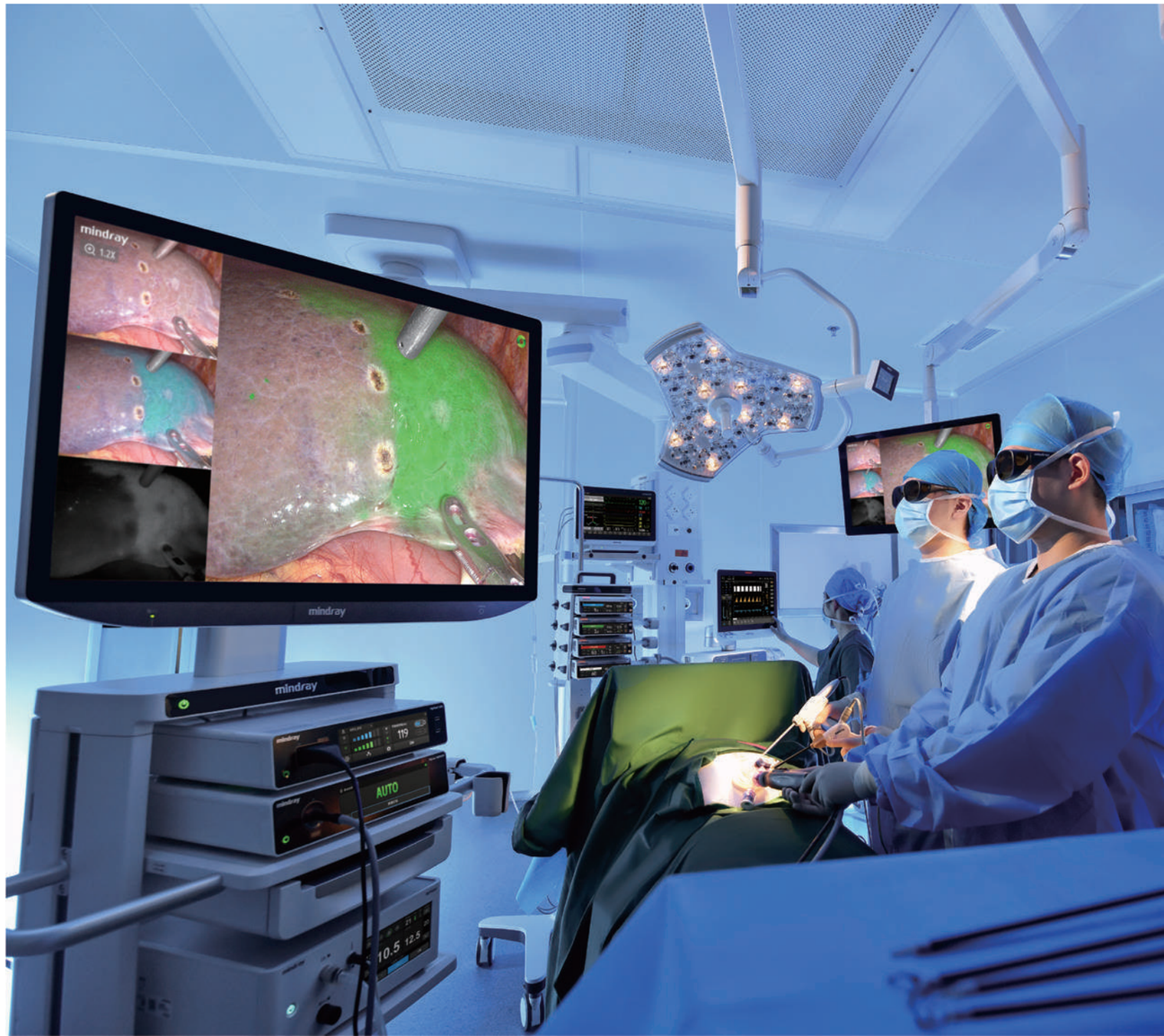
UX7 Series *4K&NIR&3D*

Endoscope Camera System

Vision beyond Imagination



This brochure can be applicable to the following models:

Monitor:
LMD-XH320T/LMD-XH550T/S3180P

Trolley:
TV-500/TV-300

Endoscope Camera System:
UX7/UX7-TEC

Endoscope Light Source:
HB500R/HB500

4K 3D Video Endoscope:
G 31030A/G 31000A/M 31030A/M 31000A

Camera Head:
CH5-SR100/CH5-SR110/CH5-SW100/CH5-SW110

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

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Location: Moldova
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www.mindray.com

P/N: ENG-UX7 Series 4K&NIR&3D Endoscope Camera System-210285X12P-20241205

mindray
healthcare within reach

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
• Recommend: LMD-XH320T/LMD-XH550T

Master Control Trolley
One-touch to start the entire set of equipment on the trolley
• Recommend: TV-500

Endoscope Camera System
Integrated with 4K Fluorescence and 3D Technologies
• Recommend: UX7

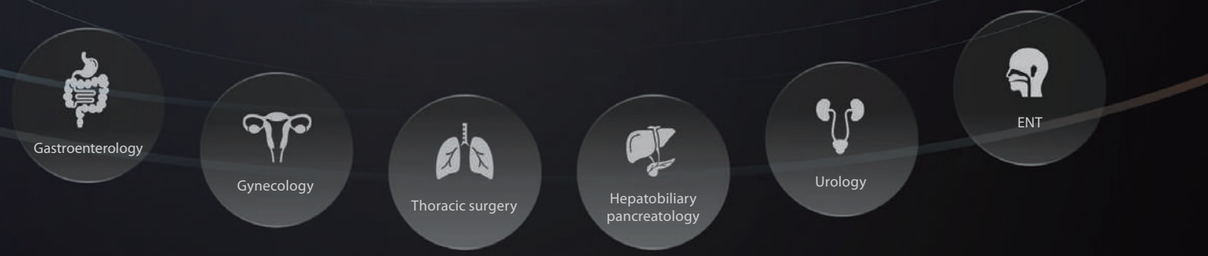
Endoscope Light Source
White Light/Fluorescence
• Recommend: HB500R

4K 3D Video Endoscope
White Light/Fluorescence
Selectable viewing angles of 0° and 30°
• Recommend: G 31030A

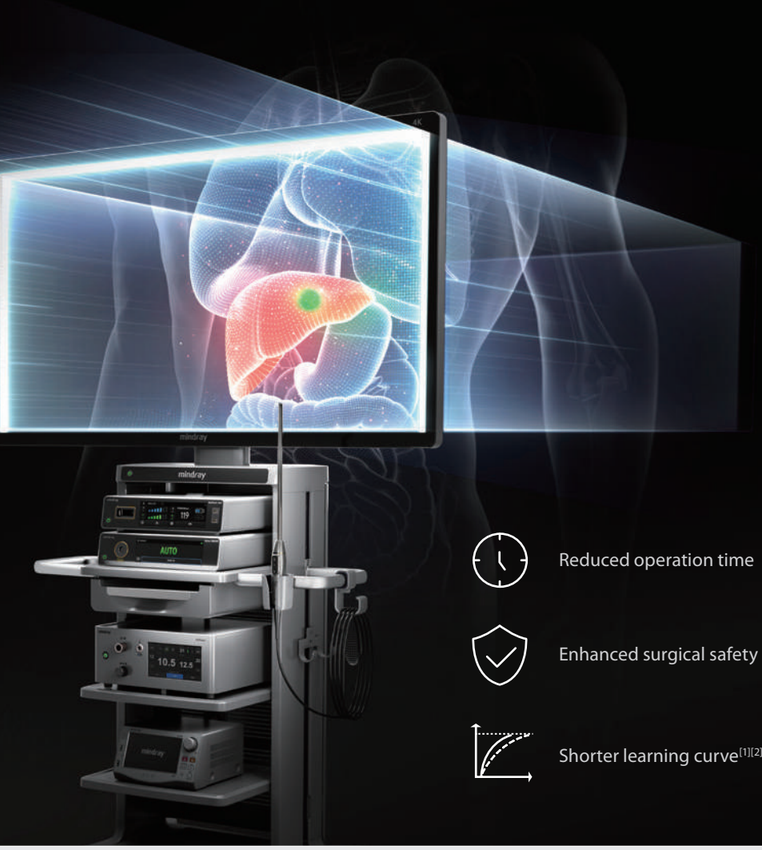
Camera Head
Multiple focal lengths available
White light camera head weight: 190 g
Fluorescence camera head weight: 240 g
• Recommend: CH5-SR100/CH5-SR110

Rigid Endoscope
Selectable diameters of 10 mm, 5 mm and 3 mm
• Recommend: G 01030A

Medical Digital Video Recorder
Access to hospital PACS system
Available to record dual-channel simultaneously
• Recommend: UR-NEXT4KHC



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
- Shorter learning curve[1][2]

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

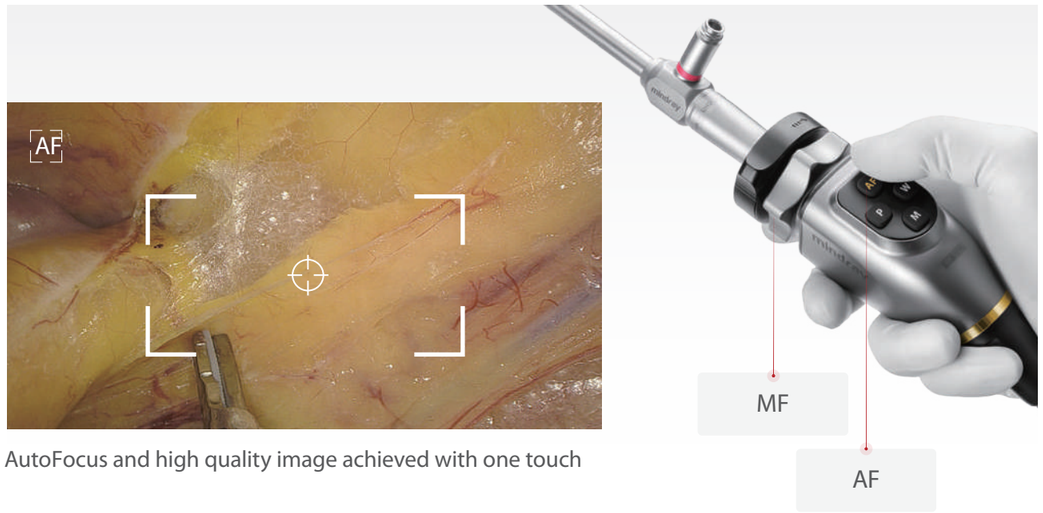
Weighs only 420 g
Titanium alloy handle, sturdy yet lightweight, allowing for easy maneuverability

[1] Arezzo A et al. The use of 3D laparoscopic imaging systems in surgery: EAES consensus development conference 2018.

[2] Velayutham V, Fuks D, Nomi T, Kawaguchi Y, Gayet B. 3D visualization reduces operating time when compared to high-definition 2D in laparoscopic liver resection: a case-matched study. Surg Endosc. 2016 Jan;30(1):147-53. doi: 10.1007/s00464-015-4174-1. Epub 2015 Mar 25. PMID: 25805241.

Smart View Exceptional Image Quality

Integrated auto and manual focus

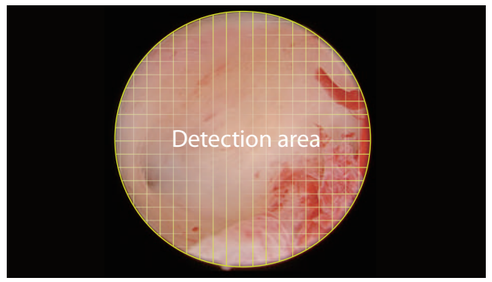


AutoFocus and high quality image achieved with one touch

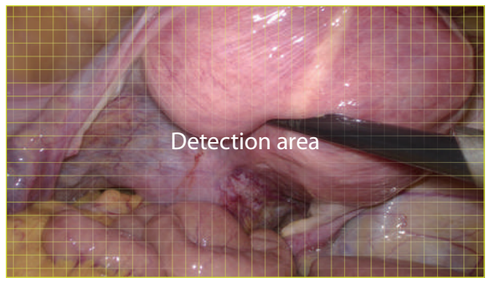
Automatic scene recognition

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.



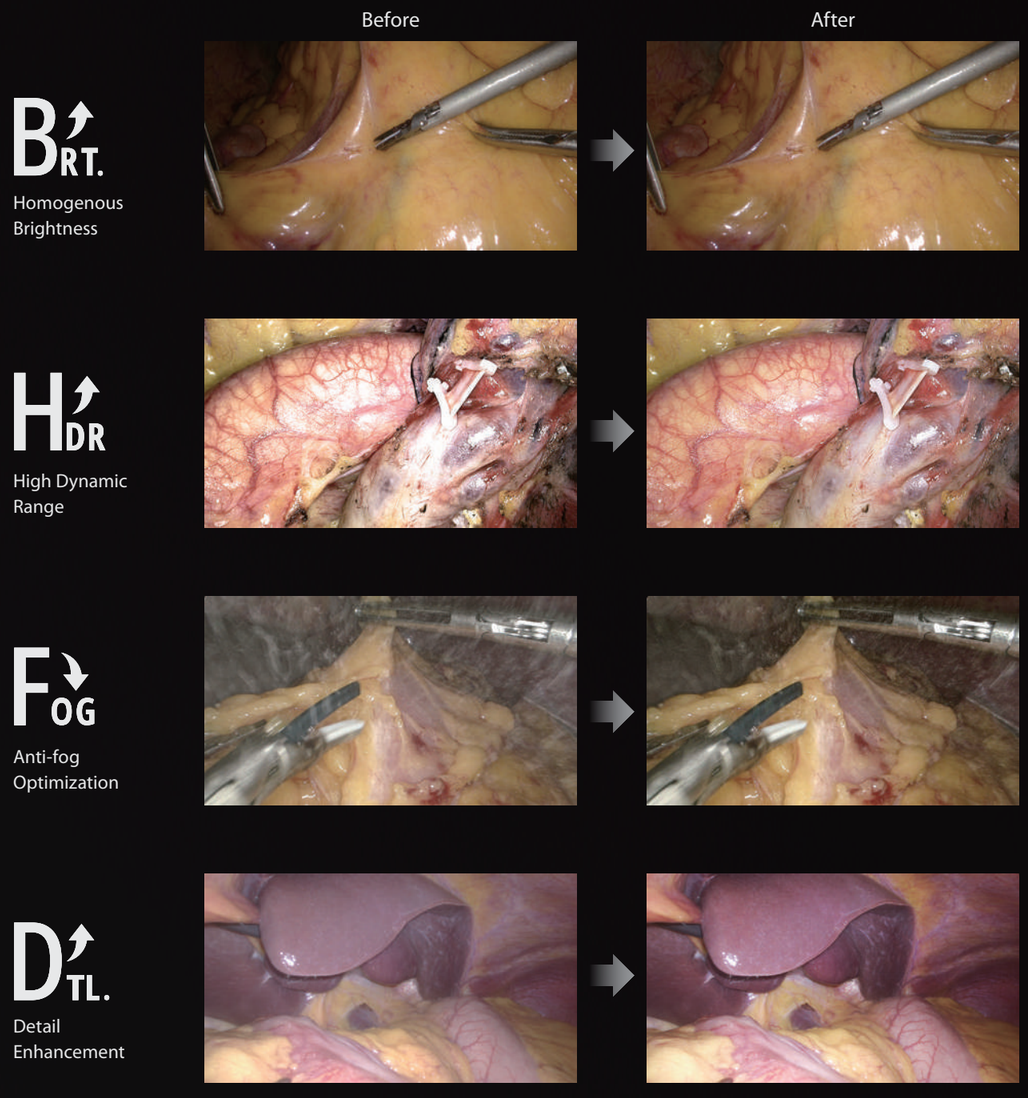
Small diameter scope scene (e.g. hysteroscope)



Laparoscope scenario

eImage 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

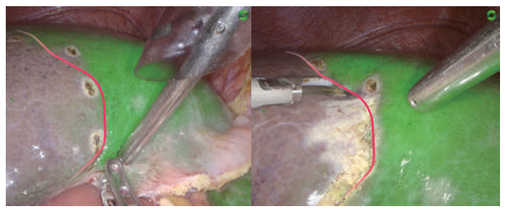
eFluo The fluorescence technology significantly boosts detection sensitivity and fluorescence imaging stability, leading to more precise navigation

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.

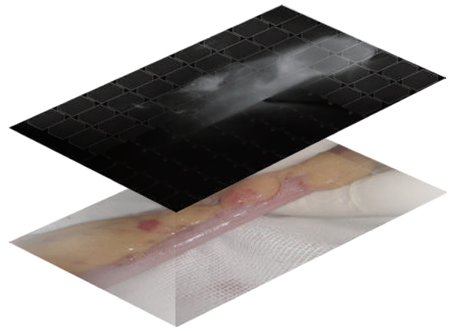
eFlo stabilization algorithm

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.



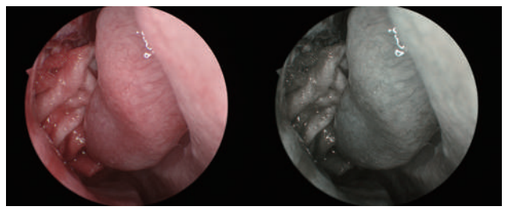
Fluorescence pixel-level fusion

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

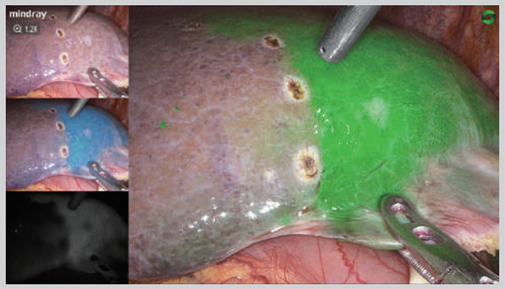
Tone filtering is used to see through the mucosal vascular network for the differentiation of anomalous vessels to assist in clinical diagnosis.



Clinical Cases

Evaluation of colorectal anastomotic blood supply

Laparoscopic liver watershed resection



SLN mapping in endometrial cancer

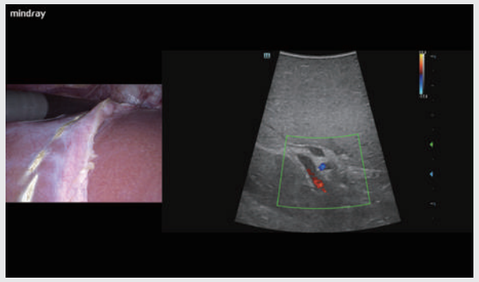
Anatomic subpulmonary lobe resection

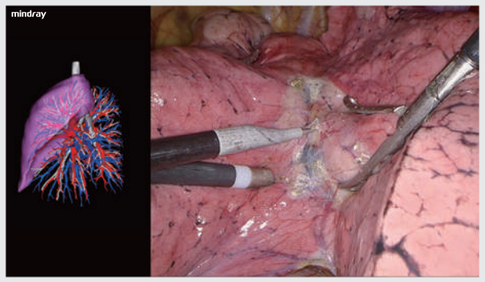
MIS Ecosystem
Unlimited Possibilities

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.

Digital OR, Upgraded Management

The UX7 Endoscope Camera System can be integrated into the Mindray digital operating room for centralized information management, enhancing the overall quality and efficiency of surgical procedures.

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

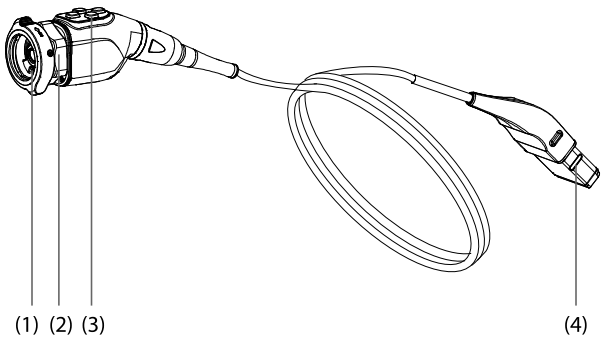
Endoscope Camera System

Operator's Manual

■ Release time: 2024-11

■ Revision: 1.0

2.9.3.2 Front View of the Camera Head



(1) Endoscope coupler: connects and secures the endoscope.

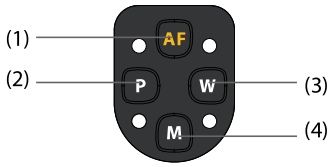
(2) Focusing ring: rotate the ring to focus the camera head.

(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)  :

- 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***.

- **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

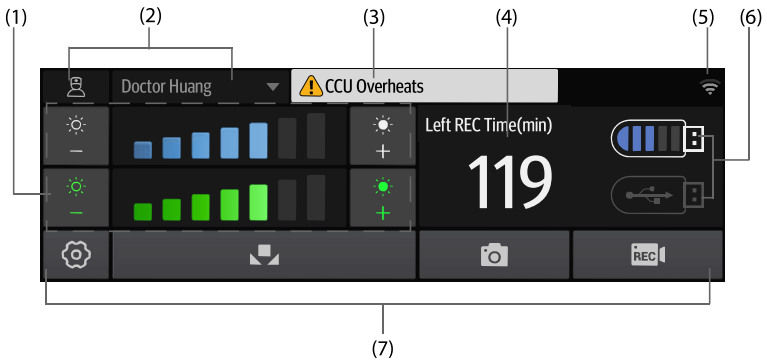
The equipment is configured with a LCD touchscreen on which you can operate and set the equipment, and view operation information.

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 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
	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.		About 80% memory is occupied.
	(Yellow) The USB drive is nearly full.		The USB drive is already full.
	Identifying USB drive.		Failed to identify the USB drive.
	Wireless network is connected. The solid part indicates network signal strength.		Wireless network is not connected.
	The CCU is matched with a location.		Failed to match the location.
	The touchscreen is unlocked		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.		White balance button: select to adjust the white balance.
	Camera button: select to capture images.		Record button: select to start/ stop recording.

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_120212.mp4	Section No._month day_hour minute second.mp4
Image (not video screenshot)	Section00_120745.jpeg	Section00_hour minute second.jpeg
Image (video screenshot)	Section01_000402.jpeg	Section No._hour 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 long-password 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 ***3.6.1 System Connection***.
	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.

mindray

4K 3D Video Endoscope

Vision beyond Imagination

This brochure can be applicable to the following models:

G 31030A/G 31000A/M 31030A/M 31000A

www.mindray.com

P/N: ENG- 4K 3D Video Endoscope -210285X4P-20241126

mindray

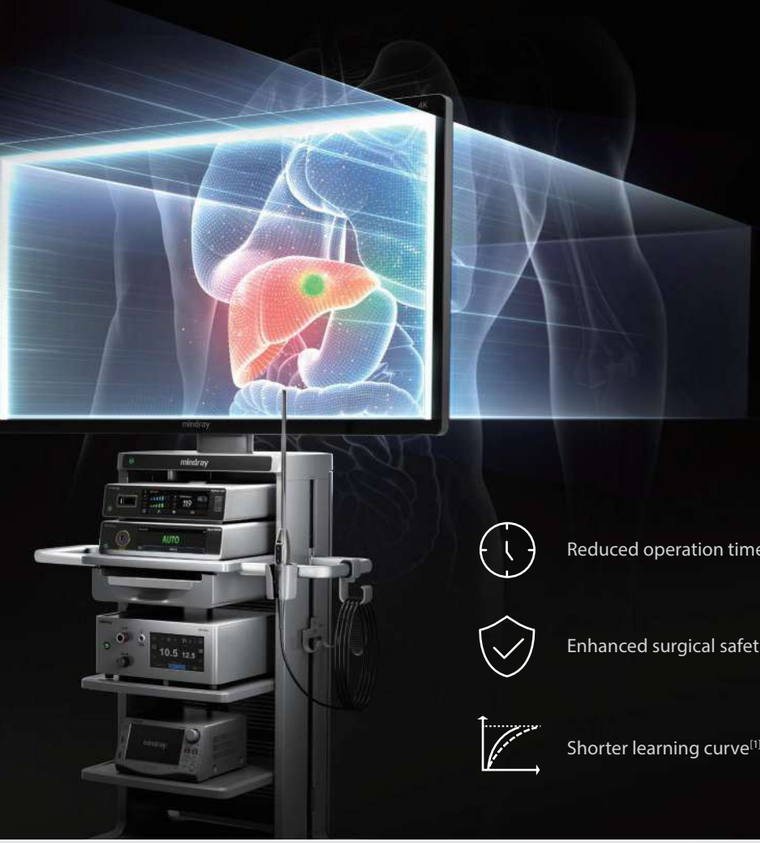
healthcare within reach

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
- Shorter learning curve[1][2]

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

[1] Arezzo A et al. The use of 3D laparoscopic imaging systems in surgery: EAES consensus development conference 2018.

[2] Velayutham V, Fuks D, Nomi T, Kawaguchi Y, Gayet B. 3D visualization reduces operating time when compared to high-definition 2D in laparoscopic liver resection: a case-matched study. Surg Endosc. 2016 Jan;30(1):147-53. doi: 10.1007/s00464-015-4174-1. Epub 2015 Mar 25. PMID: 25805241.

Model: M31030A
Order PA Code: F21EB-PA00005
Name: 4K 3D Video Endoscope
Descripcion: DOV 30°,Φ10mm, 3D white light

Model: M31000A
Order PA Code: F21EB-PA00006
Name: 4K 3D Video Endoscope
Descripcion: DOV 0°,Φ10mm, 3D white light

Model: G31030A
Order PA Code: F21EB-PA00003
Name: 4K 3D Video Endoscope
Descripcion: DOV 30°,Φ10mm, 3D NIR

Model: G31000A
Order PA Code: F21EB-PA00004
Name: 4K 3D Video Endoscope
Descripcion: DOV 0°,Φ10mm, 3D NIR

Order PA Code: 115-098836-00
Name: 3D Glasses
Descripcion: 3D Glasses(On-Ear,Large,5EA)

Order PA Code: 115-098837-00
Name: 3D Glasses
Descripcion: 3D glasses (Clip-on, Large, 5EA)

G 31030A/G 31000A/G 31030PA/G 31000PA

4K 3D Video Endoscope

Operator's Manual

CE 1639

- Release time: 2024-11
- Revision: 1.0

2.6 Contra-indications

The use of the video endoscope is contraindicated if, in the opinion of the attending physician, the surgical method as such is contraindicated or if the patient is not able to undergo surgery or anesthesia due to his or her general condition.

The video endoscope must not be used for interventions in direct contact with the central nervous system (CNS) and central cardiovascular system.

2.7 Clinical Benefits

4K 3D Video Endoscope is anticipated to shorten the operative time and reduce the amount of blood loss during laparoscopic and thoracoscopic surgery by helping surgeon's visualization.

2.8 Applied Part

The applied part of the equipment is the video endoscope itself.

2.9 Differences Among Models

Model[a]	Imaging Bands (nm)	Direction of View	Light Cable Adapter
G 31030A	400 - 760, 800 - 880	30°	Yes
G 31000A	400 - 760, 800 - 880	0°	Yes
G 31030PA	400 - 760, 800 - 880	30°	No
G 31000PA	400 - 760, 800 - 880	0°	No

[a]: "A" in the model indicates that products of this model can be autoclave sterilized.

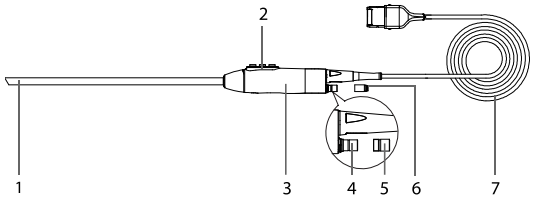
2.10 Product Components

This product consists of the tip, insertion portion, handle, and video connecting cable.

NOTE

- **4K 3D video endoscope is hereinafter referred to as "video endoscope".**

2.10.1 Front View of the Video Endoscope



(1) Tip: includes two 1/3-inch 4K CMOS image sensors and two sets of imaging light paths.

(2) Buttons: press to control the functions of camera control unit (hereinafter referred to as "CCU").

(3) Handle: hold during use.

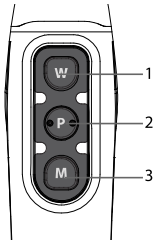
(4) Light cable connector: available for ACMI/Olympus Pro light cables.

(5) Light cable adapter: available for Mindray/Richard Wolf light cables.

(6) Light cable adapter: available for STORZ light cables.

(7) Video connecting cable: connects the CCU.

2.10.2 Video Endoscope Buttons



(1) W button: short press to switch view modes and long press to perform white balance by default. For details about view modes, refer to *3.6.3.2 Selecting View Mode*.

(2) P button: short press to take photos and long press to record videos by default.

(3) M button: short press to switch display modes circularly and long press to display external input source by default.

NOTE

- **The video endoscope has active anti-fog function, which can effectively prevent fogging of the optical window at its tip.**
- **The focus-free design of the video endoscope allows you to skip manual focus.**
- **You can customize the functions of the video endoscope buttons on the CCU. For the detailed setting method, refer to the operation's manual of the CCU.**

- Irreversible damage to a patient's tissues or unnecessary coagulation may occur.
- Surgical instruments (such as surgical drapes, plastic materials, etc.) may be combusted or burnt.
- If the light source is damaged during use, it may be a danger to patients. Therefore, a backup light source should be provided or a light source with extra bulbs is used.

WARNING

- **After long time light emitting, the surface temperature on the light cable connector and metal hood of the eyepiece end may exceed 41°C. Do not contact with these parts to avoid burns.**

3.6.3 Connecting Video Endoscope to CCU

Connect the video connecting cable of the endoscope to the CCU specified by Mindray. The equipment is applicable to the UX4/UX410/UX420/UX430/UX450/UX460/UX470/UX5/UX510/UX520/UX530/UX550/UX560/UX570/UX5-TEC/UX5-NOR/UX5-SIM/UX7/UX7-TEC/UX7-NOR/UX7-SIM camera system only.

3.6.3.1 Checking Image Quality

1. Place a piece of paper with texts about 50 mm in front of the tip of the endoscope.
2. Observe whether image blurring, loss of focus, or dark area exists in your field of view. If yes, replace the endoscope.

3.6.3.2 Selecting View Mode

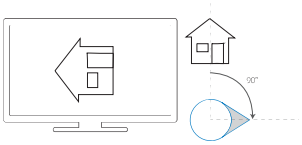
You can select one of the following view modes by setting on the CCU or by pressing a video endoscope button after customizing its function.

- 2D: displays 2D image.
- 2D AutoRotate: displays 2D image. Image can automatically rotate.
- 3D: displays 3D image.

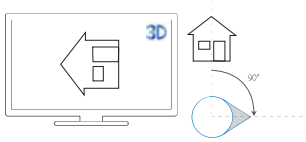
- 3D AutoRotate: displays 3D image. Image can automatically rotate.

The following are examples of image rotation in different view modes at the viewing angle of 90°.

2D:



3D:



2D AutoRotate:

3D AutoRotate:

You can also set the functions of **Autoswitch Angle**, **Parallax Setup** and **Image Zoom** on the CCU. For details about the setting method, refer to the operator's manual of the CCU (UX4/UX410/UX420/

UX430/UX450/UX460/UX470/UX5/UX510/UX520/UX530/UX550/UX560/UX570/UX5-TEC/UX5-NOR/UX5-SIM/UX7/UX7-TEC/UX7-NOR/UX7-SIM).

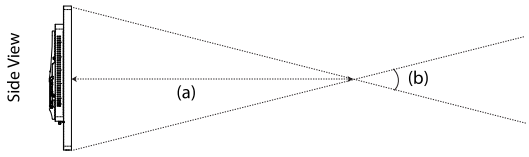
NOTE

- **In 3D mode, switch to 2D mode in case of any eye discomfort.**
- **Wear 3D glasses to view the images in the 3D or 3D AutoRotate mode.**
- **Replace the 3D glasses in case of any problems during the operation.**

3.6.3.3 Optimal Visual Zone of 3D Images

If you select the 3D mode, consult recommendations below to select a visual zone:

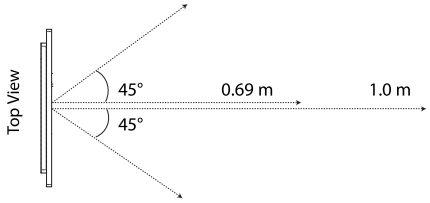
■ The recommended viewing distance is 3 times the height of the monitor screen.



(a) Recommended viewing distance (b) Vertical viewing angle

Monitor Model	Recommended Viewing Distance	Vertical Viewing Angle
32 inches	≥ 0.69m	32°
55 inches	≥ 1.0m	37°

■ In horizontal direction, the recommended viewing range of the monitor is 45° left to 45° right.



3.7 Precautions During Operation

Note the following when using the equipment:

- Put on sterile gloves before contacting the equipment.
- The endoscope is a precision optical instrument. Therefore, exercise caution during use. Do not hold the tip of the endoscope body, bend the insertion portion, or apply excessive external force.*
- Do not use strong light for an excessive long time.
- Avoid illuminating the same position for a long time. If unavoidable, pay close attention to the temperature of the area.
- Always select the minimum brightness necessary for the viewing to avoid the risk of burns.
- During use, the tip of the endoscope and the light cable connector might overheat. Do not touch these parts, or let them contact patient tissues, flammable materials, or thermo-sensitive materials.
- Prevent the surface of the objective lens, especially the light emitting surface, from being contaminated by substances like visceral fat and blood.
- In case of system failure in operation, stop the operation immediately, and pull the endoscope out from the patient carefully.
- Improper handling during use may present a risk of injury to the patient from the tip.

WARNING

- **Sapphire of the optical window at the tip of the endoscope can be wiped with 75% alcohol. When wiping, exercise caution to prevent sharp objects from scratching the front windows.**

4.5 Manual Cleaning

4.5.1 Flushing

To flush the equipment, follow the procedure below:

1. Flush the equipment with running water for 1 to 2 minutes to remove contaminations from the equipment surface.
2. Use a pressure washing gun to flush the equipment parts with complex structures, such as screw threads and gaps.

CAUTION

- **The water temperature during flushing should be 15°C to 30°C, and the maximum temperature shall not exceed 45°C. High temperature may cause denaturation and coagulation of blood or protein, increasing cleaning difficulty.**
- **Do not use a pressure washing gun to flush the eyepiece, objective lens, and light cable connector, so as not to damage these optical components.**

4.5.2 Washing

To wash the equipment, follow the procedure below:

1. Fully immerse the equipment in enzyme-containing cleanser. For requirements about immersing time, temperature, and concentration, refer to the instructions for use of the cleanser. Below is enzyme-containing cleansers of which the efficacy has been tested:

Product Name	Manufacturer	Concentration	Immersing Time
neodisher® MediClean forte	Dr. Weigert	5-20 mL/1L water	10 -30 min

2. Use a syringe with a volume of at least 10 ml to aspirate the cleanser and thoroughly flush the equipment parts with complex structures, such as screw threads and gaps. Repeat this step 5 to 10 times.
3. While immersing the equipment, use a soft brush to clean all accessible surfaces, especially parts with complex structures, such as screw threads and gaps. Brush the surfaces for 1 to 2 minute until no residue remains.
4. Use a cotton swab or a lint-free cloth soaked with 75% alcohol to wipe the surfaces of the optical components such as the eyepiece, objective lens, and light cable connector.

NOTE

- **Choose an enzyme-containing cleanser for use. Mixing cleansers may reduce the cleaning effect.**

4.5.3 Rinsing

After preliminary cleaning, follow the procedure below to rinse the equipment:

1. Rinse all accessible surfaces of the equipment thoroughly with running water. Repeat this step 3 times.
2. Flush all surfaces of the equipment, especially parts with complex structures, such as screw threads and gaps, with a pressure washing gun. Repeat this step 3 times.

For rinsing, use purified water.

4.5.4 Disinfection

Disinfect the equipment as required in the local or your hospital's servicing schedule. Clean the equipment before disinfection.

You can use the following verified disinfectant for disinfection:

Disinfectant	Method	Disinfection time
Ethanol, 75%	Wiping	1 - 3 min

NOTE

- **After disinfection, the equipment still needs to be sterilized before use.**

4.5.5 Drying

Dry the equipment with a disinfected lint-free cloth or an air gun.

NOTE

- **After manual cleaning and disinfection, check the equipment surface for stains. Repeat the cleaning procedure if necessary.**

4.6 Automated Cleaning

You can also use an automated cleaning and disinfection machine to clean and disinfect the endoscope. The tested machine is as follows:

Brand	Model	Manufacturer
Steris	AMSCO 3052	STERIS Corporation

Disassemble the equipment before putting it into the cleaning and disinfection machine. Refer to the instructions for use of the machine for cleaning method and parameters.

Enzyme-containing cleanser is recommended for automated cleaning. The tested cleaning parameters are as follows:

Procedure	Temperature	Time	Water Quality	Cleanser
Pretreating	Room temperature	2min	Tap water	/
Cleaning	55°C	10min	5 mL/1 L purified water	neodisher® MediClean forte (Dr. Weigert)

Procedure	Temperature	Time	Water Quality	Cleanser
Rinsing 1	Room temperature	2min	Purified water	/
Rinsing 2	Room temperature	2min	Purified water	/
Rinsing 3	Room temperature	1min	Purified water	/
High temperature disinfection	9 0°C	5min	Purified water	/
Drying	82.2°C (Low Mode)	25min	/	/

NOTE

- **Select an automated cleaning and disinfection machine that is certified and meet local regulations.**
- **Maintain and inspect the cleaning and disinfection machine regularly.**
- **Put the equipment in a meshed tray to ensure all parts can be flushed.**
- **For moist heat disinfection, use purified water.**
- **After automated cleaning and disinfection, check the equipment surface for stains. Repeat the cleaning procedure if necessary.**
- **After disinfection, the equipment still needs to be sterilized before use.**

4.7 Sterilization

Recommended sterilization methods that have been verified are as follows:

- Autoclave sterilization
- Low temperature plasma sterilization
- Ethylene oxide (EO) sterilization

CAUTION

- **Clean and disinfect the equipment before sterilization.**
- **Perform sterilization in accordance with the methods described in this chapter. Otherwise, sterilization may fail.**
- **Before cleaning and disinfecting the equipment, put on the protection cover of the plug, and remove the cover before sterilization. Otherwise, contaminations might get inside the plug.**
- **Autoclave sterilization must be performed with purified water that meets the requirements of the medical institution and relevant standards.**
- **Use one of the recommended methods consistently on the same equipment. Using different sterilization methods may change equipment appearance.**
- **After autoclave sterilization, allow the equipment to naturally cool down to room temperature. Quick cooling down may damage the equipment.**
- **The equipment is very sensitive to impacts at high temperature. Therefore, avoid impacting and vibrating the equipment at high temperature.**
- **After each reprocessing, make sure that the equipment has been taken out of the sterilizer. In other cases, the equipment in the sterilizer shall not be considered sterilized.**

4.7.1 Maintenance, Inspection and Testing Before Sterilization

Before sterilization, follow the method in ***3.5 Inspection*** to check the equipment. Ensure the equipment is intact and functions normally. If there are visible signs of wear, the equipment should no longer be reused.

In addition, lubricate the equipment by applying water-based lubricant to its moving parts or joints.

4.7.2 Packaging Before Sterilization

Place the equipment in a proper container and double wrap the container with sterile sheet or any other sterile packing materials,

preventing equipment contamination during storage and transportation.

Recommended specifications of the sterile sheet are as follows:

Dimension	Gram Weight	Materials
1.2m x 1.2m	45g	100% polypropylene, 5-layer SMMMS laminates

4.7.3 Autoclave Sterilization

As the sterilizer and its operating conditions may affect sterilization, it is recommended that the sterilization process be reconfirmed and monitored before sterilization in accordance with related international standards (for example, ISO 17665), national standards, or hospital management rules.

To perform autoclave sterilization, follow the procedure below:

1. Place the packaged container into the sterilizer.
2. Sterilize the equipment following the instructions for use of the sterilizer.

Sterilization parameters of autoclave sterilizer are as follows:

Device	Temperature	Required minimum time
Pre-vacuum	132°C	4min
	134°C	

CAUTION

- **After autoclave sterilization, do not use liquid to forcibly cool the endoscope. Otherwise, the endoscope may be damaged.**

4.7.4 Low Temperature Plasma Sterilization

You are advised to use the following low temperature hydrogen peroxide plasma sterilizer that has been tested:

Manufacturer	Product	Cycle Mode
Advanced Sterilization Products (ASP)	STERRAD® 100NX System	Standard cycle

To perform low temperature plasma sterilization, follow the procedure below:

1. Place the packaged container into the sterilizer, and ensure:
   - The container is adequately exposed in the hydrogen peroxide plasma.
   - Do not allow any object to contact the inner sides of the sterilizer.
2. Set the sterilizer to standard cycle and sterilize the equipment following the instructions for use of the sterilizer.

For detailed instructions and precautions, refer to the instructions for use of the sterilizer.

NOTE

- **After long time sterilization, the color of the color ring will fade, which is a normal phenomenon. It will not affect the sealing performance and the whole machine function.**

4.7.5 EO Sterilization

1. Place the packaged container into the sterilizer.
2. Sterilize the equipment following the instructions for use of the sterilizer. You are advised to apply the following EO sterilization parameters that have been tested:

EO Concentration	Temperature	Relative Humidity	Sterilization Time
About 760 mg/L	55°C	40% - 85%	60 min

3. To ensure the EO residues remain at a level that does no harm to the body of an adult patient, the sterilized equipment should go through a 12-hour aeration or longer in a well-ventilated aeration area at 55°C before reuse. For a pediatric or neonatal patient, the

sterilized equipment should go through a 24-hour aeration or longer in a well-ventilated aeration area at 55°C before reuse.

4.8 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 cords, connectors and the housing of the equipment
- Reduced service life of cables
- Degradation of performance
- Equipment malfunction

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 Physical Specifications

Weight (insertion portion & handle)	≤ 420 g
Dimension	Length (insertion portion & handle): 470±10mm Width (handle): 32±3mm Hight (handle): 43±3mm

A.4 Basic Parameters

Field of view, 2W (°)	80 ± 15%
Direction of view, θ (°)	G 31030A/G 31030PA: 30 ± 10 G 31000A/G 31000PA: 0 ± 10
Working length (mm)	325 ± 3%
Maximum width of the insertion portion (mm)	10.45
Diameter of the insertion portion (mm)	10 ± 0.45

A.5 Optical Performance

On-axis angular resolution $r_a(d)$ (white light imaging mode)	9.02 C/(°), tolerance -10%. **Note**: It can be converted to 13.68 lp/mm.

Range of effective depth of field	3 - 200 mm

A.6 Image Performance

Signal to noise ratio	Nominal value: 30 dB, tolerance -20% Peak value: 82 dB, tolerance -20%
Static image tolerance	300, tolerance -20%
Image display pixels	Dual-channel 4K CMOS, supporting 3840 x 2160 and 4096 x 2160 pixels UHD image display **Note**: The pixel product is about 8.29 million and 8.85 million.
Video display pixels	Dual-channel 4K CMOS, supporting 3840 x 2160 and 4096 x 2160 pixels UHD video display **Note**: The pixel product is about 8.29 million and 8.85 million.
Video output frequency	50 Hz/60 Hz
3D image performance	Time difference between left and right images: 0, tolerance +10 ms Vertical parallax between left and right images: 0, tolerance +2%

A.7 Operating Environment

Hardware configuration	Processor: FPGA Flash: 256M

HB500R/HB500R-TEC/HB500/HB500-TEC

Endoscope Light Source

Operator's Manual

CE 0123

CE

■ Release time: 2023-10

■ Revision: 2.0

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 near infrared light is provided.
HB500R-TEC	10	
HB500	12	Output of white light is provided.
HB500-TEC	10	

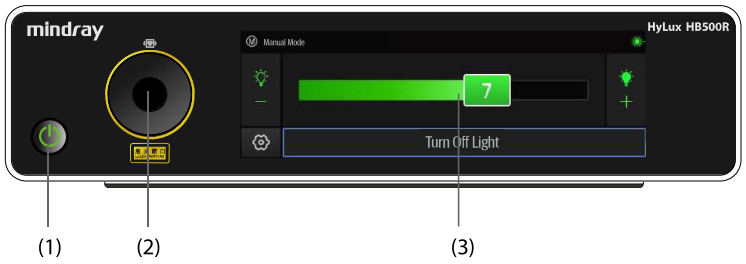
2.7 Applied Part

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



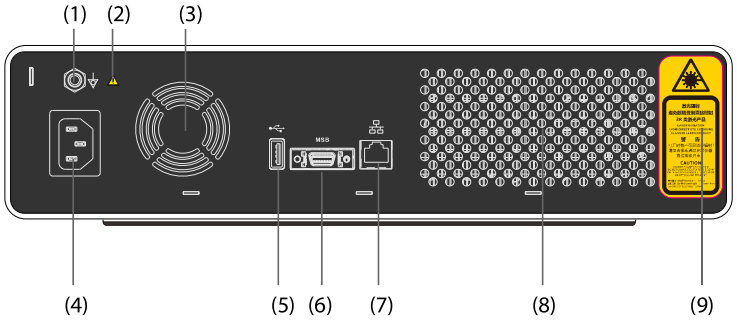
(1) Power switch: turns on or off the main unit. The switch also has an embedded light that indicates the power status of the main unit:

- 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.

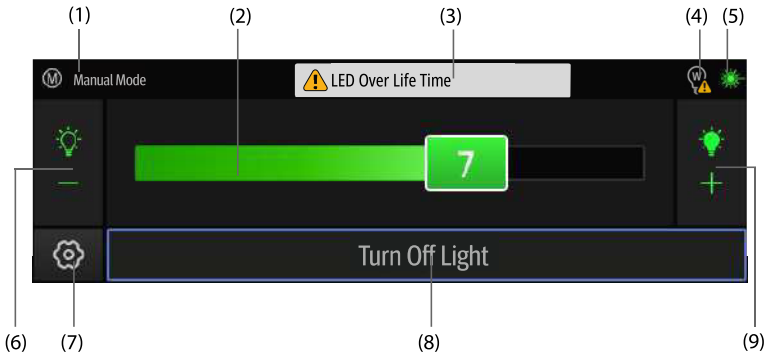
(9) Laser warning label: read the messages carefully to avoid any possible safety risks.

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:



(1) 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:

1. 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**.
2. 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 ± 5 mm Width: 350 ± 5 mm Height: 80 ± 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 ± 10nm ; Full width at half maximum (FWHM): 5 nm ± 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 Output Power of Transmitter Watts (W)	**Separation Distance According to Frequency of Transmitter (m)**			
	150 kHz - 80 MHz Out ISM bands $d = 1.2\sqrt{P}$	150kHz - 80MHz in ISM bands $d = 1.2\sqrt{P}$	80MHz-800MHz $d = 1.2\sqrt{P}$	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

SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. (hereinafter called Mindray) owns the intellectual property rights to this product and this manual. Disclosure of the information in this manual in any manner whatsoever without the written permission of Mindray is strictly forbidden.

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).

mindray is the registered trademark owned by Mindray in China and other countries.

The issue date of this manual is 2021-5.

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.
   (2) Damage or loss caused by force majeure such as fires, earthquakes, floods, and lightning.
   (3) 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 indicated as well.
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
5. 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.

⚠ 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.

(2) Use a soft cloth dipped in an appropriate amount of water to remove leftover on the surface of the light cable.

(3) Use a clean soft cloth dipped in an appropriate amount of ethanol (75%) to wipe the surface of the light cable.

(4) 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:

(1) Remove the light source adapter from the light cable.

(2) Put the product in a sterilization box, and wrap two layers of sterile sheets to prevent contamination during storage and transportation after sterilization.

(3) 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 well-ventilated room.

X. Equipment Symbols

Symbol	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

Company Contact

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
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Website:	www.mindray.com
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EC-Representative:	Shanghai International Holding Corp. GmbH (Europe)
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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)

声明

本说明书详细地介绍了产品的用途、功能和操作使用。使用本产品之前，请认真阅读并理解本说明书中的内容，以保证能够正确地使用本产品，并确保病人和操作者安全。在下列条件都满足的情况下，迈瑞公司将对产品的安全性、可靠性和性能负责：

(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

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。

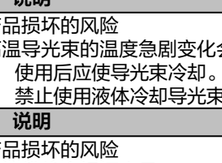
一、预期用途

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

型号	LC0005S	LC0003S
导光束长度	3000 mm ± 10%	
出射端光纤直径	Φ4.8 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

⚠ 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

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。

光纤保护套

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

⚠ 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损坏。

- 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°C ~ +35°C
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°C ~ +60°C
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
	注意！查阅随机文件
	生产日期
	CF 型应用部分
	批次代码
	温度极限
	湿度极限
	大气压力极限
	电子产品环保使用年限（20 年）

售后服务单位

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