## mindray

## UX7 Series 4K&NIR&3D

Endoscope Camera System

## Vision beyond Imagination



#### This brochure can be applicable to the following models:

Monitor: LMD-XH320T/LMD-XH550T/S3180P 4K 3D Video Endoscope: G 31030A/G 31000A/M 31030A/M 31000A

Trolley: TV-500/TV-300 Camera Head: CH5-SR100/CH5-SR110/CH5-SW100/CH5-SW110

Endoscope Camera System: UX7/UX7-TEC

Rigid Endoscope: G 01030A/G 01000A/G 00530A/G 00500A/G 10530A/ G 10500A/M 01030A/M 01000A

Endoscope Light Source: HB500R/HB500



## www.mindray.com



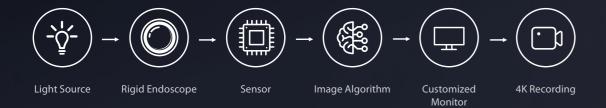


## **Full-chain Independent R&D**

The advancement of minimally invasive technology has significantly generates the demand for precision surgeries. This has led to increased requirements for the resolution, real-time navigation, and accurate restoration of 3D structures within the cavity.

Based on full-chain independent R&D, Mindray's new generation UX Series Endoscope Camera System has been innovatively integrated with 4K fluorescence and 3D technologies. It provides a comprehensive enhancement in imaging performance and operational experience, enabling clinical breakthroughs in complex surgical procedures.

With various configuration options suitable for multiple departments, it is a truly "all in one imaging platform" for the operating room.







#### **4K Monitor**

Options of 32 inch and 55 inch Options of 2D and 3D

#### **Master Control Trolley**

One-touch to start the entire set of equipment on the trolley

#### **Endoscope Camera System**

Integrated with 4K Fluorescence and 3D Technologies

#### **Endoscope Light Source**

White Light/Fluorescence

#### **4K 3D Video Endoscope**

White Light/Fluorescence Selectable viewing angles of 0° and 30°

#### **Camera Head**

Multiple focal lengths available White light camera head weight: 190 g Fluorescence camera head weight: 240 g

#### Rigid Endoscope

Selectable diameters of 10 mm, 5 mm and 3 mm

#### **Medical Digital** Video Recorder

Access to hospital PACS system Available to record dual-channel simultaneously













## 3D Intelligent Bionics, **Natural Space Perception**

### **Dual Chips True 4K**

Dual-4K 3D imaging reproduces the structure in the cavity, making the surgery safer and more efficient.

## 5.6 mm Large Pupil Distance

Enhanced depth of 3D vision can discern small depth differences for more precise surgical positioning.

## **3D Fluorescence Imaging**

Stable stereo fluorescence navigation makes surgical operations more precise.



Reduced operation time



Enhanced surgical safety





#### **AutoRotate Correction**

Built-in high-precision attitude sensor secures real-time perception of the endoscope movement AutoRotate Correction of the endoscope enables all-around view observation



#### **Enhanced Anti-Fog**

The Chip-on-Tip design achieves active heating and defogging, dramatically reducing the frequency of intraoperative lens wipes



#### **Focus-Free Design**

The large depth of field eliminates the need to focus, while presenting clear image for a smoother surgical process



#### **Autoclave Available**

A new breakthrough in sterilization processes with a high reliability

The whole Video Endoscope supports Autoclave/Low Temperature Plasma/EO Sterilization

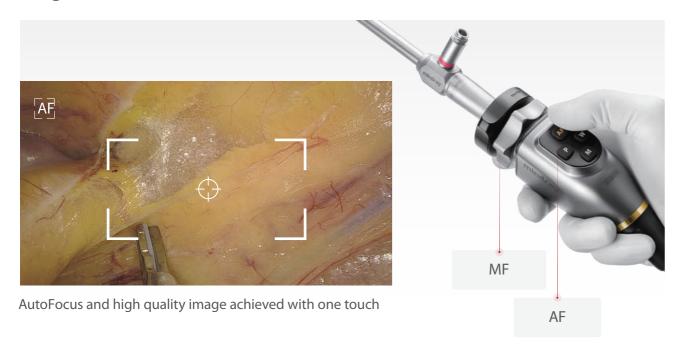


#### Weighs only 420 g

Titanium alloy handle, sturdy yet lightweight, allowing for easy maneuverability

## **Smart View** Exceptional Image Quality

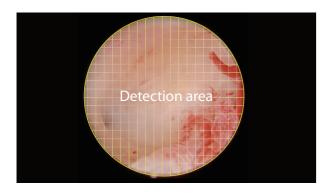
## Integrated auto and manual focus



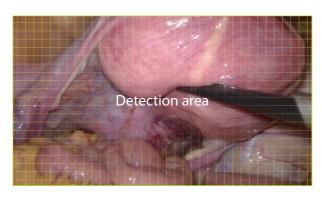
## **Automatic scene recognition**

Smart exposure: Determine different detection areas according to different scenes, and accurately match the exposure parameters without the need to manually switch department modes.

Automatic dimming: The camera system can automatically adjust the intensity of the light source in real time based on the current exposure requirements, ensuring optimal brightness at all times.



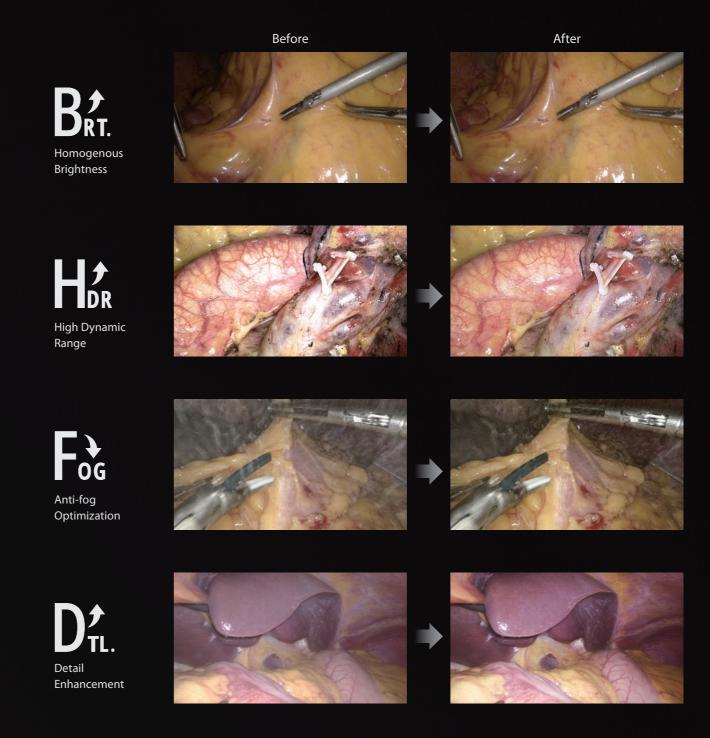
Small diameter scope scene (e.g. hysteroscope)



Laparoscope scenario

## **elmage** Intelligent Image Algorithm, Even in Extreme Circumstances

A variety of post-processing image algorithms make up for any uneven lighting, local overexposure, thick fog and other inherent physical defects in specific situations, to deliver clear, structured, and layered images, even in extreme circumstances.



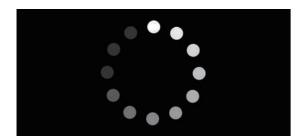
## **Sensitive Perception, Precise Navigation**



The fluorescence technology significantly boosts detection sensitivity and fluorescence imaging stability, leading to more precise navigation

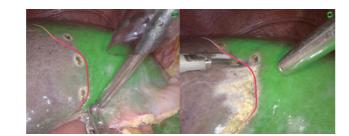
### **Ultra-high fluorescence sensitivity**

Dual optimization of the excitation and imaging pathways achieves fluorescence signal capture sensitivity as low as nmol levels, which helps the clinical detection of low-dose micro-metastases and offers greater penetration capability at equivalent doses.



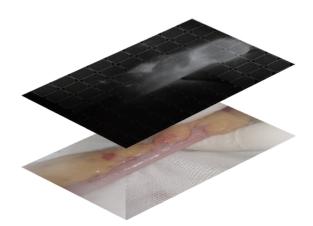
### eFlo stabilization algorithm

Accurately reproduces the distribution of the contrast agent, effectively avoiding signal attenuation caused by distance and angle variations. This significantly enhances fluorescence stability, ensuring consistent boundary delineation.



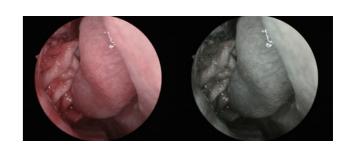
## Fluorescence pixel-level fusion

Strict control of the assembly process ensures the white light and fluorescence image pixel-by-pixel alignment and fusion. The fluorescence image with white light texture details can also help with the entire fluorescence-guided surgical process.



#### **Tone Enhancement**

Tone filtering is used to see through the mucosal vascular network for the differentiation of anomalous vessels to assist in clinical diagnosis.

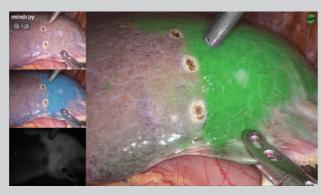


## **Clinical Cases**

## Evaluation of colorectal anastomotic blood supply



## Laparoscopic liver watershed resection



## **SLN mapping in endometrial cancer**



## **Anatomic subpulmonary lobe resection**

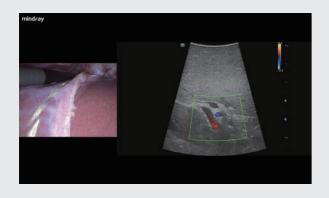


# MIS Ecosystem Unlimited Possibilities

## **Multimodal Image Fusion**

The real-time display of ultrasound images on the endoscope screen helps the surgeon localize the hidden lesion. Simultaneous recording of ultrasound and endoscope images on the same screen makes teaching and sharing more efficient.

The endoscope can display a 3D reconstruction of the organs' structure, together with the surgical view on the same screen, to assist the surgeon with real-time correction needed during the procedure.





## **Vital Sign Data Sharing**

The patient's vital signs data can be customized and displayed on the endoscope screen, allowing the surgeon to evaluate them timely during surgery.









## Future-proof UX7 Endoscope Camera System, Unstoppable Innovation and Exploration Journey

Flexible endoscope, pendulum camera head, multispectral fluorescence, quantitative fluorescence...

Opening up possibilities for more cutting-edge applications.

UX4/UX410/UX420/UX430/UX450/UX460/ UX470

UX5/UX510/UX520/UX530/UX550/UX560/ UX570/UX5-SIM/UX5-NOR/UX5-TEC

**UX7/UX7-TEC/UX7-NOR/UX7-SIM** 

**Endoscope Camera System** 

**Operator's Manual** 



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Revision: 1.0

- When using the system for body checking, avoid contact between metal parts of the accessories such as endoscope and other metal parts. Otherwise, unintended current may flow through the patient body.
- 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.
- When energized endoscopes are used with energized endotherapy devices, patient leakage currents may be additive. It should be noted if a type CF applied part endoscope is used, in which case a type CF applied part energized endotherapy device should be used in order to minimize total patient leakage current.
- When a defibrillator is discharged, the image displayed on the monitor may be interfered with for less than 1s.
- Do not disconnect the power cord or turn off the equipment during the surgery.
- Check if the equipment and accessories (such as connecting cords of instruments) are intact prior to each use. Do not use them if any damage is detected. Replace defective accessories with new ones, and contact Mindray for damaged equipment.

#### 1.1.2 Cautions

#### **CAUTION**

- 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 and the IEC 60601-2-18. 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 and the IEC 60601-2-18. If you have any questions, contact Mindray.
- The equipment shall 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 electrosurgery unit (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 weight of objects stacked on the equipment should not exceed 20 kg.
- Use only endoscopes, and light source 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 Mindray 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, prepare a backup endoscope camera system to avoid surgery interruption due to possible system failure.
- An ESU may interfere with the image display of the monitor, resulting in disordered image tone.
- Do not plug or unplug the system or its accessories when the power is on, otherwise it will cause system damage.
- Do not pull, bend, or twist the connecting cords with excessive force to avoid cord or equipment damage.
- Do not press the connectors with excessive force, or the connectors might be damaged.
- Do not block the ventilation outlet. Otherwise the equipment may overheat, which might trigger system self-protection or cause equipment damage or fire.
- Do not pour liquid on the equipment or let any liquid enter the interior of the equipment, or there will be risks of electric shock or equipment damage. If liquid is 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.

- (9) External control extension connector: connects an external video recorder, and supports starting/stopping recording and taking screenshots.
- (10) USB connector 3: connects a USB drive for system software upgrade, supporting USB 2.0 protocol.
- (11) MSB (Mindray Serial Bus) connector: connects to a light source, controlling the brightness of the light source.
- (12) Network connector 1: supports software upgrade.
- (13) Network connector 2: reserved.
- (14) CAN (Controller Area Network) connector 1: connects external devices other than light source.
- (15) CAN connector 2: connects external devices other than light source.
- (16) 3G/12G SDI (Serial Digital Interface) out: connects a high definition/4K video device for high definition/4K video output, such as monitor.

### 2.9.3 Endoscope Camera Head

This system is compatible with the following models of camera head:

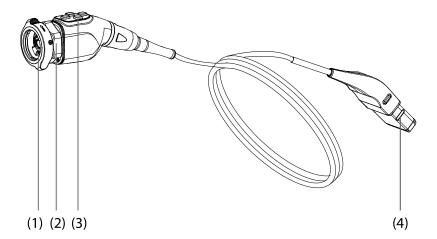
Model	Standard Cable Length	Function
CH5-SW100	4.5m	Supports white light imaging.
CH5-SW110	3m	Supports white light imaging.
CH5-SR100	4.5m	Supports white light and fluorescence imaging.
CH5-SR110	3m	Supports white light and fluorescence imaging.

#### 2.9.3.1 Working Principle of Endoscope Camera Head

The camera head is used together with the CCU to receive 400 nm to 880 nm visible and near-infrared light, supporting visible and near-infrared light imaging.

It provides dual progressive scan CMOS (including a 1/1.8-inch native 4K BSI CMOS) for white light and fluorescence imaging, supporting 4K output display. By using the camera head, you can observe fluorescent images outside the body cavity of patients.

#### 2.9.3.2 Front View of the 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: four functional buttons.
- (4) CCU connector: connects the CCU.

#### 2.9.3.3 Camera Head Buttons

There are four buttons on the camera head, and three of them can be set to perform different functions. After the camera head is connected to the CCU, the button functions are displayed on the monitor. After a button is pressed, the function prompt disappears. More descriptions are shown below:



- (1) AF: press to perform autofocus.
- (2) P: short press to take photos and long press to record videos by default. This button can also be set to other functions. For details, refer to **5.5.2 Setting Button Functions**.
- (3) w: short press to zoom the image and long press to perform white balance by default. This button can also be set to other functions. For details, refer to 5.5.2 Setting Button Functions.

#### (4) M:

- for fluorescence camera head, short press to switch display modes circularly and long press to display external input source by default;
- for white light camera head, short press to switch tone enhancement modes and long press to display external input source by default.

This button can also be set to other functions. For details, refer to **5.5.2 Setting Button Functions**.

is installed in a chassis, sufficient space shall be left in front and behind of the chassis to facilitate operation or maintenance. 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 using the equipment.

#### 3.5 Installation of the Main Unit

The system can be installed as follows:

- On a flat surface
- On a medical supply unit
- On a trolley

#### NOTE

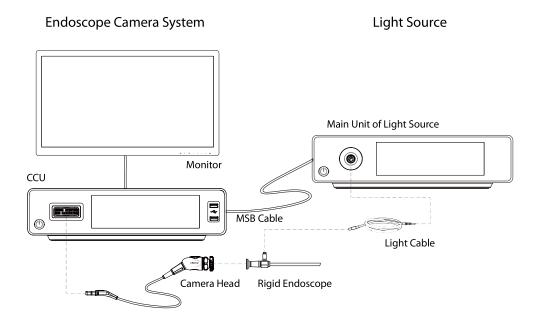
- You are advised to install the main unit on a stable trolley rather than on the floor.
- If the equipment is to be used with a trolley, there will be risks of falling or collision during movement. For more safety instructions, refer to the instructions for use accompanied with the trolley.
- If the equipment is installed on a trolley, make sure the capacity of the trolley is higher than the total power consumption of all the equipment connected to the mains outlet of the trolley. If the power supply voltage is reduced due to insufficient capacity, tripping may occur, turning off the main unit and all other equipment connected to the trolley.

## 3.6 Device Connection

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

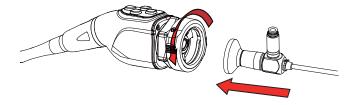
## 3.6.1 System Connection

The equipment can be connected with endoscopes, light sources and monitors to provide high definition images through denoise in multiple dimensions combining spatial and time domains. The connection of the modular-designed system is shown as below:



To connect devices in the diagram, follow the procedure below:

- 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.
- 2. Connect a light source to the MSB connector on the back of the CCU with a MSB cable (System Ctrl Cable-Light Source).
- 3. Plug the connector of the camera head to the camera head connector on the front panel of the CCU.
- 4. To connect the camera head and endoscope, follow the procedure below:
  - a Rotate the endoscope coupler as indicated by the arrow on it.
  - b Align the eye piece of the endoscope with the endoscope coupler on the camera head.



- c Push the endoscope to the camera head and release the endoscope coupler.
- d Pull the endoscope slightly to check if the endoscope is secured.

To remove the endoscope, follow the procedure below:

1. Hold the camera head with one hand, and the endoscope with the other.

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.

#### 3.6.5 Connecting USB Drive

Images and videos can be stored in USB drives connected to the CCU. Before recording, plug USB drives to the USB connector on the front panel. You can connect two USB drives simultaneously. The system detects the status of the USB drives 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 NTFS, FAT32, or exFAT USB drives from a qualified manufacturer. The CCU supports connecting hard drives with memory greater than or equal to 6 TB. You are advised to choose a USB drive with memory greater than 32 GB. The following are the recommended USB drives:

Video Quality	Recommended Manufacturer
4K quality, HD High Quality	SanDisk Z25 series SSD Samsung T7 series SSD
HD Standard Quality	SanDisk CZ600 series U disk SanDisk CZ880 series U disk

You are advised to format the USB drive before use. For details about formating USB drives, refer to **5.6.3 Formatting USB Drive**.

You are advised to use the PotPlayer or KMPlayer to play videos stored in the USB drives.

#### **CAUTION**

- Select USB drives from qualified manufacturers. Otherwise file corruption or system failure could result. It is not recommended that you use a card reader instead of an USB drive.
- Formatting a USB drive will clear all data stored in it. Make sure a backup of data you need is made.

## 3.7 Using the Touchscreen

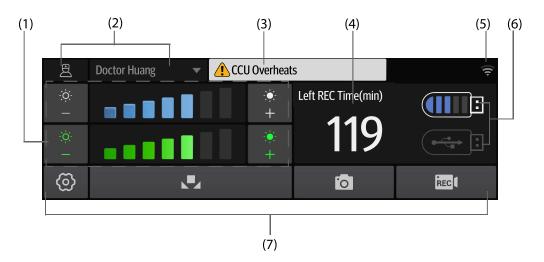
The equipment is configured with a LCD touchscreen on which you can operate and set the equipment, and view operation information.

#### NOTE

Dry the equipment immediately in case of rain or water spray.

## 3.7.1 Operation Screen Introduction

The following figure shows the operating screen of the equipment:



- (1) Brightness setting area: displays the current brightness level and fluorescence intensity. Select a button to set the brightness of the image displayed or the fluorescence intensity. There are 7 levels that can be adjusted.
- (2) User configuration area: displays the current user configuration. Select the User configuration button  $\beta$  to customize the configuration.
- (3) Error message area: displays error messages.
- (4) Left REC Time (min): indicates the estimated recording time (in minutes) the current connected USB drive supports.
- (5) System status area: displays the network connection status.
- (6) USB status area: indicates the current status of the USB drive connected to the USB connector on the front panel.
  - **NOTE:** Keep observing the Left REC Time (min) value and replace the USB drive if necessary.
- (7) Button area: displays available buttons. For detailed introduction of the buttons, refer to **3.7.3 Available Buttons**.

## 3.7.2 On-screen Symbols

The following table lists the on-screen symbols displayed on the main screen:

Symbol	Description	Symbol	Description
• <del>•</del>	No USB drive is connected.		About 0% memory is occupied.
	About 20% memory is occupied.		About 40% memory is occupied.
	About 60% memory is occupied.		
	(Yellow) The USB drive is nearly full.		The USB drive is already full.
0 0 :	Identifying USB drive.	<b>A</b> :	Failed to identify the USB drive.
((1)	Wireless network is connected. The solid part indicates network signal strength.	( <u>&amp;</u>	Wireless network is not connected.
<b>©</b>	The CCU is matched with a location.	9	Failed to match the location.
	The touchscreen is unlocked	O	The touchscreen is locked

## 3.7.3 Available Buttons

The following table lists the available buttons displayed on the main screen:

Button	Description	Button	Description
(©)	Setup button: select to display the setup menu.	7	White balance button: select to adjust the white balance.
.0	Camera button: select to capture images.	REC	Record button: select to start/ stop recording.

- after the light source is changed; and,
- when the color of the image is anomalous.

To perform white balance, follow the procedure below:

- Ensure that the connected light source is emitting light. If Smart Light is enabled, skip this step. For details about how to set Smart Light, refer to 5.7.2.2 Setting Switches of Interconnection Functions.
- 2. Point the camera head or endoscope to a white gauze or any white object, and make sure your sight is filled with white. Do not shake the camera head or the endoscope in the process.
- 3. Adjust the brightness to an appropriate level and avoid overexposure.
- 4. Long press the W button on the camera head to start white balance. You can also press the white balance button on the main screen to start the function.
- 5. Check the prompt message on the monitor. If white balance is indicated to be failed, repeat the procedure.

When the white balance is successfully performed, the displayed image color becomes natural. If the white balance is not performed, the white balance parameters set last time are used by default.

The long-press function of W button on the camera head is set to **White Balance** by default. The long-press function of P or M button can also be customized to **White Balance**. For details about how to customize the button function, refer to **5.5 Setting Camera Head Functions**.

## 4.9 Adjusting Image Brightness





Select the brightness increase button + or brightness decrease button - on the main screen to adjust the image brightness. The brightness slider in the middle indicates the current brightness level. You can also drag the slider to the left or right to adjust the brightness.

In addition, if the short-press function of P, W, or M button on the camera head is set to **WL Brightness**, you can short press the button to adjust the brightness. For details about how to set the functions of camera head buttons, refer to **5.5 Setting Camera Head Functions**.

## 4.10 Adjusting Fluorescence Intensity

After the CCU is correctly connected to the Mindray light source (HB500R/HB500R-TEC),





you can select the fluorescence increase button + or fluorescence decrease button - on the main screen to adjust the fluorescence intensity. The fluorescence slider in the middle indicates the current fluorescence intensity. You can also drag the slider to the left or right to adjust the fluorescence intensity.

In addition, if the short-press function of P, W, or M button on the camera head is set to **Fluor Intensity**, you can short press the button to adjust the fluorescence intensity. For details about how to set the functions of camera head buttons, refer to **5.5 Setting Camera Head Functions**.

## 4.11 Adjusting Image Focus

Camera heads compatible with the CCU does not support detachable lenses. The focal length of the camera heads is  $25 \text{ mm} \pm 20\%$ .

You can press the AF button on the camera head to perform autofocus, or rotate the focusing ring to perform manual focus.

#### 4.12 Zoom In/Out

In the setup menu, select **Image Zoom** to zoom in/out on the displayed image. For detailed setting method, refer to **5.3.1 Adjusting Image View**.

In addition, if the function of P, W, or M button on the camera head is set to **Image Zoom**, you can press the button to adjust the image magnification. For details about how to set the functions of camera head buttons, refer to **5.5 Setting Camera Head Functions**.

## 4.13 Switching Display Modes

The system provides the following display modes:

- WhiteLight: displays the visible light image.
- Overlay: detected near-infrared light (NIR) signal is overlaid on white light image in green.
- Monochromatic: displays the NIR signal without white light.
- Intensity Map: detected NIR signal is overlaid on white light image in pseudo color.
- WL-Quad Screen: the monitor displays in split-screen mode, by default with WhiteLight image on the right, Monochromatic image on the top left, Intensity Map image on the middle left, and Overlay image on the bottom left.
- OL-Quad Screen: the monitor displays in split-screen mode, by default with Overlay image on the right, WhiteLight image on the top left, Intensity Map image on the middle left, and Monochromatic image on the bottom left.
- Mono-Quad Screen: the monitor displays in split-screen mode, by default with Monochromatic image on the right, WhiteLight image on the top left, Intensity Map image on the middle left, and Overlay image on the bottom left.
- IS-Quad Screen: the monitor displays in split-screen mode, by default with Intensity Map image on the right, WhiteLight image on the top left, Monochromatic image on the middle left, and Overlay image on the bottom left.

When different camera head or 3D video endoscope is connected to the CCU, the supported display modes are as follows:

CCU Model	Camera Head or 3D Video Endoscope	Display Mode	
UX4 series	Fluorescence camera head	All modes	
	White light camera head 3D video endoscope	WhiteLight only	
UX5 series	Fluorescence camera head	All modes	
	White light camera head 3D video endoscope	WhiteLight only	
UX7 series	Fluorescence camera head G series 3D video endoscope	All modes	
	White light camera head M series 3D video endoscope	WhiteLight only	

You can customize the short-press function of P, W, or M button on the camera head to **Mode Cycle**, and short press the button to switch the display mode. For details about how to set the functions of camera head buttons, refer to **5.5 Setting Camera Head Functions**.

In addition, you can switch modes on the **Display Mode** page. For detailed setting method, refer to **5.3.3 Setting External Input Source**.

## 4.14 Taking Photos or Recording Videos

During surgery, you can press the buttons on the touchscreen or press the camera head buttons to take photos or record videos. The images and videos can be stored in the USB drives or an external video recorder. The specification of images and videos are as follows:

Item	Storage Format	Performance	
Image	.jpeg	Highest storage resolution: 4K	
Video	MP4	Frame rate: 60 fps Bit width: 10bit or 8bit Encoding standard: H.265	

After startup, set the storage location and video quality by referring to **5.6 Setting Recording Function**.

After setting, when you take photos or videos for the first time, a new file directory will be generated under the storage location, and images and videos recorded during this surgery will be saved to this file directory.

The name of a file directory shows the time of the corresponding surgery, and the name of a video screenshot indicates the name of the corresponding video. The name formats of file directory, video and image are as follows:

Item	Example of Name	Format Meaning
File directory	20230510_1202	year month day_hour minute
Video	Section01_0510_12021 2.mp4	Section Nomonth day_hour minute second.mp4
Image (not video screenshot)	Section00_120745.jpeg	Section00_hour minute second.jpeg
Image (video screenshot)	Section01_000402.jpeg	Section Nohour minute second.jpeg

When recording is stopped and "Saving Video" is displayed in the lower left corner of the monitor, do not disconnect the USB drives or the external video recorder.

## 4.15 Connecting the Wireless Network

You can add wireless networks for the system. The CCU can interconnect with external devices supporting open communication protocols via wireless networks to send, receive, and display device parameters or status. For detailed setting method, refer to **5.7.2.3 Setting Wireless Network**.

If connecting the current wireless network fails, the CCU automatically connects other wireless networks in the order when they were added.

#### CAUTION

- The maximum distance of distinct vision between the equipment and a wireless interconnected device is 30 m.
- Wireless network designing, deploying, debugging, and maintenance should be executed by Mindray service personnel or authorized technicians.
- Always set the wireless network according to local wireless regulations.
- Use the 5 GHz band as much as possible since the 2.4 GHz band has more interference.
- Private AP/wireless routers are not allowed, which will cause data loss.
- Data communication must be performed within a closed network provided by a hospital for all network functions. The hospital is responsible for ensuring the security of the network.
- Adopt WPA2-PSK and WPA2-Enterprise authentication and encryption as far as possible. Failure to use them may cause device malfunction or patient information leakage. You are advised to use WPA2-Enterprise and longpassword encryption.
- Keep network authentication information (such as password) safe, protecting the network from being accessed by unauthorized users.

- Do not connect non-medical devices to the network of the main unit.
- If wireless network signal is poor, there may be a risk of data loss.
- RF interference may result in wireless network disconnection.
- Disconnecting from the network may result in data loss and function failure.
   Check the patient in case of network disconnection and solve the network problem as soon as possible.
- Ensure that the IP address setting is correct. Changing the network settings may result in network disconnection. Contact your service personnel if you have any problems on setting the IP address.

#### **NOTE**

 When the network is reconnected, the wireless connection is restored automatically.

## 4.16 Error Messages

Message	Possible Cause	Attemptable Solution
Light Source Disconnected.	The light source is not properly connected to the CCU.	Connect the light source to the CCU by referring to <b>3.6.1 System Connection</b> .
	The light source is not turned on.	Turn on the light source.
Incompatible Light Source.	The light source connected to the CCU is not compatible.	Use the light source specified by Mindray.
DVR Initialization Error	The DVR module failed to initialize.	Restart the CCU. If the problem persists, contact Mindray.  If USB storage is not required, the surgery will not be affected.
Camera Head Connection Error	The camera head is not properly connected.	Reconnect the camera head.
	The camera head is faulty.	Replace the camera head.
Camera Head Disconnected	The camera head is not properly connected.	Connect the camera head to the correct connector on the CCU.
	The camera head cable is broken.	Replace the camera head.
Incompatible Camera Head	The camera head connected to the CCU is not compatible.	Use the camera head specified by Mindray.

- ◆ Select **Mode 1** to display the external input image in the main window on the right and the image captured by the system in the small window on the left.
- ◆ Select **Mode 2** to display the image captured by the system in the main window on the right and the external input image in the small window on the left.
- 4. If two monitors are connected, you can select **Dual-Screen Display**, and set **Dual-Screen Display**.
  - ♦ When **Close** is selected, the monitors will display only image captured by the system.
  - ◆ Select **Dual-Screen Display** to display the external input image and the image captured by the system on each of the two monitors.

## 5.3.4 Setting 3D View Effects

When connecting a 3D video endoscope, to set the 3D view effects, follow the procedure below:

- 1. In the setup menu, select **Display** → **3D Setup**.
- 2. Set View Mode to 2D, 2D AutoRotate, 3D, or 3D AutoRotate.
  - ◆ 2D: displays 2D image.
  - ◆ 2D AutoRotate: displays 2D image. Image can automatically rotate.
  - ♦ 3D: displays 3D image.
  - ◆ 3D AutoRotate: displays 3D image. Image can automatically rotate.
- 3. Select **Advanced Setup** to enter the **Advanced Setup** page.
- 4. Select the + or icon to set **Parallax Setup** or select **Reset** to restore the factory defaults.
- 5. Select the + or icon to set **Autoswitch Angle** and **Set Transition Angle**.
- 6. Switch on or switch off **Direction Indication Arrow.** 
  - If it is switched on, an arrow is displayed to indicate the actual forward direction in 2D AutoRotate or 3D AutoRotate mode.
  - If it is switched off, no arrow is displayed.

#### NOTE

- To select a 3D view mode, set the monitor to 3D display mode in advance.
- For details about the view modes, refer to the operator's manual of the 3D video endoscope.

## 5.4 Setting Image Mode

Select the Setup button on the main screen to access the setup menu. Select the **Image** tab. On this tab, you can perform image optimization, adjust image color, set fluorescent image, and set specialist image.

## 5.4.1 Performing Image Optimization

To perform image optimization, follow the procedure below:

- 1. In the setup menu, select Image → Image Opt..
- 2. Switch on or switch off **Detail Enhancement**, **Color Enhancement**, **Homogenous Brightness** and **Anti-fog**.
- 3. When connecting a camera head, switch on or switch off **HDR**.

#### **NOTE**

 After Anti-fog is switched on, the equipment applies algorithms to implement image defogging.

### 5.4.2 Adjusting Image Color

To adjust the image color, follow the procedure below:

- 1. In the setup menu, select Image → Color Setup.
- 2. Set **Color Style**. For detailed introduction of the options, refer to **2.7 Differences Among Models**.
- 3. Select the + or icon to set **Saturation**, **Red Gain**, or **Blue Gain**. Or select **Reset** to restore the factory defaults.

## 5.4.3 Setting Fluorescent Image

When connecting a fluorescence camera head or G series 3D video endoscope, you can set fluorescent image. Follow the procedure below:

- 1. In the setup menu, select **Image** → **Fluorescence**.
- 2. Set Fluorescence Sensitivity.
  - ◆ Select Level 1, Level 2 or Level 3(Autofluorescence).
  - Select **Level 0**, high-sensitivity processing is not performed.

## **5.4.4** Setting Image Parameters for Special Departments

To set image parameters for special clinical departments, follow the procedure below:

- 1. In the setup menu, select **Image** → **Specialty**.
- 2. When connecting a camera head, switch on or switch off **De-grid Optimization** and **Anti-laser Optimization** under **Special Function**.

- 3. Switch on or switch off **Tone Enhancement**. After switching on it:
  - ◆ Set **Tone Enhancement Mode** to **Mode R** or **Mode G** as needed. After setting, the system enhances the image color contrast by color inversion.
  - Set **Display Mode** to **Full Screen** or **Dual Split** as needed.

## 5.5 Setting Camera Head Functions

Select the Setup button on the main screen to access the setup menu. Select the **Camera Head** tab. On this tab, you can set functions of the P, W, and M buttons to performing white balance, taking photos, recording, or controlling the brightness of light.

### 5.5.1 Introduction to Short-press/Long-press Functions

The following table lists the short-press functions that you can set for the buttons:

Short-Press Function	Description
Capture	Short press the button to capture the image displayed on the monitor.
Mode Cycle	Short press the camera head button to cycle through display modes.
Image Zoom	Short press the button to zoom in or out of the image displayed on the monitor.
WL Brightness	Short press the button to increase or decrease the image brightness.
Fluor Intensity	Short press the button to increase or decrease the fluorescence intensity.
3D/2D Switching (with 3D video endoscope)	Short press the button to cycle through 3D view modes.
External Source	Short press the button to display the external input source on the monitor.
Interconnection	Short press the button to display parameters of interconnected devices on the monitor.
Tone Enhancement	Short press the button to cycle through the tone enhancement modes.
Counter	Short press the button to start/stop timing or reset the timer. The recorded time is displayed on the monitor.
Smoke Evacuation	Short press the button to turn on or off the smoke exhaust function of the interconnected insufflator.
Anti-fog	Short press the button to turn on or off the image defogging function.

Short-Press Function	Description
Image Flip	Short press the button to switch the image flip mode.
No Function	Short-press of the button will not activate any function.

The following table lists the long-press functions that you can set for the buttons:

Long-Press Function	Description
Capture	Long press the button to capture the image displayed on the monitor.
REC	Long press the button to start/stop recording video displayed on the monitor.
White Balance	Long press the button to start white balance.
3D/2D Switching (with 3D video endoscope)	Long press the button to cycle through 3D view modes.
External Source	Long press the button to display the external input source on the monitor.
Interconnection	Long press the button to display parameters of interconnected devices on the monitor.
Tone Enhancement	Long press the button to cycle through the tone enhancement modes.
Counter	Long press the button to start, stop timing or reset the timer. The recorded time is displayed on the monitor.
Insufflator Switch	Long press the button to turn on or off the inflation function of the interconnected insufflator. Prompts of insufflation status and insufflator parameters will be displayed on the monitor.
Smoke Evacuation	Long press the button to turn on or off the smoke exhaust function of the interconnected insufflator.
Light Switch	Long press the button to stop the interconnected light source from emitting light or turn on the brightness automatic adjustment.
Anti-fog	Long press the button to turn on or off the image defogging function.
Image Flip	Long press the button to switch the image flip mode.
No Function	Long-press of the button will not activate any function.

#### **5.5.2 Setting Button Functions**

To set the functions of the camera head buttons, follow the procedure below:

- 1. In the setup menu, select **Camera Head**.
- 2. On the **P Key** page, set the short-press function and long-press function of the P button.
- 3. On the **W Key** page, set the short-press function and long-press function of the W button.
- 4. On the **M Key** page, set the short-press function and long-press function of the M button.
- If the short-press function is set to Mode Cycle, set Display Mode Selection as needed.
- 6. If the short-press function is set to **Image Zoom**, set **Image Zoom Selection** as needed.
- 7. If the short-press or long-press function is set to **External Source**, set **Display External Source** as needed. For detailed introduction of the display modes, refer to **5.3.3 Setting External Input Source**.
- 8. If the short-press or long-press function is set to **Tone Enhancement**, set **Tone Enhancement Mode Selection** as needed.
- 9. If the short-press or long-press function is set to **Counter**, set **Reminder Interval** as needed.

## 5.6 Setting Recording Function

Select the Setup button on the main screen to access the setup menu. Select the **REC** tab. On this tab, you can set recording or screenshot function, or format USB drives.

## 5.6.1 Setting Recording Function

To set the recording function, follow the procedure below:

- 1. In the setup menu, select **REC**  $\rightarrow$  **REC** Setup.
- 2. Set **Storage Location**.
  - ◆ Internal Recorder: Videos and images are saved to USB drives by default.
  - External Recorder: Videos and images are saved to the external video recorder.
  - ♦ Internal&External Recorder: Videos and images are saved to USB drives and the external video recorder at the same time.
- 3. Select **Video Segment** to set the size of each video saved to USB drives.
- 4. Select **Video Quality** to set the quality of the videos saved to USB drives.
  - ◆ **4K HQ**: Record video at 120 Mbps.

- 3. Set **Language**. Select the current language and all the languages the system currently provide are displayed. Select the target language.
- 4. Restart the system for the settings to take effect.

#### 5.7.1.6 Setting System Time

To set the system time, follow the procedure below:

- 1. In the setup menu, select **System** → **General Setup**.
- Select Setup on the right side of Language&Date&Time to access the Language & Time Settings screen.
- 3. Set **System Date** and **System Time**. Select the edit button and enter the current date and time.

#### **NOTE**

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

#### 5.7.1.7 Checking Version Information

To check the software version of the system, follow the procedure below:

- 1. In the setup menu, select **System** → **General Setup**.
- 2. The software version is displayed on the right of **Version**.

## 5.7.2 Setting Device Interconnection Function

After setting the equipment location, wireless network, and multicast parameters, you can enable the device interconnection function when interconnected devices are correctly connected to the CCU. To set these information, follow the operations below.

#### **5.7.2.1 Setting Equipment Location**

To set the location of this equipment, follow the procedure below:

- 1. In the setup menu, select **System** → **Device Connect**.
- 2. Switch on or switch off **Auto Position Acquisition**.
  - If it is switched on, the CCU will obtain the device location automatically, and there is no need to set **Device Location**.
  - If it is switched off, select Device Location.
- 3. Set **Dpt.** and **Hospital**. Select the edit button and enter names for the department and hospital.

After setting, this equipment can be interconnected to medical devices that are set to the same department, hospital, and device location, for example, a patient monitor.

## mindray

# Rigid Endoscope Small Diameter, Big Vision









## Small Diameter, Big Vision

The heatable front end provides effective anti-fogging, which helps deliver smooth surgery.

A large depth of field of 3-200mm provides consistently clear views, eliminating the need for repeated refocusing.

A channel diameter of  $\Phi$ 5.45mm ensures greater luminous flux while smoothly passing through a variety of 5mm-size trocars.

The control body has been specially polished to retain grease more easily, allowing for smooth entry and exit of trocars.

The Standard 300mm and Lengthened

450mm Type are adaptable for use in

various surgeries.

The format size is consistent with that of the  $\Phi$ 10mm endoscope, which enables easy full-screen view.





## Standard 5mm Type

G Series-Compatible with fluorescent & white light



Recommended Surgery: Single-port gynecologic surgery, thoracic surgery

Product	Diameter	Working Length	Field of View	Code
0°	5.45mm	300mm	85°	G 00500A
30°	5.45mm	300mm	85°	G 00530A

## **Lengthened 5mm Type**

G Series-Compatible with fluorescent & white light

G Series-Compatible with fluorescent & white ligh

M Series-Applicable with white light



Recommended Surgery: ==

Single-port gynecologic surgery, single-port bariatric surgery, breast and thyroid surgery

Product	Diameter	Working Length	Field of View	Code
0°	5.45mm	450mm	85°	G 10500A
30°	5.45mm	450mm	85°	G 10530A

## Standard 10mm Type

Recommended Surgery: General Surgery

Product	Diameter	Working Length	Field of View	Code
0°	10mm	321mm	80°	M 01000A / G 01000A
200	10mm	321mm	80°	M 01030A / G 01030A



## Rigid Endoscope Tray

Product Name	Placed Items	Dimensions (mm)	Code
Small Rigid Endoscope Tray	Standard 5 or 10mm Rigid Endoscope	496×90×44	X TR500944
Long Rigid Endoscope Tray	Lengthened 5mm or 3D Electronic Endoscope	643×158×75	X TR641675

## HB500R/HB500R-TEC/HB500/HB500-TEC

**Endoscope Light Source** 

**Operator's Manual** 



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Release time: 2023-10

Revision: 2.0

1

For endoscopic interventions, the responsible physician must decide whether the prescribed application is admissible based on the general condition of the patient.

#### 2.6 Differences Among Models

The differences among models are shown below:

Model	Levels of Light Intensity	Output Light
HB500R	12	Output of white light and
HB500R-TEC	10	near infrared light is provided.
HB500	12	Output of white light is
HB500-TEC	10	provided.

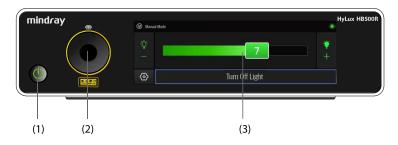
#### 2.7 Applied Part

Light cable is considered as type CF applied part except the proximal end connected to the main unit of light source.

#### 2.8 System Components

The light source consists of a main unit and cables.

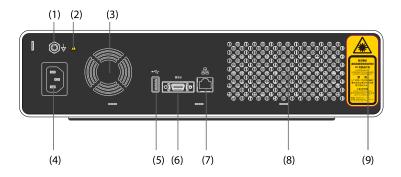
#### 2.8.1 Front View of the Main Unit



- (1) Power switch: turns on or off the main unit. The switch also has an embedded light that indicates the power status of the main unit:
  - Off: AC (Alternating Current) power is not connected.
  - Orange: AC power is connected, but main unit is off.
  - Green: the main unit is on.
- (2) Light outlet and light cable connector: the light outlet, used to connect a light cable.

(3) Touchscreen: displays equipment status and changes settings.

#### 2.8.2 Back View of the Main Unit



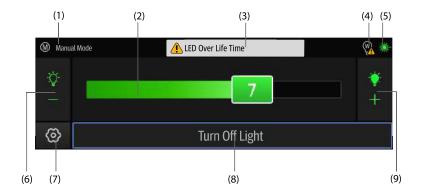
- (1) Equipotential grounding terminal: when using the equipment together with other devices, connect their equipotential grounding terminals together to eliminate potential difference.
- (2) General warning sign
- (3) Ventilation outlet: used for heat dissipation.
- (4) AC power input: connects the AC Mains.
- (5) USB connector:connects a USB drive for system upgrade.
- (6) MSB (Mindray Serial Bus) connector: connects to a camera control unit (CCU).
- (7) Network connector: supports software upgrade.
- (8) Ventilation outlet: used for heat dissipation.
- (9) Laser warning label: read the messages carefully to avoid any possible safety risks.

#### **NOTE**

Dry the equipment immediately in case of rain or water spray.

#### 3.7.1 Operation Screen Introduction

The following figure shows the operating screen of the equipment:



- Mode area: indicates the current mode. Select this area to switch between the manual mode and auto mode.
- (2) Brightness indication area: indicates the current brightness of light. Move the slider to adjust the brightness of light. If the equipment is in the auto mode, "AUTO" is displayed in this area.
- (3) Error message area: displays error messages.
- (4) Bulb status symbol: indicates the service life status of the bulb. For detailed introduction of the symbols, refer to 3.7.2 On-screen Symbols.
- (5) Laser diode (LD) status symbol: indicates the status of LD output. This symbol is dimmed when the LD is off. For detailed introduction of the symbols, refer to 3.7.2 On-screen Symbols.

(6)

Brightness decrease button :: select to decrease the brightness of light (the illumination intensity of the light source).

- (7) Setup button : select to display the setup menu.
- (8) Light control button: select to turn on/off the light output.

#### **NOTE**

 Do not press the power switch of the equipment with sharp or hard objects to avoid damaging the button.

#### 4.3 Check Before Startup

Check the following items before starting the equipment:

- The temperature, humidity, and atmospheric pressure meet the requirements, and installation sites are clean.
- No condensation occurs.
- Surface of the equipment and peripheral devices have no signs of distortion, damage, or contamination.
- All devices and accessories connected with the equipment are compatible.
- No rough surface, sharp edges, or protrusions exist 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.
- No irrelevant objects are on top of the equipment. The ventilation outlet is not covered by dust or other objects.
- No obstacles are in the movement range of the system or near the ventilation outlet.

#### 4.4 Starting the System

- 1. Connect the equipment to the AC mains.
- 2. Press the power switch on the front panel to turn on the equipment.

#### 4.5 Check Before Operation

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

- The system does not emit abnormal noise, smell, or excessive heat.
- Put a hand near the ventilation outlet and check that there is air flowing out.
- The touchscreen displays and functions correctly.
- After light cable is connected, light is emitted normally.
- Adjust the light brightness to a proper level, and confirm that the image brightness meets surgical requirements.

#### **CAUTION**

- Do not put the system in use before the system is checked and works normally.
- Do not use an optical observer (such as an amplifier) to or directly look at the light outlet of the light source.
- If you need to connect or disconnect a light cable when the light source is on, make sure that the light source is not emitting light. Otherwise, eye injury may result.
- When no light cable is connected, the equipment generates a prompt and does not emit light by default. However, do not look directly at the light outlet in case the light cable detection fails.
- 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 Switching Between Manual and Auto Modes

Select the Mode area on the main screen to switch between manual and auto modes.

- In manual mode, you can adjust the brightness of light on the main screen. For detailed operations, refer to 4.8 Adjusting the Brightness of Light.
- After the light source is connected to a Mindray UX5 series CCU, you can switch to the auto mode. In Auto mode, the CCU can automatically adjust the brightness of light.

#### 4.7 Turning On the Light

The light source does not emit light after startup. You can select the Light control button on the main screen to turn on the light.

When a Mindray UX5 series CCU is interconnected, you can turn on the light by using a camera head button or the CCU touchscreen. For detailed setting method, refer to the operator manual of the CCU.

For HB500R/HB500R-TEC, after you select the Light control button, white light is emitted by default. Further, if a Mindray UX5 series CCU is interconnected, when you enable the IR display mode, the light source emits LD. You can also turn on LD on the touchscreen. For detailed operations, refer to **4.9.1 Changing Function Setup**.

#### **WARNING**

 To reduce the impact of laser on the human body, turn on the LD only when the endoscope enters the human body and the fluorescence observation is necessary. Turn the LD off immediately after the fluorescence observation is completed.

#### **NOTE**

• After a compatible CCU is interconnected, if you press the white balance button, the light source begins emitting light automatically and quickly adjusts the brightness to a proper level. If you press any other camera head button, the light source begins emitting light as well, but in slower way to minimize damage to the operator's eyes. Once the endoscope is withdrawn from the patient, the light will automatically dim. For detailed setting method, refer to the operator's manual of the CCU.

#### 4.8 Adjusting the Brightness of Light



In manual mode, you can press the Brightness decrease button — or Brightness increase



button + on the main screen to decrease or increase the brightness of light, meeting the brightness requirements of different clinical operations. You can also move the slider in the Brightness indication area to the left or right to adjust the brightness.

#### **NOTE**

- Always adjust the equipment to the minimum brightness necessary for the observation, to avoid the risk of burns.
- Do not use strong light for a long time.

## 4.9 Changing Settings

#### 4.9.1 Changing Function Setup

Select the Setup button on the main screen to access the setup menu. The **Light Source** tab is displayed. In this tab, you can set **Upper Limit**. For HB500R/HB500R-TEC, you can also switch on or switch off **NIR**.

#### **NOTE**

If the white light is not turned on, the switch of NIR is unavailable.

#### 4.9.2 Changing System Settings

Select the Setup button on the main screen to access the setup menu. Select the **System** tab. In this tab, you can set general system information.

General system information includes lock screen function, system language, system time, and version information. To set these information, follow the operations below.

#### 4.9.2.1 Setting Lock Screen Function

To set the lock screen function, follow the procedure below:

- 1. In the Setup menu, select **System** → **General Setup**.
- 2. Switch on or switch off **Screen Lock Function**.
  - Select ON to enable the lock screen function. When this function is enabled, the touchscreen will be locked automatically if no operation is detected in one minute.
  - ◆ The lock screen function will not be enabled if **OFF** is selected.

#### 4.9.2.2 Setting System Language

To set the system language, follow the procedure below:

- In the Setup menu, select System → General Setup.
- 2. Set **Language**. Select the current language and all the languages the system currently provide are displayed. Select the target language.
- 3. Restart the system for the settings to take effect.

#### 4.9.2.3 Setting System Time

To set the system time, follow the procedure below:

- 1. In the Setup menu, select **System** → **General Setup**.
- Set System Date and System Time. Select the Edit button to set the current date and time.

#### NOTE

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

#### 4.9.2.4 Checking Version Information

To check the software version of the system, follow the procedure below:

- 1. In the Setup menu, select **System** → **General Setup**.
- 2. The software version is displayed on the right of **Version**.

#### 4.10 Error Messages

Message	Possible Cause	Attemptable Solution
Device Initialization Error	Equipment failure occurs.	Remove the system from use and use the backup one.
CCU Disconnected.	The MSB cable is not correctly connected.	Check the connection of MSB cable and reconnect the cable.
	The CCU is not turned on.	Turn on the CCU.
Incompatible CCU.	The CCU connected to the light source is not compatible.	Use the CCU specified by Mindray.
Device Overheats	The ventilation outlet is blocked.	Clear the blockage from the ventilation outlet.
	The room temperature exceeds the limit.	Reduce the room temperature.
LED Over Life Time NIR Over Life Time	The bulb has reached the end of its service life.	Contact your service personnel.
Connect light cable with a click.	The light cable is not properly connected.	Replug the light cable.

#### **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.

## 4.11 Removing the System from Use

To remove the system from use after the surgery or if system failure occurs, follow the procedure below:

- 1. Withdraw the endoscope from the patient.
- 2. Turn the equipment off.
- 3. Remove the light cable from the endoscope.

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

#### **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 the service personnel.

## **A.3** Power Supply Specifications

Working power supply	100-240VAC (±10%), 50/60 Hz (±3 Hz)
Input power	260VA

## A.4 Physical Specifications

Dimension	Depth: $380 \pm 5$ mm Width: $350 \pm 5$ mm Height: $80 \pm 5$ mm (excluding the rubber feet)
Weight	≤ 10 kg

### **A.5** Hardware Specifications

Display type (CCU)	Touchscreen
Display size (CCU)	7.8 inches
Device interfaces	Power socket: 1, connecting the AC Mains
	MSB connector: 1, supporting serial communication protocol
	USB connector: 1, supporting USB 2.0 protocol. Fixed time synchronization pulse specified by the USB protocol
	Network connector: 1, RJ45 interface, supporting 100BASE-TX protocol.  Calibration protocol of TCP/IP
	Light cable connector: 1, connecting the light cable
Bulb type	HB500R/HB500R-TEC: LED, which outputs white light, and semiconductor lasers (class 3R), which output near-infrared light HB500/HB500-TEC: LED, which outputs white light

Service life of bulb	LED: over 60000 hours Semiconductor lasers: over 15000 hours
Bulb specification	LED: 3.5 V, 27 A Semiconductor lasers: 4 V, 8.5 A
Diameter of light outlet	Φ7.2 ± 0.5 mm

## **A.6** Performance Specifications

Maximum central illumination	≥ 3000000 Lux
Color temperature	3000K - 7000K
Color rendering index	≥90, in the white light mode
Maximum noise	≤ 55 dBA
Defibrillation recovery time	1s

## A.7 Laser Performance (for HB500R/HB500R-TEC)

Laser wavelength	780nm $\pm$ 10nm ; Full width at half maximum (FWHM): 5 nm $\pm$ 5nm
Beam divergence angle	70° ± 10°
Classification	3R
Test value of laser output safety sign	≤ 50 mW

## **A.8** Operating Environment

Hardware configuration	CPU: 500 MHz RAM: 2 Gb Flash: 4 GB
Software environment	LINUX

NOTE: The above is the minimum requirements of operating environment.

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#### TABLE EMC-6

## RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATION DEVICE AND ENDOSCOPE LIGHT SOURCE

Endoscope Light Source is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and device as recommended below, according to the maximum output power of the communication equipment.

Rated Maximum	Separation Distance According to Frequency of Transmitter (m)			
Output Power of Transmitter Watts (W)	$150 \text{ kHz} - 80 \text{ MHz}$ Out ISM bands $d = 1.2 \sqrt{P}$	$150 \text{kHz} - 80 \text{MHz}$ in ISM bands $d = 1.2 \sqrt{P}$	$80 \text{MHz-} 800 \text{MHz}$ $d = 1.2 \sqrt{P}$	800 MHz - 2.7 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.2	0.12	0.23
0.1	0.38	0.64	0.38	0.73
1	1.2	2	1.2	2.3
10	3.8	6.4	3.8	7.3
100	12	20	12	23

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.

Note1: 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.

#### LC0005S/LC0003S Light Cable Instructions for Use

#### Statement

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

Mindray is responsible for the effects on safety, reliability and performance of this product, only if:

- (1) this product is used in accordance with the instructions for use. (2) this product is not damaged by human factors. Human factors
- refer to unintentional falling, intentional damaging, etc. In the event that it becomes necessary to return a unit to Mindray, please contact the Mindray Service Department and obtain a Mindray Customer Service Authorization Number. The Mindray Customer Service Authorization Number must appear on the outside of the shipping container. Return shipments will not be accepted if the Mindray Customer Service Authorization Number is not clearly visible. Please provide the model number, serial number, and a brief description of the reason for return. The customer is responsible for freight charges when this product is shipped to Mindray for service (including any relevant customs fees or other freight related charges).

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#### **Notification of Adverse Events**

As a health care provider, you may report the occurrence of certain events to SHENZHEN 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, SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. requests to be notified of device failures or malfunctions. This information is required to ensure that SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. provides only the highest quality products.

#### **Important Information**

- 1. It is the customer's responsibility to maintain and manage the product after delivery.
- 2. The warranty does not cover the following items, even during the warranty period:
  - (1) Damage or loss due to misuse or abuse.
  - Damage or loss caused by force majeure such as fires, earthquakes, floods, and lightning.
  - Damage or loss involving the product purchased from a channel other than Mindray or its authorized agency.
- 3. This product shall not be modified without permission.
- 4. In no event shall Mindray be liable for the damage caused by alteration, modification, or repair performed by personnel other than those designated by Mindray.
- 5. At the end of the service life of the product, please contact Mindray or its agency. Mindary shall not be liable for the result if you do not consult Mindray or its agency about disposal of the product.
- 6. This manual contains warnings regarding foreseeable potential dangers, but you shall always be alert to dangers other than those
- 7. Mindray shall not be liable for damage or loss that results from negligence or from ignoring the precautions and operating instructions described in this manual.
- 8. This manual shall always be kept properly so that it can be obtained conveniently as needed.

#### I. Intended Use

The light cable is used to transmit light during the endoscopic diagnosis and treatment. In the medical field, it is used with the cold light source of endoscopes.

#### 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.

#### II. Specifications

Model	LC0005S	LC0003S
Length of light cable	3000 mm ± 10%	
Diameter of exit optical fiber	Φ4.8 mm ± 0.1mm	Φ3.5 mm ± 0.1mm
Minimum bending radius	50mm	

#### III. Introduction



- 1. Connector (to light source)
- 2. Light source adapter
- 3. Connector sleeve
- 4. Anti-bending device
- Connector (to endoscope)

#### **IV. Safety Precautions**

#### **↑** WARNING

Risk of patient injury

- Ensure that all endoscopic equipment is properly connected and functioning before inserting the endoscope into a patient.
- Use this product only along with the endoscopic device specified by Mindray.

#### **∴** CAUTION

Risk of patient injury

Light source produces a lot of heat, causing a high temperature at the connector and front end of the endoscope. It may result in the following risk:

- Scalding the patient (for example, when the small cavity of the lumen is exposed to excessive lighting, or the front end of the endoscope is close to the tissue).
- Burn of the patient or user's skin.
- Combustion or burning-out of surgical instruments (such as surgical drapes, and plastic materials).
- It is forbidden to place the endoscopic equipment on the patient's skin, flammable materials, or temperature-sensitive materials
- Adjust the output power of the light source to make the minimum brightness required to illuminate the target area. Avoid excessive exposure to strong light.

#### M CAUTION

Risk of user injury

When the light source is on, do not look straight at the endoscopic connector of the light cable because that may cause eye injury.

#### V. Removal After Use

### **∴** CAUTION

Risk of user injury

Touching the light cable connector when its temperature is high may cause scalding.

Cool the light cable after use.

#### INSTRUCTION

Risk of product damage

Sudden change in temperature may cause damage to the product.

- Cool the light cable after use.
- It is forbidden to use liquid to cool the light cable.

#### **INSTRUCTION**

Risk of product damage

Pulling the cable may damage the product.

• To unplug the light cable from the light source, grasp the plastic shell of the connector.

#### VI. Cleaning, Disinfection, and Sterilization

Clean, disinfect and sterilize this product regularly based on the local or hospital's regulations related to cleaning, disinfection, and sterilization. A protective cap is provided together with the product before delivery, as shown in the following figure. Remove the protector before cleaning, disinfection, and sterilization.



#### 1. Cleaning and Disinfection

- (1) Disconnect the light cable from the devices, including light source and endoscope.
- Use a soft cloth dipped in an appropriate amount of water to remove leftover on the surface of the light cable.
- Use a clean soft cloth dipped in an appropriate amount of ethanol (75%) to wipe the surface of the light cable.
- Use a dry soft cloth to wipe off detergent on the surface of the light cable, and place the light cable in a ventilated and cool environment to air dry it.

#### 2. Sterilization

The recommended sterilization method is pressure steam sterilization. For loading method of pressure steam sterilization, please refer to the corresponding sterilizer operation instructions.

The procedure is as follows:

- Remove the light source adapter from the light cable.
- Put the product in a sterilization box, and wrap two layers of sterile sheets to prevent contamination during storage and transportation after sterilization.
- Perform pressure steam sterilization as instructed in the manual for using the sterilizer.

The pressure steam sterilization parameters are as follows:

Sterilization process	Temperature	Minimum required time
Pulsation vacuum	132°C - 134°C	4min

#### **↑** WARNING

Risk of patient/medical staff injury

Improper or inadequate cleaning, disinfection, and sterilization may result in infection of the patient or medical staff or product damage.

- Clean, disinfect, and sterilize the product for the first use and before each use.
- Clean, disinfect and sterilize the product properly according to this manual.

#### VII. Warranty

If a user or unauthorized person repairs or modifies the product privately, the warranty of the Mindray becomes invalid. The product damage caused by improper use is not covered by the warranty.

#### **VIII. Operating Environment**

- 1. Temperature: 0°C +35°C
- 2. Humidity: 30% 85% RH, non-condensing
- 3. Atmospheric pressure: 70 kPa 106 kPa

#### IX. Storage and Transportation Environment

- 1. Temperature: -20°C +60°C
- 2. Humidity: 30% 95% RH, non-condensing
- 3. Atmospheric pressure: 70 kPa 106 kPa

Put clean and disinfected products in packages capable of isolating the products from bacteria, and store them in a dark, cool, and wellventilated room.

#### X. Equipment Symbols

bol Description	
Medical Device	
Manufacturer	
Date of manufacture	
TYPE CF APPLIED PART	
Batch code	
Temperature limit	
Humidity limitation	
Atmospheric pressure limitation	
The product bears CE mark indicating its conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfils the essential requirements of Annex I of this directive.  Note: The product complies with the Council Directive 2011/65/EU.	
Refer to instruction manual/booklet	
Authorized representative in the European community	
Comply with the requirements of Directive 2012/19/ EU Waste Electrical & Electronic Equipment	

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## mindray

### LC0005S/LC0003S

## 导光束 使用说明书

Light Cable Instructions for Use



046-020513-00/3 0

#### <u>声明</u>

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- (1) 按照《使用说明书》使用本产品。
- (2) 非人为因素造成的产品损坏。人为因素是指不小心摔落、 蓄意破坏等。

确实需要向迈瑞公司退货时,请联系迈瑞公司售后服务部,告知 产品型号和系列号,并简述原因。若产品的系列号模糊不可辨认, 退货请求将不予接受。

说明书编制日期: 2021年5月

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#### 重要信息

- 1. 购买本产品后,客户对产品的维护和管理负全部责任。
- 2. 即使在保修期内,对下列情况迈瑞将不负责保修:
  - (1) 由于操作不当或故意损坏造成的损坏。
  - (2) 由于不可抗力如火灾、地震、洪水、闪电等造成的损坏。
  - (3) 不是从迈瑞公司或指定的分销商手中购买的迈瑞产品,如 果发生损坏,将不予保修。
- 3. 禁止擅自对本产品做任何改动。
- 4. 非迈瑞公司指定人员对设备进行的重新改装、改动或维修造成的 损坏,迈瑞将不负任何责任。
- 5. 产品报废处理前请联系迈瑞公司或其代理机构。未向迈瑞公司或 其代理机构咨询而对产品进行处理,迈瑞公司不对其所产生的后 果负责。
- 6. 本说明书对可以预见的危险做出了警告。但请在任何时间保持警 惕以防出现其他危险。
- 7. 由于疏忽没有按照说明书中的指引而产生的问题,迈瑞公司将不 对此负责。

8. 请妥善保管本说明书,以确保管理和操作人员可以随时查阅。

#### 一、预期用途

导光束用于在内窥镜诊断和治疗中传输光线。医学领域中,它与 医用内窥镜冷光源配套使用。

#### 二、主要技术参数

<b>型</b> 号	LC0005S	LC0003S
导光束长度	3000 mm ± 10%	
出射端光纤直径	Ф4.8 mm ,允差 ±0.1mm	Φ3.5 mm,允差 ±0.1mm
最小可弯曲半径	50mm	

#### 三、导光束结构



- 1. 导光束接头(光源侧)
- 2. 导光束光源适配套
- 3. 接头套管
- 4. 防折弯装置
- 5. 导光束接头(内窥镜侧)

#### 四、安全注意事项

#### **魚 警告**

患者受伤的风险

- 将内窥镜插入患者体内之前,应始终正确连接内窥镜设备。
- 本产品仅可与迈瑞指定的内窥镜设备配合使用。

#### ⚠ 小心

患者受伤的风险

光源会产生大量热量,导致内窥镜接头与先端部温度升高。可能 会存在以下风险:

- 患者组织烫伤(例如,管腔较小的腔隙暴露在过强的照明下,或内镜先端部与组织距离过近)。
- 患者或用户皮肤烧伤。
- > 手术器械燃烧或烧毁(例如,手术铺巾,塑料材料等)。
- 禁止将内窥镜设备放置在患者皮肤、可燃性材料或对温度敏感的材料上。
- 调节光源的输出功率,达到照亮目标区域所需的最低亮度。避免强光的过度暴露。

#### ⚠ 小心

用户受伤的风险

在光源打开的情况下,直视导光束的内镜接头可能导致眼睛损伤。 因此,光源打开的情况下,禁止直视导光束的内镜接口。

#### 五、使用后拆卸

#### ⚠ 小心

<u>——</u> 用户受伤的风险

导光束上的接头温度过高时,触摸接头可能会导致烫伤。

• 使用后应使导光束冷却。

#### 说明

产品损坏的风险

高温导光束的温度急剧变化会损伤产品。

- 使用后应使导光束冷却。
- 禁止使用液体冷却导光束。

#### 说明

产品损坏的风险

拉拽缆线会损坏产品。

• 从光源上拔下导光束时,应拉动接头的塑料外壳。

#### 六、清洗、消毒和灭菌

请根据当地或医院关于医疗设备清洁消毒的规定定期对本产品进 行清洁、消毒和灭菌。

本产品出厂时配送光纤保护套,如下图所示,清洁消毒及灭菌前请先取下保护套。



#### 1. 清洁和消毒

- (1) 断开导光束与光源、内窥镜等设备的连接。
- (2) 使用一块软布蘸取适量的水除去导光束表面的残留物。
- (3) 使用干净的软布蘸取适量乙醇(75%)擦拭导光束表面。
- (4) 用干的软布擦去导光束表面的清洁剂,并将导光束置于通 风阴凉的环境下风干。

#### 2. 灭菌

推荐使用经验证过的灭菌方法:压力蒸汽灭菌。

压力蒸汽灭菌的装载方法,请参照相应灭菌器的操作说明。 步骤如下:

- (1) 卸下导光束光源适配套。
- (2) 将产品放置在灭菌盒中,并包裹两层无菌单,以防止灭菌 后在存放、运输过程中染菌。
- (3) 参照灭菌器的使用说明书执行压力蒸汽灭菌。

压力蒸汽灭菌器灭菌参数如下:

设备类别	温度	所需最短时间
预真空式	132°C ~ 134°C	4min

#### **魚 警告**

患者 / 医务人员受伤的风险

清洗、消毒和灭菌不当或不充分可能导致患者或医务人员感染和产品提供

- 首次及此后每次使用产品之前,应该进行清洗、消毒和灭菌。
- 按照本说明书,正确进行产品清洗、消毒和灭菌。

#### 七、保修

如果用户或未经授权的人员私自维修或改造产品,则迈瑞公司的 保修将失效。因使用不当导致的产品损坏不在保修范围之内。

#### 八、工作环境

1. 温度: 0℃~+35℃

2. 湿度: 30% ~ 85% RH (无凝露) 3. 大气压: 70 kPa ~ 106 kPa

#### 九、存储和运输环境

1. 温度: -20℃~+60℃

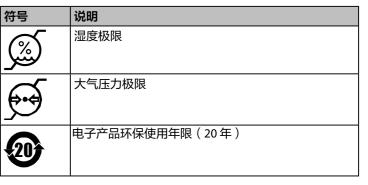
2. 湿度: 30% ~ 95% RH(无凝露)

3. 大气压: 70 kPa ~ 106 kPa

将清洗和消毒处理后的产品置于能隔离细菌的包装中,存放在避 光、阴冷、通风良好的室内。

#### 十、符号

符号	说明
$\overline{\mathbb{V}}$	注意! 查阅随机文件
$\sim$	生产日期
	CF 型应用部分
LOT	批次代码
1	温度极限



#### 售后服务单位

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