About This Manual

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

Documentation

Understand the meanings of the following items clearly before reading this manual.

Item	Meaning
⚠ WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
⚠ CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in malfunction or damage of the system.
NOTE	Indicates precautions or recommendations that should be used in operating the system.
Boldfaced Word	Indicates controls on the control panel, or on-screen objects such as menu items or keys.
Click	Move the cursor to the controls on the display and press the confirm key.

Item	Meaning
>	Select a menu item or a key following the path.

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Contents

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1 Safety

This chapter describes important information for operating this device. To ensure the safety of both user and patient, read relevant details in this chapter carefully before use.

The operator should be completely familiar with the precautions provided in this manual. Otherwise, the manufacturer is not responsible for the effects on safety, reliability and performance of the device.

1.1 Intended Use

The device is intended to provide illumination for the endoscope in clinics. It is used with the endoscope, the image processor and other peripheral devices provided or approved by the manufacturer.

The device should be used in the medical institution. The operator of the device should be a physician or a medical staff supervised by a physician, both of whom have received sufficient training in clinical endoscopy technology.

1.2 Device Compatibility

The device is used with the image processor (HD-500 series and HD-550 series) and the endoscope (EG-550 series, EC-550 series, EB-5H20 series, EG-UC5T, EG-UR5, EC-P550S series, EC-P560 series and EG-P550N) provided by the manufacturer.

1.3 Safety Precautions

Read and understand all precautions in this manual before attempting to use the device. Keep this manual with the device at all times. Periodically review the procedures for operation and safety precautions.

1.3.1 Electrical Safety

⚠ WARNING

- Only the personnel authorized or trained by the manufacturer can maintain the device. Any unauthorized personnel should not assemble or disassemble the device.
- Do not operate the device in an atmosphere containing flammable gases such as anesthetic gases, hydrogen or ethanol, because there is a danger of explosion.
- Connect the protective earth conductor only before powering on the device. Disconnect the ground wire only after powering off the device. Otherwise, electrical shock may occur.
- Do not service or maintain the device while it is in use with a patient.
- Do not position the device to make it difficult to disconnect it.
- Connect the device to other electrical equipment by using the potential equalization lead wire before connecting the power plug of the device to an electrical outlet.
- Do not place the multi-socket outlet on the floor.
- Within the environment that is 1.8 meters (6 feet) around a patient, connect peripherals to the auxiliary power outlet which is capable of isolation protection; or, power the peripherals by the auxiliary output cable or the isolation transformer complied with EN/IEC 60601-1, or the power input of the same safety level.

- Do not pour any fluid onto device surfaces, as fluid seepage into electrical circuitry may cause excessive electrical current leakage or device failure. If any water is spilled onto the device carelessly, stop using the device and contact the local distributor immediately.
- The AC power connector plug for the device is a three-prong grounded plug and should never be adapted to any two-prong outlet or by using an adapter. Connect the AC power plug of the multi-socket outlet to a hospital-grade power outlet.
- Disconnect the power cable from the electric outlet to ensure that the device is powered off.
- Do not connect the device and high frequency surgical instrument to the same power outlet. Place the device away from high frequency surgical instrument.
- Place the device away from the laser instrument which has a high starting voltage.
- A spare light source is recommended to be placed in the examination room in case the device appears abnormal.
- The performance of the device and its accessories may be degraded over time. Perform periodic maintenance as described in this manual to ensure the safety of the device.
- Maintain and store the device as described in this manual after use. Improper maintenance and storage may cause cross infection, damage to the device or performance degradation.
- Do not touch the patient and the ports of the device simultaneously. Otherwise, there is a danger of electric shock.

⚠ CAUTION

- Select a qualified multi-socket outlet with protective grounding, and ensure that its maximum output power exceeds the required one of the device.
- The multi-socket outlet can only be used to provide power to the recommended peripherals of this system.
- Do not connect other devices to the multi-socket outlet. Otherwise, it may result in interference and overload.
- If the non-medical electrical equipment used with the system is supplied by a multi- socket outlet with separating transformer, connect the AC power plug of the multi- socket outlet to a hospital-grade power outlet. Consult a professional to ensure that the connection complies with the safety standards.
- Accessory equipment connected to analog and digital interfaces must be certified according to the respective EN/IEC standards (for example, EN/IEC 62368-1 for data processing equipment and EN/IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with EN/IEC 60601-1.

1.3.2 Accessory Safety

⚠ WARNING Only the accessories provided or approved by the manufacturer can be used. Using other accessories may damage the device and cannot achieve the expected performance described in this manual.

1.4 Safety Symbols

The following table is provided for user's identification of important symbols located in labels on the device.

Symbol	Meaning
	Refer to instruction manual
	Caution
	Manufacturer

Symbol	Meaning
SN	Serial Number
∼	Alternating current
⏻	Stand-by
◯	OFF (Power)
❘	ON (Power)
CE 0197	This product is provided with a CE marking in accordance with the regulations stated in Regulation (EU) 2017/745.
EC REP	Authorized representative in the European community
人	Type BF Applied Part
⚠	Hot surface
⏚	Equipotentiality
⎓	Fuse
♲	This symbol indicates that waste electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.
#	Model number
CHN	Country and date of manufacture, CHN is the country code of China.
MD	Medical device
UDI	Unique device identifier
🌡	Temperature limit
%	Humidity limitation

Symbol	Meaning
	Atmospheric pressure limitation
	Stacking limit by number
	Fragile, handle with care
	Keep away from rain
	This way up

2 Overview

To ensure the performance of the device, the operator should be completely familiar with the operations and functions of the device.

2.1 Packing

Make sure that all the following items are in the packaging box of the device.

- Light source
- Water bottle
- Power cable
- Fuse

Others: see the Packing List in the packaging box.

2.2 Component Introduction

2.2.1 Front Panel
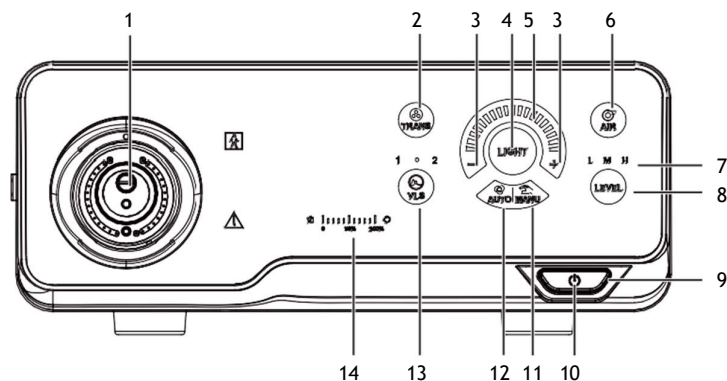
Figure 2-1 Front Panel

No.	Part Name	Description
1	Endoscope Port	Used for connecting the air pipe and light guide of the endoscope.
2	**TRANS** Button	Press it to enable or disable the light transmission feature.
3	⊕ / ⊖ Button	Press them to adjust the brightness.
4	**LIGHT** Button	Press it to turn on or off the lamps.
5	Intensity Indicator	Indicates the brightness level.
6	**AIR** Button	Press it to enable or disable the air-feeding feature.

No.	Part Name	Description
7	Air Pump Indicator	Indicates the current air-feeding pressure level (L-Low, M-Medium, H-High).
8	**LEVEL** Button	Press it to adjust the air pressure.
9	Power Indicator	Indicates the power status of the device
10	⏻ **ON/OFF** Button	Press it to turn on or off the device.
11	**MANU** Button	Press it to enable manual brightness adjustment.
12	**AUTO** Button	Press it to enable automatic brightness adjustment.
13	**VLS** Button	Used to select an illumination mode and the corresponding indicator lights. Illumination modes corresponding to the lighted indicator are determined by the user settings. For detailed setting methods, refer to the image processor user manual.
14	Service Time Indicator	Indicates the accumulated working time of the lamps. This indicator starts blinking when the lamps reach the end of its service time.

2.2.2   Rear Panel
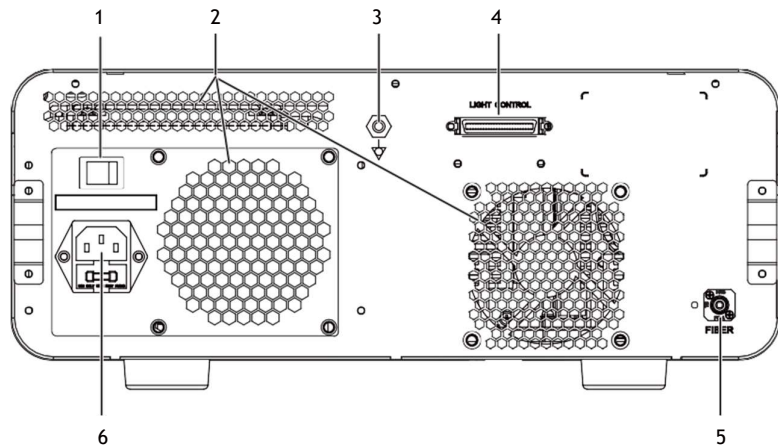
Figure 2-2 Rear Panel

No.	Part Name	Description
1	Main Power Switch	Used for powering on or off the device.
2	Ventilation Holes	Used for ventilation.
3	Equipotential Terminal	Used for equipotential connection, balancing the protective earth potentials between the device and other electrical equipment.
4	**LIGHT CONTROL** Port	Used for connecting the image processor with the light control cable.
5	**FIBER** Port	Used for connecting the image processor with the optical fiber cable.
6	Power Input Port	Used for connecting the power cable.

2.2.3   Side Panel
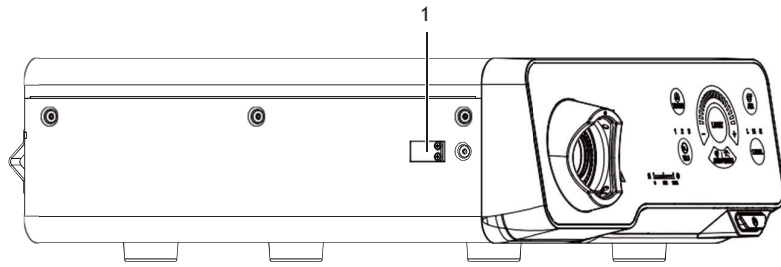
Figure 2-3 Side Panel

No.	Part Name	Description
1	Water Bottle Bracket	Used for holding the water bottle.

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3 Preparations

Preparations are necessary before use, which should include device installation, connection, and inspection.

For other devices used with this device, inspect them according to the relevant user manuals. If any malfunction is found, do not use the device.

⚠ WARNING Read through this chapter carefully before using the device to ensure that the installation and connection are correct. Otherwise, damage to the device or personal injury may occur.

⚠ CAUTION
- Power off the device and all the peripherals before system connection. Otherwise, damage to the device, malfunction or data loss may occur.
- Only the cables provided by the manufacturer can be used for connection. Otherwise, damage to the device or malfunction may occur.
- Do not block the ventilation holes of the device or place the device in a location without adequate ventilation. Otherwise, the internal heat may cause damage or malfunction.
- Do not place the device where:
  — Water may drip or splash.
  — Flammable and explosive gas exists.
  — It is damp and of high temperature.
  — It is under the sunlight.

3.1 Placing the Device

Place the device on the trolley (sold separately) steadily, and then put the image processor on the device, as shown in Figure 3-1.

NOTE:
- *Ensure that the four feet of the device are positioned within the anti-slip strips Do not move the device casually.*
- *Refer to the user manual for the installation information of the trolley.*
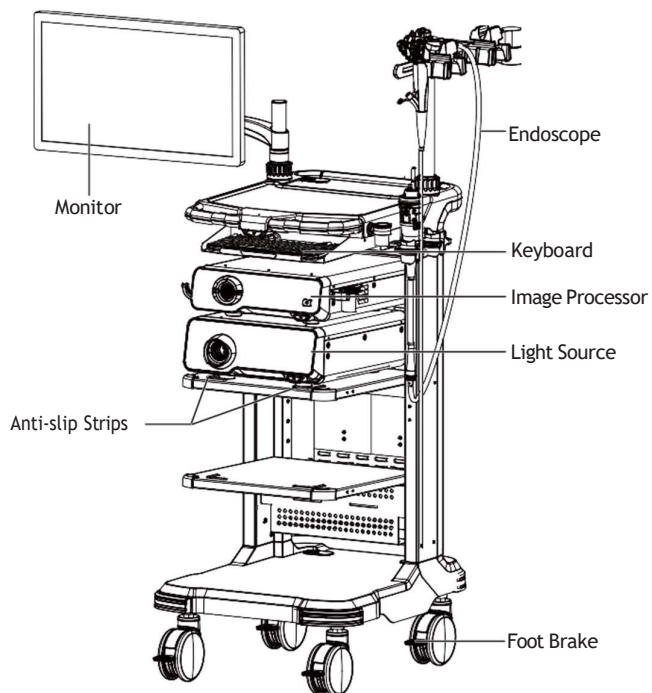
Figure 3-1 Placing the Device

3.2   Connecting the System

After placing the device, connect it to the image processor, the power cable, the endoscope and the water bottle in turn, as shown in Figure 3-1.
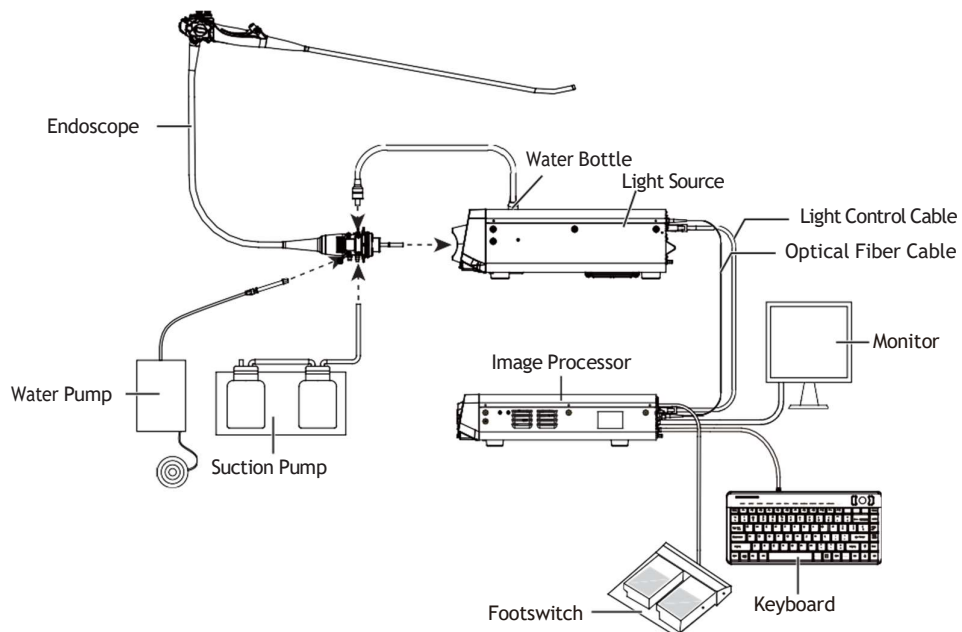
Figure 3-1 Connection of Endoscopy System

3.2.1 Connecting the Image Processor
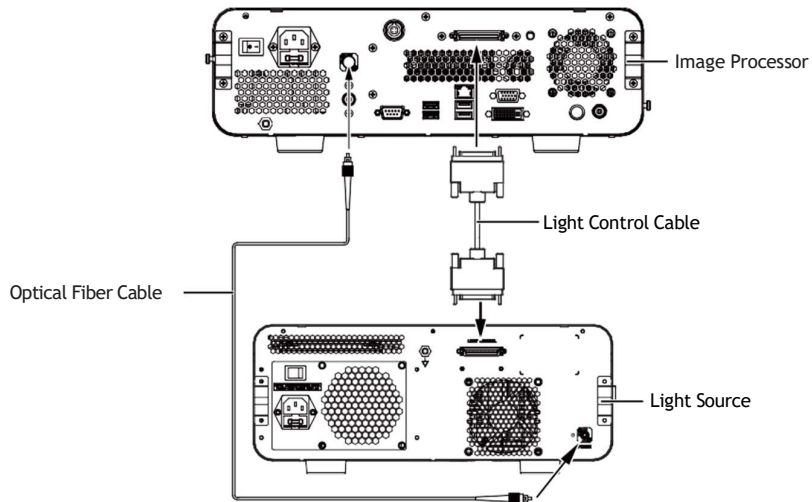
Figure 3-2 Connecting the Image Processor

■ **To use the light control cable**

NOTE:

Only the image processor provided by the manufacturer is allowed to be connected to the light control port.

Connect the light control cable corrected to the light control port of the device and the light control port of an image processor.

■ **To use the optical fiber cable**

NOTE:

Connect the optical fiber cable only when the device is connected to the HD-550 series image processor.

Connect the optical fiber cable correctly to the optical fiber port of the device and the optical fiber port of an image processor.

3.2.2 Connecting the Power Supply

⚠ WARNING Do not bend, drag or twist the power cable excessively. Otherwise, the power plug may be damaged or short circuit may occur, causing fire or electrical shock.

Perform the following steps.

1. Connect the device to earth or the equipotential terminals of other devices.

2. Connect one end of the power cable to the device and the other end to the AC power outlet.

3.2.3 Connecting the Endoscope

⚠ WARNING Wipe the connector section of the endoscope carefully and ensure that it is completely dry before connection. Otherwise, electrical shock or damage to the device may occur.

NOTE:

Do not touch the connector section or endoscope port when the endoscope is just removed from the device. Otherwise, the high temperature may cause skin burns.

Insert the connector section of the endoscope into the endoscope port of the device firmly.
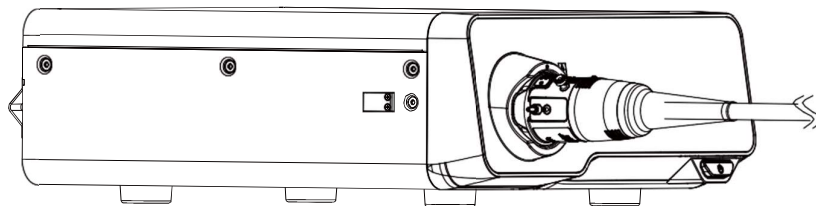
3.2.4 Connecting the Water Bottle

⚠ WARNING Do not fill the water bottle with sterile water when it is connected to the device. If water is spilled on or into the device, it may cause electric shock or device damage.

The water bottle is as shown as follows.
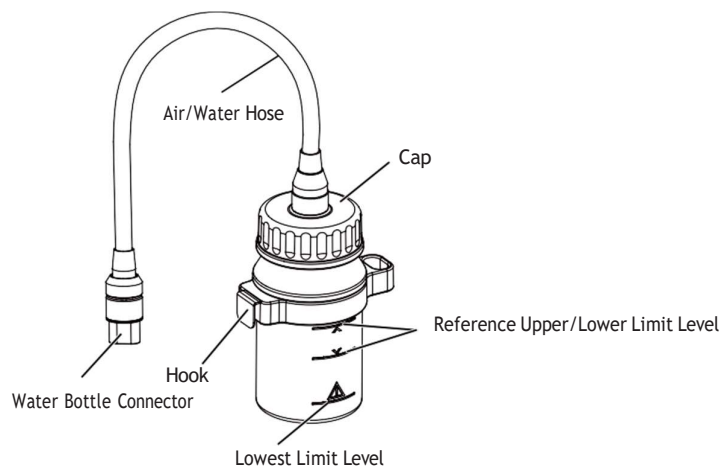
NOTE:

- *Change sterile water in the bottle every day.*
- *Add sterile water if the water level is under the lowest limit level of the bottle.*

Perform the following steps.

1. Tighten the bottle cap, then fix the water bottle on the bracket, as shown in Figure 3-3.
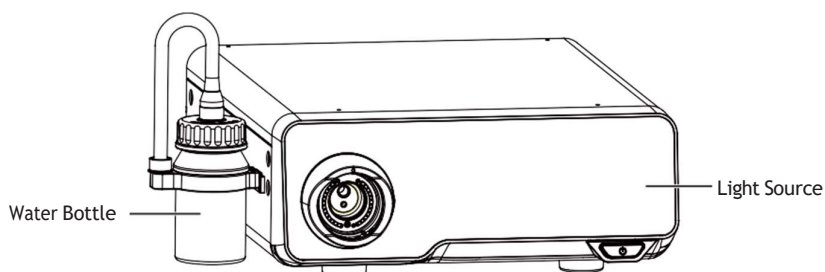
Figure 3-3 Water Bottle Installation

2. Connect the water bottle to the endoscope firmly, as shown in Figure 3-4.
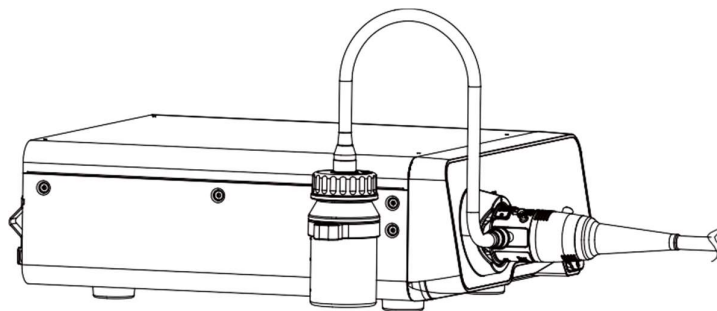
Figure 3-4 Pipe Connection

3.3   Powering On/Off the Device

■   **To power on the device**

Perform the following steps.

1. Set the power switch on the rear panel to the ▬ position.

2. Press the ⏻ button on the front panel to turn on the device.

■   **To power off the device**

Perform the following steps.

1. Press the ⏻ button on the front panel to turn off the device.

2. Set the power switch on the rear panel to the ◯ position.

3.4   Inspecting the Device

Before each use, strictly follow the descriptions below to inspect the device. Follow the relevant user manuals to inspect the peripherals connected to this device. If any problem exists, refer to Section 5.4 Troubleshooting. If the problem still exists, stop using the device and contact the local distributor.

3.4.1   Inspecting Air-feeding

Perform the following steps.

1. Press the **AIR** button to activate the air-feeding feature. Press the **LEVEL** button repeatedly to set the air pressure to **H (**high).

2. Immerse the distal end of the endoscope in a container filled with sterile water to a depth of 10 cm.

3. Cover the air/water valve with a finger to feed air. Ensure that bubbles continuously come out from the air/water nozzle, as shown in Figure 3-5. Refer to the relevant endoscope user manual for details.

Press the air/water valve

Air/Water Nozzle
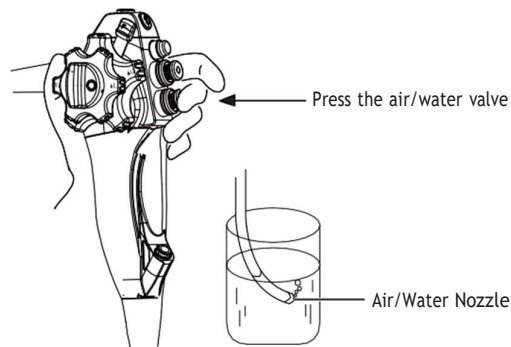
Figure 3-5 Air Feeding Inspection

NOTE:

If the distal end of the endoscope is immersed in the water to a depth less than 10 cm, a few bubbles will appear even if the air/water valve is not operated. This is normal.

4. Press the **LEVEL** button repeatedly to adjust the air-feeding pressure. Ensure that the number of bubbles varies with the air-feeding pressure.

5. Press the **AIR** button to stop air feeding. Ensure that no bubble comes out from the nozzle.

6. Take the distal end out from the sterile water. Check the water feeding feature according to the endoscope user manual.

3.4.2   Inspecting Brightness Adjustment

⚠️ WARNING Do not stare at the distal end of the endoscope or output light of the device. Otherwise, the strong light may result in injury to eyes.

■   **AUTO Mode**

Perform the following steps to inspect the brightness adjustment feature in **AUTO** mode.

1. Press the **LIGHT** button on the front panel to turn on the lamps.

2. Press the **VLS** button on the front panel to select the desired illumination mode.

3. Press the **AUTO** button on the front panel to enable the automatic brightness adjustment feature.

4. Press the ⊕ or ⊖ button to set the brightness to the desired level.

5. Move the distal end of the endoscope up and down and keep the distance between the distal end and the object within a range of 2 - 100 mm. Ensure that the brightness of the image displayed on the screen does not change obviously, as shown in Figure 3-6.
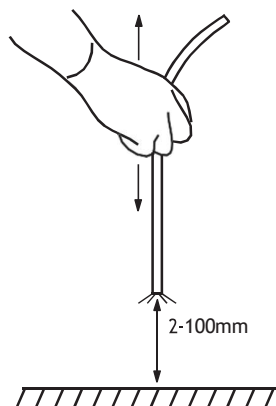
Figure 3-6 Brightness Observation

■   **MANU Mode**

⚠ WARNING To avoid injury to eyes, adjust the brightness to the lowest level necessary for normal clinical observation in **MANU** mode.

Perform the following steps to inspect the brightness adjustment in **MANU** mode.

1. Press the **LIGHT** button on the front panel to turn on the lamps.

2. Press the **VLS** button on the front panel to select the desired illumination mode.

3. Press the **MANU** button on the front panel to enable the manual brightness adjustment feature.

4. Press the ⊕ or ⊖ button to adjust the brightness and ensure that the brightness of the image displayed on the screen changes accordingly.

3.4.3   Inspecting Transillumination

Perform the following steps.

1. Press the **LIGHT** button on the front panel to turn on the lamps.

2. Press the **VLS** button on the front panel to select the desired illumination mode.

3. Press the **TRANS** button on the front panel to enable the transillumination feature.

   The light reaches the maximum intensity and starts twinkling. Six to eight seconds later, the light intensity is automatically adjusted to the original intensity.

3.4.4   Inspecting Illumination Mode Switch Feature

Perform the following steps.

1. Press the **LIGHT** button on the front panel to turn on the lamp.

2. Press the **VLS** button on the front panel to switch the illumination modes and the corresponding indicators lights.

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4　Operations

This manual does not explain or discuss clinical endoscopic procedure. It only describes basic operations and precautions related to the device.

The device will save the current settings automatically when it is powered off.

⚠ WARNING Stop the examination immediately if the device works abnormally. Withdraw the endoscope slowly from the patient's body in accordance with the descriptions in the endoscope user manual. Take measures with a reference to Section 5.4 Troubleshooting.

4.1　Turning On the Lamps

⚠ WARNING To avoid injury to eyes, set the brightness to the minimum before turning on the lamps.

Perform the following steps.

1. Press the **LIGHT** button to turn on the lamps.

2. Press the **VLS** button to select the desired illumination mode.

Light is emitted from the distal end of the endoscope.

4.2　Adjusting the Brightness

⚠ WARNING To avoid burns, adjust the brightness to the lowest level necessary for normal clinical observation.

For different endoscopy systems and body parts, adjust the brightness of the lamps according to the actual requirement. You can select **AUTO** mode or the **MANU** mode as required.

■ **AUTO Mode**

Perform the following steps.

1. Press the **AUTO** button on the front panel to enable the automatic brightness adjustment feature.

2. Press the ⊕ or ⊖ button to adjust the brightness to the desired level.

Once you set the brightness to the desired level in **AUTO** mode, the light intensity will be automatically adjusted to keep the image brightness roughly the same.

NOTE:

In **AUTO** *mode, the system automatically enters the low brightness mode when the connected endoscope is idle for more than 1 min.*

■ **MANU Mode**

Perform the following steps.

1. Press the **MANU** button on the front panel to enable the manual brightness adjustment feature.

2. Press the ⊕ or ⊖ button to set the brightness to the desired level.

Brightness is fixed once it is set in **MANU** mode. However, the image brightness will be affected by the distance between the distal end and the observed object.

NOTE:

If the endoscope keeps working at highest light intensity for a long time, mist may appear on the image because tissues (such as residual blood and moisture) attached to the lens evaporate due to excessive heat of the light guide. If the examination is interfered under this condition, take out the endoscope, and wipe the distal end with the lint-free cloth dampened with 75% alcohol. Then reinsert the endoscope to continue the examination.

4.3   Selecting the illumination Mode

Different illumination modes can be adopted in different observation distances and their effects differ.

- **White light mode (WL)**: This mode can restore the true color of images and realize the high-brightness and high-contrast observation, which is applicable to normal inspections and lesion identification.
- **Enhanced white light mode (EWL)**: This mode can highlight the contour of the mucosal vessels with a color tone similar to the white light mode, which is applicable to the normal inspections and lesion identification in the middle and far fields.
- **Spectral focused imaging (SFI)**: This mode can enhance the contour of the superficial and middle-layer mucosal vessels in the image, which is applicable to lesion identification and early cancer screening under the near-field and far-field observation.
- **Versatile intelligent staining technology (VIST)**: This mode can enhance the contour of the superficial mucosal vessels and the micro-structure of the mucosal surface, which is applicable to the accurate diagnosis of early cancer under the near-field and far-field observation.

Press the **VLS** button on the front panel to choose the desired illumination mode..

4.4   Using Transillumination

⚠ WARNING Use the transillumination feature only when necessary.

You can locate the distal end of the endoscope inside the patient's body by using the transillumination feature.

Press the **TRANS** button to enable the transillumination feature. After it is enabled, the light automatically reaches the maximum intensity and starts twinkling. Six to eight seconds later, the light intensity is automatically adjusted to the original intensity.

NOTE:

*You can disable this feature by pressing the **TRANS** button again or other buttons (except the power button and **LIGHT** button) on the front panel to disable the transillumination feature and the light can be restored.*

4.5   Adjusting Air-feeding Pressure

Perform the following steps.

1. Press the **AIR** button to start air feeding, and press the **LEVEL** button to adjust the air-feeding pressure to the desired level **(L, M, H**).

2. Perform the air-feeding operation according to the endoscope user manual.

3. Press the **AIR** button again to stop air feeding.

4.6   Turning Off/StandBy the Lamps

Press and hold the **LIGHT** button for about 2 seconds to manually turn off the lamps. Additionally, the light source will automatically enter StandBy mode if the image processor detects no video signal or inactivity for a defined period of time.

5 Maintenance

To ensure the safety and functionality of the device, follow the descriptions in this chapter to clean and maintain the device.

During use, any serious incident that has occurred in relation to the device should be reported to the local distributor and the competent authority of the Member State.

⚠ WARNING
- To avoid electrical shock and damage to the device, power off the device and disconnect it from the AC power outlet before cleaning.
- To ensure the device performance, maintain the device periodically (not more than a year), and ensure that the grounding of the device is correct and complies with the safety requirements.
- The lamp can be replaced only by the local distributor of this manufacturer. Before replacing, ensure that the device is closed and unplugged. Otherwise, the electric shock or damage to the device may be caused.

5.1   Cleaning the Device

⚠ WARNING
- Ensure that the device is completely dry before use to avoid electrical shock.
- Wear personal protective equipment during the cleaning. Otherwise, the blood, mucous membrane and other potential source of infection adhered to the device may result in cross-contamination.
- Do not wipe the endoscope port or other ports. Otherwise, deformation or bad contact may occur to the pins inside the ports.

NOTE:
If the device is contaminated, perform the cleaning procedure below immediately after use. If cleaning is delayed, the debris may dry up and become difficult to be cleared up.

■   **To clean the surface**

Perform the following steps.

1. Power off the device and disconnect it from the AC power outlet.

2. In case of potentially infectious substances such as blood or body fluid, use a lint-free soft cloth dampened with neutral detergent solution to clean the surface.

3. Use the lint-free soft cloth dampened with 75% ethyl alcohol to clean the surface dirt. Ensure that the device is completely dry.

■   **To clean and disinfect the water bottle**

Perform the following steps.

1. Take down the water bottle connector from the endoscope and uninstall the water bottle from the holder.

2. Open the water bottle cap and uninstall the tube from the water bottle.

3. Soak the water bottle, cap and the tube into the high-level and non-corrosive chemical disinfectant for disinfection.

4. Flush the remained disinfectant with the sterile water and dry it for standby.
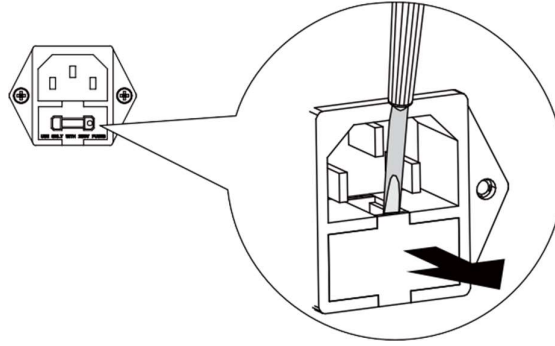
NOTE:

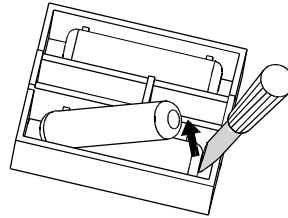*Change the sterile water in the water bottle each day.*

5.2 Replacing the Fuse

Perform the following steps.

1. Power off the device and disconnect the power cable.

2. Take out the fuse box with a slotted screwdriver.

3. Replace the blown fuse.

4. Push the fuse box back into the place and fasten the screws on the fuse box.
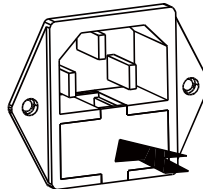
5. Connect the power cable, and press the power button to power on the device. Ensure that the power indicator is illuminated. Contact the local distributor of the manufacturer if the device cannot be powered on.

5.3 Storing the Device

NOTE:
- *To avoid malfunction, do not excessively bend, pull, twist or squeeze the power cable during storage.*
- *Store the device in the environment of good ventilation and avoid direct sunlight.*

Perform the following steps.

1. Power off the device and disconnect the power cable.

2. Disconnect all the peripherals from the device.

3. Place the device on a clean and level surface at room temperature.

5.4   Troubleshooting

The troubleshooting should be performed by qualified technical personnel. If a problem persists after the troubleshooting, stop using the device immediately and contact the local distributor of the manufacturer for repair.

Description	Inspection Item	Solution
The prompt that the endoscope is connected is not displayed; or, white screen appears.	Light control cable	Ensure that the light control cable is connected properly.
Blurred screen appears after the endoscope is connected.	Optical fiber cable	Ensure that the optical fiber cable is connected properly.
		Wipe the front end of the optical fiber cable with an alcohol cotton ball, and then insert the optical fiber cable.
The device emits only the white light or the bluish violet light.	Device temperature	Ensure that the rear fan of the case works normally.
		Ensure that ventilation holes are not blocked.
The device cannot be connected to the endoscope.	Endoscope and the device	Ensure that they are compatible with each other.
The device cannot be powered on.	Power cable	Ensure that the power cable is connected properly.
	Fuse	Replace the fuse.
The buttons on the front panel cannot work properly.	Front panel	Ensure that the front panel is clean and free of water drops.
	Power cable	Ensure that the power cable is well connected to the ground.
The indicators cannot work properly.	Front panel	Check if the indicators can respond to the pressing of the buttons on the front panel. Restart the device if the indicators cannot respond.
The intensity of light is low.	Lamps	Check if the lamps have reached lifespan.
No light is emitted from the distal end.	Connection of the endoscope and the device	Ensure that the endoscope is properly connected to the device.
The intensity buttons do not work.	Intensity indicator	Check if the intensity is adjusted to the maximum or the minimum level.
The image is too bright or too dim.	Connection of the endoscope and the device	Ensure that the endoscope is properly connected to the device.
	Light transmission	The device automatically restores to normal state 6 - 8 seconds later.

Description	Inspection Item	Solution
The image color is abnormal.	SFI or VIST mode	Check if the device is in SFI mode or VIST mode. If this mode is enabled, press the **VLS** button to switch to the WL mode or EWL mode.
	White balance	If the current illumination mode is the white light mode, perform the white balance feature.
Unable to feed water/air.	Connection of the endoscope and the device	Ensure that the endoscope is properly connected to the device.
	Air pump	Ensure that the air pump is turned on and noise can be heard during working.

5.5 Disposing of the Device

The manufacture date of the device can be found on the label, and the expected service life of the device is five years with normal use. You should dispose of the device or its accessories in accordance with local laws or regulations. For detailed disposal information, consult the local distributor. The manufacturer is not responsible for any device content or accessories that have been discarded improperly.

The expected service life of the lamps and air pump are shown as follows.

Component	Expected Service Life
Lamps	20,000 hours, continuous operation
Air pump assembly	5,000 hours, continuous operation

5.6 Customer Service

Only the service personnel of or authorized by the manufacturer can service the device. Any feedback or inquiries concerning our product or services should be directed to the manufacturer.

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