

MS-8

Image Processor

Instructions for Use

Description

Thank you for purchasing the Image Processor.

Please read the Instructions for Use (hereinafter referred to as "IFU") carefully before use for proper use of the product.

Please keep this Instructions for Use for future reference.

Product name: Image Processor

Product model: MS-8

Date of manufacture: See the product label

Service life: 3 years

Preparation/revision date: 2025-05-13

IFU version: 1.0

Software release version: V1

Product performance, structure and composition: It consists of an image processor and accessories, which include a power cord and a signal cable.

Intended use: This product shall be used in conjunction with the compatible medical electronic endoscope or laryngoscope for displaying images of the in vivo operative region during endoscopic surgery.

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Intellectual Property

The IFU and the intellectual property of the product belong to Shenzhen HugeMed Medical Technical Development Co., Ltd. (hereinafter referred to as "Manufacturer").

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Statement

The Manufacturer reserves all the rights for the final interpretation of the IFU.

The Manufacturer reserves the right to modify the IFU without prior notice. Modifications to the content of the IFU will be reflected in the latest version.

The Manufacturer shall not be held responsible for any software and equipment not manufactured for and distributed by Endo-Therapeutics.

Only when all of the following requirements are met shall the Manufacturer be held responsible for the safety, reliability, and performance of the product:

- Assembling, expansion, adjustment, improvement, and repair shall be carried out by professionals recognized by the Manufacturer;
- All replaced parts involved in repair and supporting accessories and consumables are genuine (original) parts of or approved by the Manufacturer;
- The related electrical equipment complies with national standards and the requirements specified in the IFU;
- This product shall be operated according to the IFU.



Warning

- **The product should be used by a professional clinician, medical electrical specialist, or professionally trained clinical medical personnel in the designated setting. Personnel using the product should be adequately trained. Any unauthorized or untrained personnel should not perform any operation.**
 - **Stay meticulous and attentive while working to avoid accidents!**
 - **Daily care and maintenance are necessary.**
-

Cautions

- **Federal (USA) Law restricts this device for sale to or on the order of a physician. Prescription only.**
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Foreword

Description

This IFU details the purpose, functions, and operation of the product. Prior to using this product, please read carefully and understand the IFU to ensure its correct use as well as the safety of the patient and operator.

The IFU describes this product in its most complete configuration, and some of the features described may not apply to the product you have purchased. If you have any questions or experience issues with the product, please contact Endo-Therapeutics.

These operation instructions contain precautions on how to operate the Image Processor safely, correctly, and effectively. They help reduce failure and improve the reliability and service life of the instrument. It can be used not only as an IFU, but also as a reference manual. Therefore, this IFU must be kept next to the device and available at any time.

Read Chapter 1 "Safety" carefully before using it for the first time.

Applicable Objects

The IFU is intended for use only by specially trained clinical medical staff.

Illustrations

All illustrations provided in the IFU are for reference only. The settings or data in the illustrations may not be exactly the same as the actual display of the product.

Key to Conventions Used

- ***Italics*** Bold italics are used in the IFU to represent the chapters quoted.
- Terms such as hazard, warning, caution, and note are used in the IFU to prompt any hazard information and its severity.

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Chapter 1 Safety

1.1 Safety Information

This chapter lists the basic safety information that users must pay attention to and observe when using the Image Processor. Other safety information that is identical, similar, or relevant to specific operations will appear in respective chapters.

Hazard

- Indicates an urgent danger that, if not avoided, may result in death, serious physical injury or property damage.
-
-



Warning

- Indicates a potentially dangerous or unsafe operation that, if not avoided, may result in death, serious physical injury, or property damage.
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Caution

- Indicates a potentially dangerous or unsafe operation that, if not avoided, may result in minor physical injury, product failure, damage, or property damage.
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Note

- Stresses important precautions, provides instructions or explanations for better use of the product.
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1.1.1 Hazard

There is no such safety risk.

1.1.2 Warning



Warning

- The Image Processor shall be used in conjunction with our endoscope or laryngoscope, and can only be used by professional clinicians, medical electrical specialists, or trained clinical medical staff in a designated situation.
- The responsible surgeon must take charge of the operating procedures and technical application of the equipment! The trained surgeon (responsible surgeon) is entitled to decide how to make full use of the equipment in light of the actual application conditions.
- Prior to first use, please read the IFU carefully.
- Before using the Image Processor, the user must check the Image Processor and its accessories to ensure their proper and safe operation.
- It shall not be used in an environment where flammable or explosive items are placed to prevent fire or explosion.
- The Image Processor and its supporting equipment shall be properly installed or carried to protect the Image Processor from falling, being collided, receiving intensive oscillation, or being damaged due to other external mechanical forces.
- The electromagnetic field may affect the performance of the Image Processor and its supporting equipment, so the equipment in use near the Image Processor and its supporting products must meet the corresponding EMC requirements, otherwise, electromagnetic interference may result in failure or collapse to the Image Processor. Mobile phones, X-ray or MRI equipment are all possible sources of interference, all of which may emit high intensity electromagnetic radiation.
- All other devices. For example, some similar digital interference devices must meet relevant requirements in the standards when they are connected to an Image Processor. The person responsible for connecting the equipment must ensure the operability of the system and be responsible for meeting the system requirements. If you have any other questions, please consult Endo-Therapeutics.
- Relevant local regulations or the hospital's regulations on waste disposal must be followed when handling the packaging materials.
- The Manufacturer shall not be held accountable for any personal injury and property damage because:
 - Equipment parts are not original parts of the Manufacturer;
 - The IFU is lost;
 - Installation, commissioning, revision, upgrading, and repair are done by personnel not authorized by the Manufacturer.

- The Manufacturer will not be responsible for any damage or incident arising from using consumables or accessories that are not of the specifications required by the Manufacturer.
 - The Image Processor is prohibited from use while charging. The Manufacturer will not be responsible for any damage or incident caused by unauthorized use.
 - A notice that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
-

1.1.3 Caution

Caution

- The use environment and power supply of the Image Processor must comply with the requirements in *Section 4.2 Technical Parameters*.
-

1.1.4 Note

Note

- Please place the IFU near the Image Processor so that it is easily and promptly accessible when required.
 - The IFU describes the product in its most complete configurations and functions, and the Image Processor you have purchased may not have certain configurations or functions.
-

1.2 Labels and Identification

	Warning		Type BF applied part
	RX Only		Refer to instruction manual/booklet
	Manufacturer		Serial number
	Date of manufacture		Medical Device
	Temperature limit		Waste electrical and electronic equipment directive
	Atmosphere pressure limitation		Humidity limitation
	Fragile, handle with care		Keep dry
	This way up		Stacking limit by five
	Unique device identifier		

Chapter 2 Overview

2.1 Product Description

2.1.1 Intended use

This product shall be used in conjunction with the compatible single use endoscopes for displaying images of the in vivo operative region during endoscopic surgery.



Warning

-
-
- **Before using the Image Processor, the user must inspect the Image Processor and its accessories to ensure their proper and safe operation.**
-
-

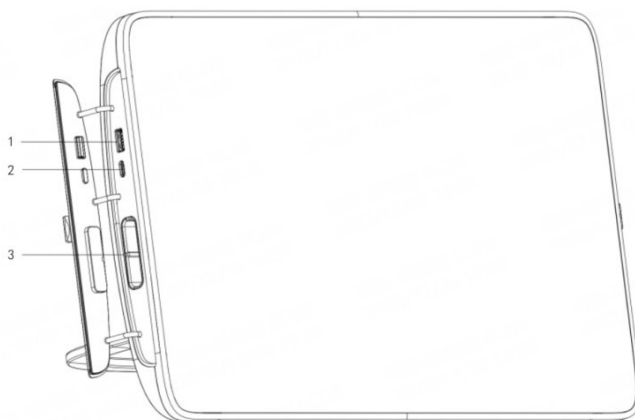
2.1.2 Structural Composition

It consists of an image processor and accessories, which include a power cord and a signal cable.

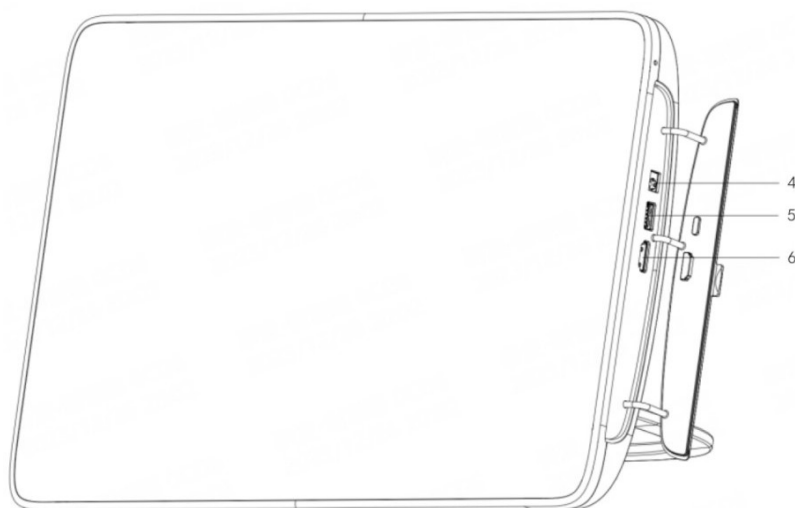
2.1.3 Contraindications

Used in conjunction with the electronic endoscope or laryngoscope distributed by Endo-Therapeutics, which is equivalent to the contraindications of endoscope or laryngoscope.

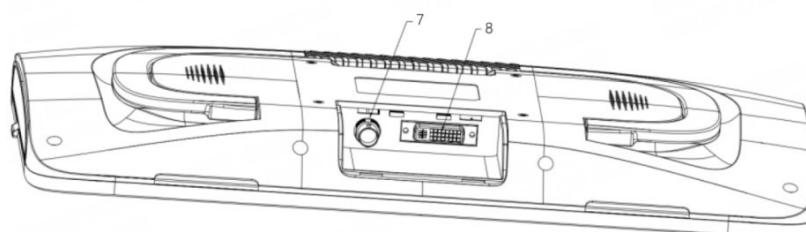
2.1.4 Product Structural Diagram



[Fig. 2-1] Left front view of MS-8



[Fig. 2-2] Right front view of MS-8



[Fig. 2-3] Rear view of MS-8

Tab.2-1 Instructions of ports

No.	Port	Instructions
1	USB I	Data copy, USB flash drive upgrade, etc.
2	VL-Port	To connect the video laryngoscope
3	Endoscope Port	To connect the endoscope
4	DC	Power input port
5	USB II	Online upgrade and debugging port
6	HDMI	High-definition multimedia interface (HDMI) port
7	SDI	Serial digital interface (SDI) port
8	DVI	Digital visual interface (DVI) port

2.1.5 Battery

2.1.5.1 Overview

The Image Processor has a built-in lithium-ion battery (hereinafter referred to as the "Battery") and operates on battery power. The Battery will charge when the Image Processor is connected to the power adapter. When charging in the power-on state, the Image Processor will enter the charging mode and cease to operate.

Note

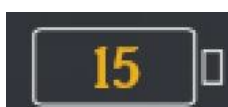
- Do not charge if the mains voltage fluctuates significantly.
- It takes 4–5 hours to charge the battery in full when the battery is drained. Rechargeable batteries have a continuous operating time of approximately 3–5 hours with load.
- If this product will not be used for a long time, please charge and discharge the battery at a 3-month interval to avoid battery damage.
- The battery is a consumable part and, once exhausted and failed, must be replaced. If the battery drains a short time after it is fully charged, it may have been damaged or failed. The power supply time of the battery depends on the configuration and frequency of use of the Image Processor, e.g. long-time backlight of the display screen.
- If the battery needs to be replaced, contact Endo-Therapeutics.

2.1.5.2 Battery Level

The battery icon will show the battery level.



White = 20% < battery level ≤ 100%



Orange = 10% < battery level ≤ 20%



Red = 0% ≤ battery level ≤ 10%



Charging

2.1.5.3 Battery Maintenance

To ensure safe operation and prolong the battery life as much as possible, please pay attention to the following guidance for use:

- Every 3 months of use (or storage) or when the running time of the Image Processor becomes significantly short, the battery shall be fully charged and discharged (the Image Processor shall be discharged first, and then charged to 100%) to ensure that the battery is charged for storage.

2.1.5.4 Battery Recycling

If the battery suffers from obvious damage (bulging, deformation, weeping) or the battery level is exhausted, contact Endo-Therapeutics at complaintsETI@endotherapeutics.com.



Warning

- **Do not disassemble the battery, put it into fire or make it short-circuit. Battery burning, explosion and leakage may cause personal injury.**
-
-

Chapter 3 Use and Maintenance

3.1 Installation and Use



Warning

- The software copyright of the Image Processor is owned by the Manufacturer, and no organization or individual is allowed to tamper, copy, or exchange it by any means or in any form without permission.
 - The Image Processor main unit must be connected to the endoscope or laryngoscope distributed by Endo-Therapeutics. The Manufacturer shall assume no responsibility for any damage or incident caused by connecting to endoscopes not distributed by Endo-Therapeutics.
 - When the endoscope connected to the Image Processor main unit loses its function, it shall be removed from the patient immediately and disconnected from the Image Processor main unit.
 - Do not use this product in the presence of high-frequency electrosurgical equipment, as it may cause injuries to patients or damage to equipment.
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3.1.1 Unpacking and Inspection

Before unpacking, please carefully check the packing box to determine whether the product is damaged during transportation. Notify Endo-Therapeutics at complaintsETI@endotherapeutics.com immediately if any damage is found.

If the package is intact, please unpack it correctly, carefully take out the Image Processor from the packing box, and count one by one according to the packing list. Check whether the product has suffered from any mechanical damage and whether the items are complete. If you have any questions, please feel free to contact Endo-Therapeutics at complaintsETI@endotherapeutics.com.



Warning

- The user shall keep the packaging materials away from children. Relevant local regulations or the hospital's regulations on waste disposal must be followed when handling the packaging materials.
-
-

Note

- Please keep the packing box and packaging materials for future shipping or storage.
 - If you open the package and find that some fittings are missing, please contact Endo-Therapeutics as soon as possible.
-

3.1.2 Charging Requirements

The Image Processor shall be charged with an adapter of the *following specification* that complies with the requirements of IEC 60601-1:2005 + A1:2012 + A2:2020.

Adapter	
Specification	Parameter
Output voltage	DC 12V
Output current	6 A



Warning

- The appropriate power supply must be selected according to the recommended adapter specification. Otherwise, it may cause serious harm to the device.
 - Operation is prohibited while charging.
 - When disconnecting the Image Processor from the adapter, pull the plug out of the socket.
-

3.1.3 Environment Requirements

The use environment of the Image Processor shall comply with the requirements in *Section 4.2 Technical Parameters*.

The use environment of the Image Processor shall also be free of noise, vibration, dust, and corrosive or flammable and explosive substances.



Warning

- To avoid electric shock risks, the device shall only be connected to the grounded power supply.
 - When disconnecting the device from the power supply, the plug must be pulled out of the wall socket. When disconnecting the Image Processor from the adapter, pull the
-

plug out of the socket.

3.1.4 Power Supply Requirements

The product shall operate in compliance with the requirements in *Section 4.2 Technical Parameters*.



Warning

- Please make sure that the Image Processor operates under the specified environmental and power conditions, otherwise, it will not meet the technical specifications stated in *A Product Specification* and may lead to unexpected consequences such as image processor failure.
-

3.1.5 Endoscopic Connection

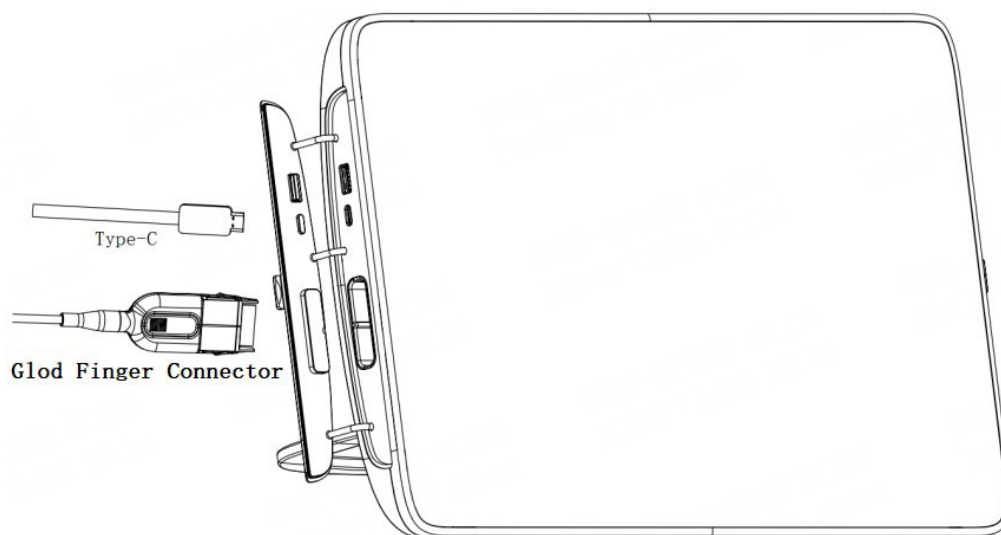
Note

- The Image Processor main unit must be connected to the endoscope or laryngoscope distributed by Endo-Therapeutics. The Manufacturer shall not assume any responsibility for any damage or incident caused by connecting to endoscopes not manufactured for Endo-Therapeutics.
-

- (1) Check whether the endoscope is intact in appearance;
 - (2) Check the IFU attached to the main unit and prepare to connect the endoscope.
 - (3) Connect the Image Processor main unit to the endoscope.
 - (4) Press the Power button to start the main unit.
-

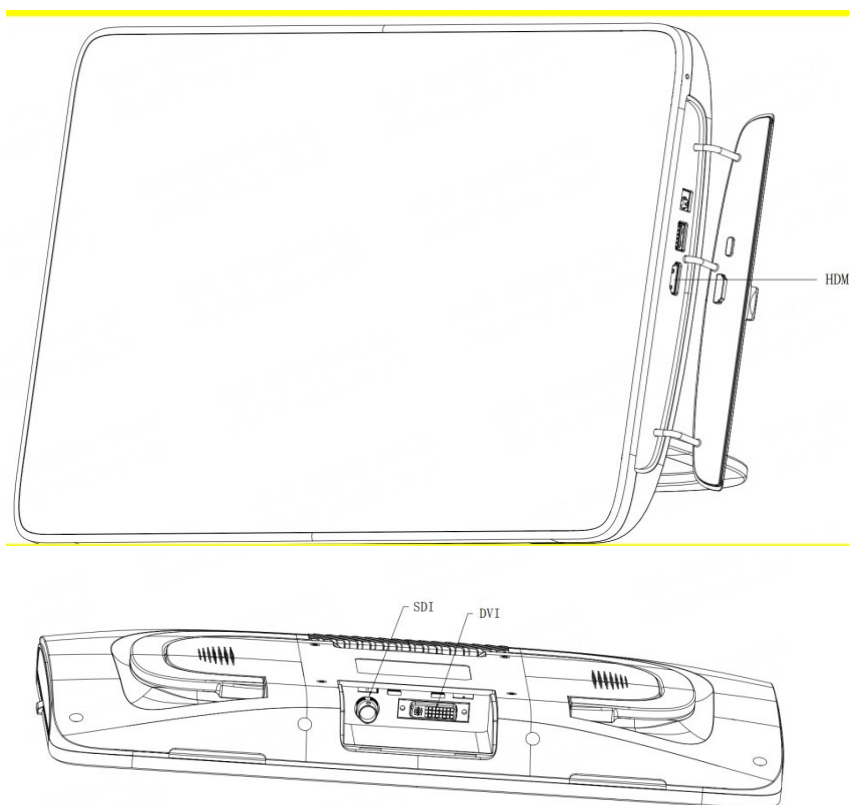
Note

- The plugs for the wiring of the Image Processor main unit and the endoscope have alignment marks. When inserting, pay attention to the direction of the connector and do not forcefully insert for connection. Applying force when not aligned may damage the plug.
-



[Fig. 3-1] Diagram of Endoscope Connection

3.1.6 Monitor (Display Device) connection



[Fig. 3-2] Diagram of Main unit Interface

Connect the video output interface of the Image Processor to the monitor with a signal connecting line.

3.2 Care and Maintenance



Warning

- **Disconnect the Image Processor from any main power supply, remove all connectors, and ensure that the Image Processor is totally switched off before care and maintenance.**
-

The main unit shell does not come into contact with the human body. After use, use a neutral cleaning agent to disinfect its external surface.

Note

- **The rag shall be moist but not dripping so as not to harm the electronics inside the display unit.**
-

Chapter 4 Operation Guide for Image Processor

4.1 Main unit System Operation

4.1.1 Interface Switching

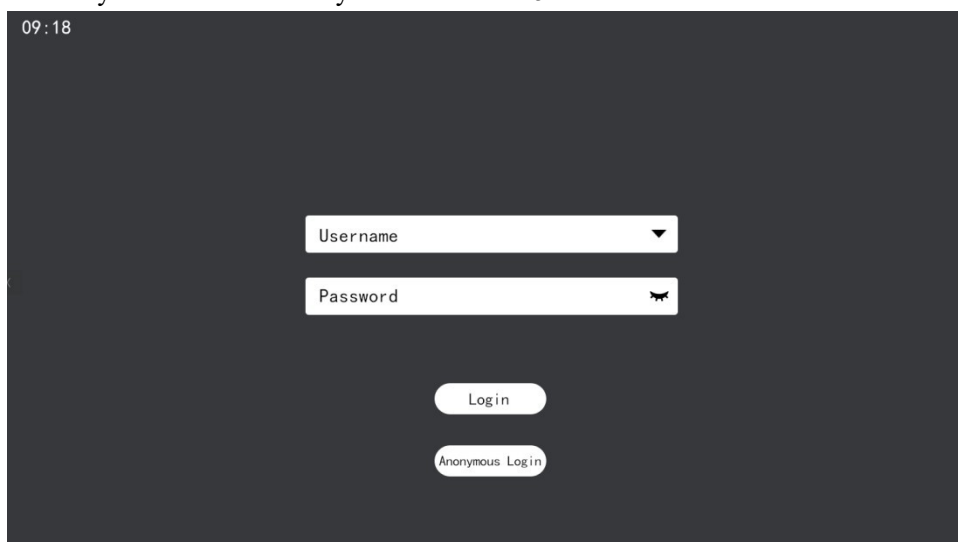
Page	Real-time Display	File	User	Setting
Marks				
Functions	Display of real-time video stream	File management	User management	System conventional settings and function settings

Click different interface icons on the touch screen to switch to the corresponding interface.

4.1.2 Login Interface

Tap the power button of the main unit machine, and the power indicator lamp and the screen will be lit. The login interface will be automatically entered after the system startup, as shown in Fig. 4-1.

Remark: If the screen quickly shuts down when turning on, it is necessary to check if the battery is sufficient. Try to maintain a battery level of at least 5%.



『Fig. 4-1』 Login page

(1) Regular login: Click , and a drop-down box for the user name will appear. Select the user or call out the keyboard to enter the user name, then enter the password, and click the "Login" button. If the user name and the password are correct, the real-time display interface will be entered, and the login user is Admin or a regular user at this time. (Click the show/hide icon )

to show/hide the password entered).

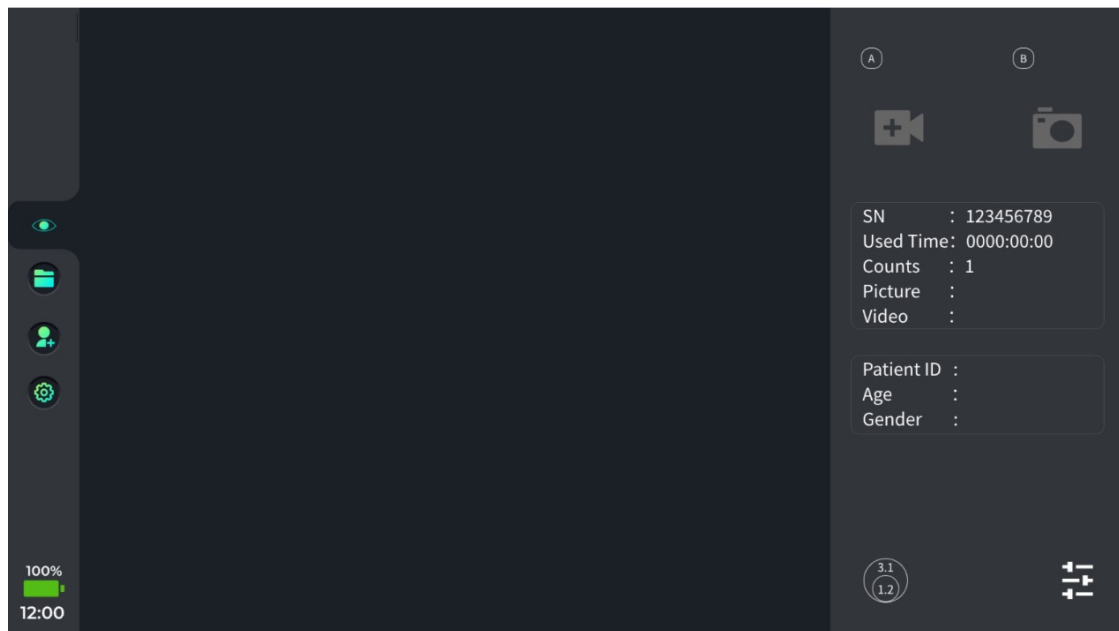
Remark: The default user name of Admin is admin, and the default password is 00000000;

(2) Anonymous login: Click the "Anonymous Login" button to directly enter the real-time display interface. The login user is an anonymous user at this time, and the anonymous user cannot set advanced options.

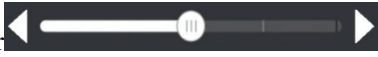
4.1.3 Real-time Display

(1) After the endoscope is connected, the Real-time Display page will display the real-time video stream of the endoscope, the use time of the endoscope will start to be counted, and the inner and outer diameters of the endoscope will be displayed in the lower right corner, as shown in Fig. 4-2.

Remark: This status is a real-time display interface. Please pay attention to selecting this status during use to avoid entering the recording viewing status in file management.



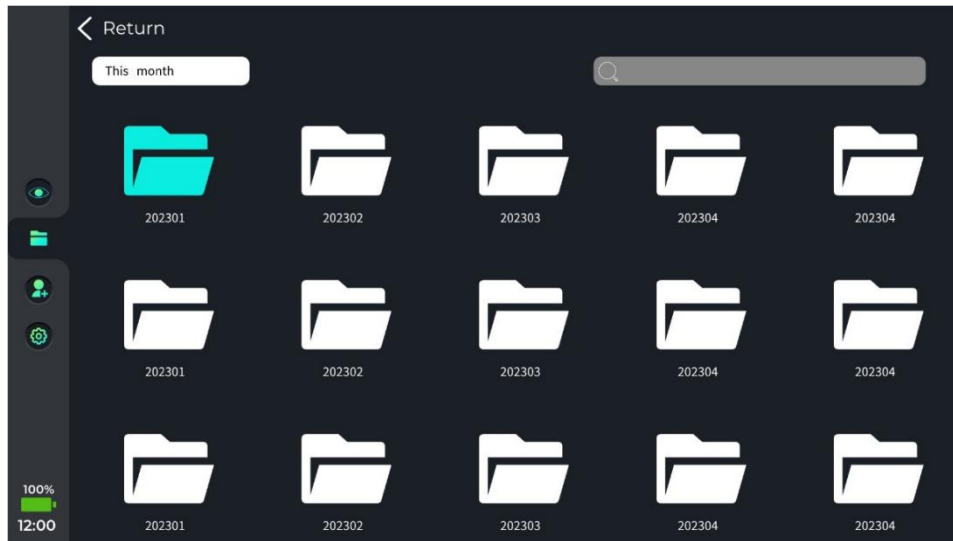
『Fig. 4-2』 Real-time Display page

(2) Image adjustment: Click the Image Settings button , then drag the slider  to adjust the hue, clarity, contrast, and LED brightness, and adjust the white balance of the real-time image for the current scene by the white balance button .

(3) Press the Custom button  or  in the upper right corner, and then select the icon to complete the corresponding function.

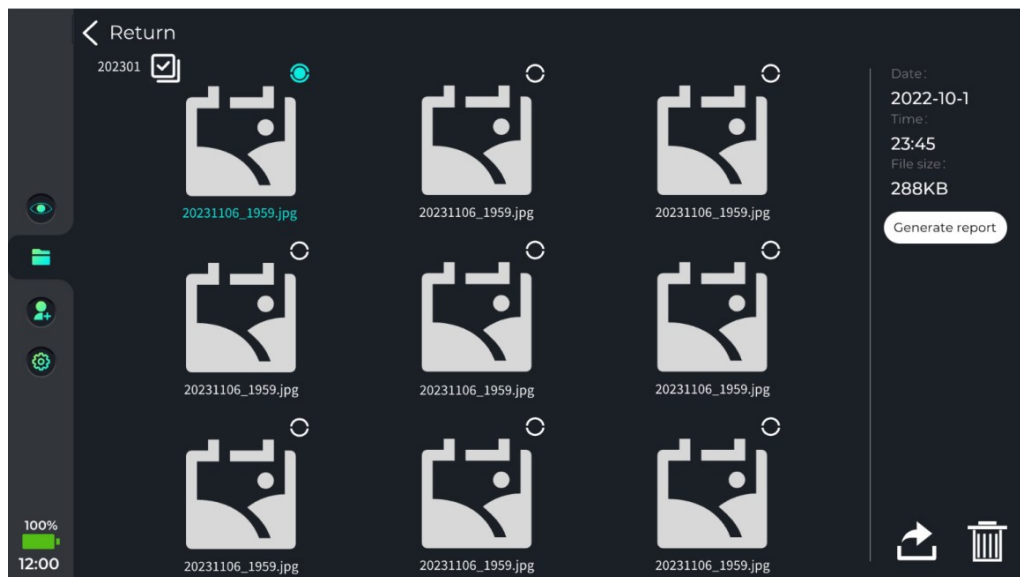
4.1.4 File management

Click  on the touch screen to enter the File page, as shown in Fig. 4-3.



『Fig. 4-3』 File page

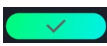
Then click on the corresponding date folder to enter the view image or video page, as shown in Fig. 4-4.

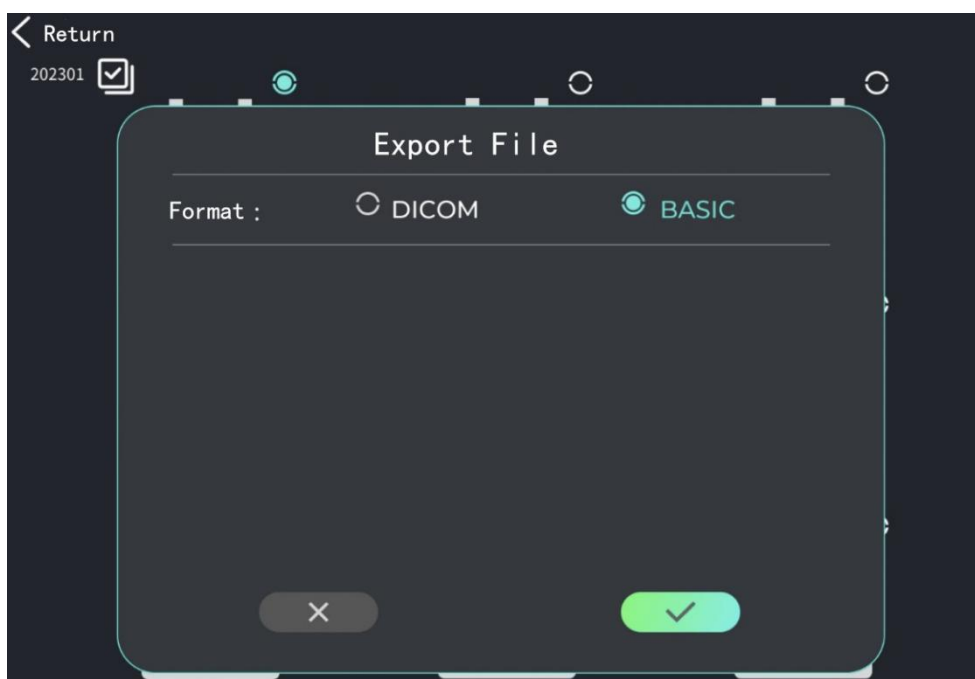


『Fig. 4-4』 File page

Click the file thumbnail to view the file content (picture, video, graphic report), and click  and  to switch files.

(1) Image view: Click  to zoom in the image, and click  to zoom it out.

- (2) Video view: Click  to play the video, and click  to pause it.
- (3) File deletion: Click  in the upper right corner of a file thumbnail to select the file. Once selected, the identifier will change to . Click  and  to delete the selected file, and click  to cancel the deletion.
- (4) File export: Connect to a USB drive, select a file and click , and the File Export pop-up window will pop up. Select the file export format, and click  to export. After the export is completed, click  to exit, as shown in Fig. 4-5.



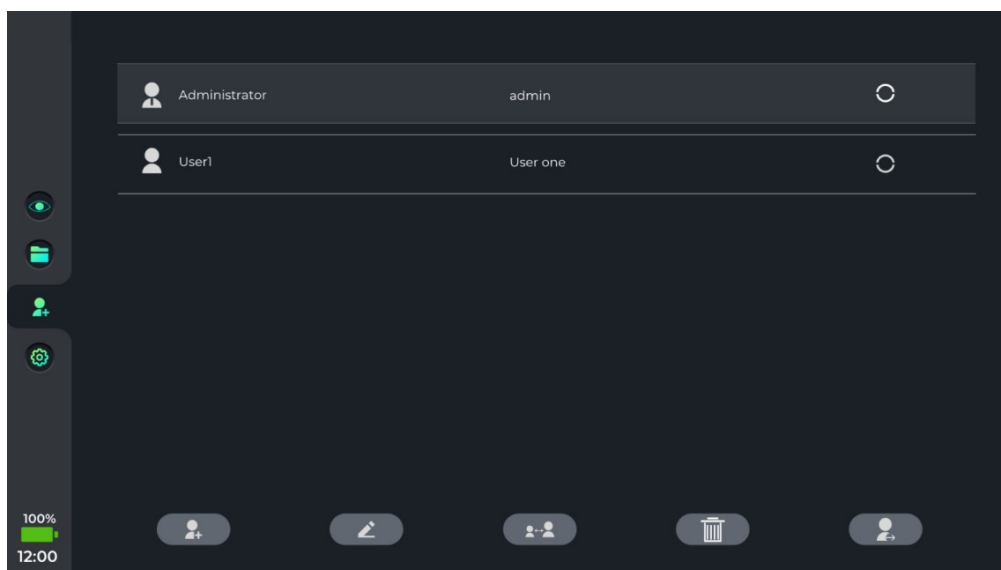
[Fig. 4-5] File Export Pop-up Window

- (5) Creation of graphic report: Select a picture, and click Create Graphic Report to enter the Input Information. Input the information, and click Create Graphic Report again to generate a graphic report.

4.1.5 User management

Click  on the touch screen to enter the User page, as shown in Fig. 4-6.

Remark: Different users have different permissions. The corresponding permissions are performed according to the login user type.



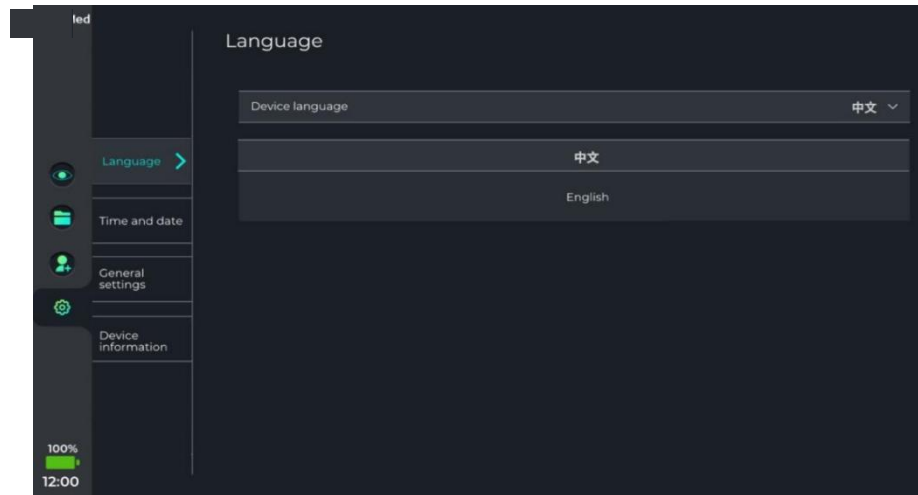
『Fig. 4-6』 User page

- (1) New user: Log in as Admin, then click  to enter the New User page, enter the user name and password, verify the password, and click . If you can see the new user name on the User page, the new user is successfully added.
- (2) Edit user: You can edit all users when logging in as Admin; You can only edit the current user when logging in as a regular user; You cannot edit any user when logging in as an anonymous user. Select the user, click  to enter the Edit User page, enter the user name and password, verify the password, and click . If you can see the edited user name on the User page, the user is successfully edited.
- (3) Switch user: Enter the User page, select the user, click  to enter the Switch User page, enter the correct password, and click . Then the user will be switched to the currently selected one.
- (4) Delete user: Log in as Admin, select the user, and click . Click  in the pop-up window Confirm Delete to delete the selected user.
- (5) Log out user: Click this button to log out the user and enter an anonymous status.

4.1.6 Setting

Click  on the touch screen to enter the Settings page, as shown in Fig. 4-7.

Remark: The setting menu assigns corresponding operation permissions to different login users.



『Fig. 4-7』 Settings page

- (1) Language settings: Click the Device Language bar to show the drop-down options.



Select a language, and the system language will be switched to the selected one.

- (2) Data and date settings:

- 1) Time zone settings: Click the Time Zone Configuration bar to show the drop-down options.



Select a time zone, and the system time zone will be switched to the selected one.

- 2) Time system settings: Select 24H or 12H, and the time system will be switched to the selected one.

- 3) Date format: Select "YYYY/MM/DD" or "DD/MM/YYYY", and the system date format will be switched to the selected one.

- 4) Date and time settings: Select the date and time by sliding up and down, and click  to confirm.

- (3) General settings:

- 1) USB Input: Switch to enable or disable exporting the file to U-disk.
- 2) View Rotation: Switch to enable or disable rotation button at preview window.
- 3) Document Access: When it is enabled, all users can access other user's folder. When it is disabled, only the admin can access another user's folder.
- 4) Boot password: Click the startup password switch  to control the login verification (turn on the switch, and login verification is required for startup);
- 5) Pre-recording: Switch to enable or disable Patient Information Window at preview window. When a patient ID is filled in the information, Photos and videos will be stored in the folder with the patient's ID.
- 6) Border setting: Switch to change Border of preview.
- 7) Restore factory settings: Click the button to restore the factory settings.
- 8) System upgrade: If a system update is required, Endo-Therapeutics will contact the customer to and take appropriate action.

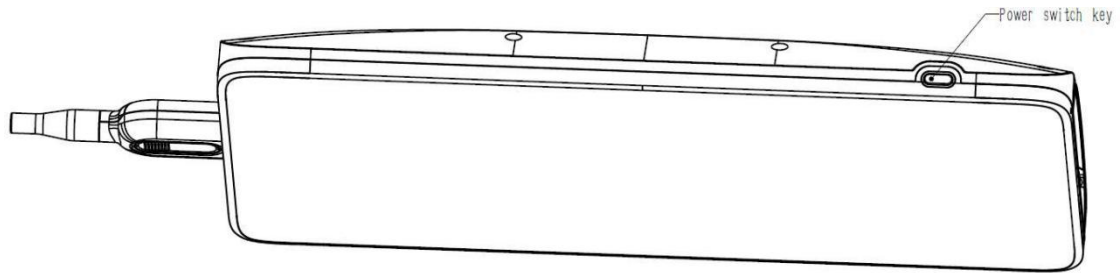
- (4) Device information: Enter the Device Information page to view the information on the main unit machine and lens body.

4.1.7 Shutdown

Lightly press the power button of the main unit for 3 seconds, and the power indicator light and screen will dim, then the system will enter a shutdown state, as shown in Fig. 4-8.

Remark:

The pressing time and whether the power button pressed properly will affect the shutdown. If it has not entered the closed state, it can be pressed for more than 3 seconds, and the maximum pressing time should not exceed 10 seconds.



『Fig. 4-8』 Shutdown operation

4.2 Technical Parameters

Storage method	SD card 64 GB
Power Supply Requirements	Nominal voltage: DC 7.4 V; battery capacity ≥ 9500 mAh
Protection against Electric Shock	Class II, Type BF applied part
Operating environment	
Temperature	5–40°C
Relative humidity	30%–80%RH, non-condensing
Atmospheric pressure	80-106kPa
Altitude	≤ 2000 m
Storage	
Temperature	-10~45°C
Relative humidity	30~80% RH, non-condensing
Atmospheric pressure	80-106kPa
Transportation	
Temperature	-20~50°C
Relative humidity	20~90% RH, non-condensing
Atmospheric pressure	80-106kPa
HDMI port	HDMI
SDI port	SDI
DVI port	DVI
USB port	USB

4.3 Compatible Products

Bronchoscope
Rhinolaryngoscope
Choledochoscope
Cystoscope
Reusable Flexible Video Ureterorenoscope
Single-use Bronchoscope
Single-use Rhinolaryngoscope
Single-use Cystoscope
Single-use Choledochoscope
Single-use Ureterorenoscope
Single-use Biliary Pancreaticobiliary Scope
Single-use Hysteroscopy
Video Laryngoscope

Chapter 5Appendix

5.1 Packing list

Part name	Quantity	Remark
MS-8	1	
Power cord	1	
Power adapter	1	
Instructions for use	1	
HDMI to DVI cable	1	
DVI to DVI cable	1	Optional
SDI cable	1	Optional
USB Flash disk (32G)	1	Optional
VL port connecting cable (type C plug to LEMO connector)	1	Optional
VL port connecting cable (type C plug to type C plug)	1	Optional
Reusable flexible endoscope connecting Cable (Gold finger plug to LEMO connector)	1	Optional