO, E.N.T, LAP User, GYN User, URO User, FIBER 2 User, E.N.T User, User 6, User 7, User 8, User 9	LAP
Zoom Threshold	1.4X, 1.6X, 1.8X, 2.0X	1.4X
Freeze	Freeze	OFF

C.2 User Setup

Tab	Items/Options	Default Setting
LAP User	Brightness, Paint Red, Paint Blue, Saturation, Sharpness, Structure, Edge, Detection Area, Peak Ratio	Same as parameter values of LAP
GYN User		Same as parameter values of GYN
URO User		Same as parameter values of URO
FIBER 2 User		Same as parameter values of FIBER 2
E.N.T User		Same as parameter values of E.N.T

C.3 Function Setup

Tab	Items/Options	Default Setting
Camera Button	Zoom Out/In	Zoom Out/In
	Brightness +/-	
REC Setup	Section Size: 1G, 2G, 4G	4G
	Quality: Low, High, Auto	Auto

C.4 System Setup

Tab	Items/Options	Default Setting
Output Setup	4K SDI OUT: 12G SDI, 3G SDI×4	12G SDI
Date&Time	Date&Time	/
Language	ENGLISH, CHINESE	ENGLISH
Logo	ON, OFF	ON
Lock Screen	ON, OFF	ON

D Units and Symbols

D.1 Units

Abbreviation	In Full
°	angle
A	ampere
°C	centigrade
cm	centimeter
dBA	A-weighted decibels
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

D.2 Symbols

Symbol	Explanation
-	minus
%	percent
/	per, divide, or
^	power
+	plus
=	equal to
<	less than
>	greater than
≤	less than or equal to
≥	greater than or equal to
±	plus or minus
×	multiply
©	copyright
φ	diameter

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