MS-8

Medical Image Processor

Instructions for Use

CE 2797

Description

Thank you for purchasing the Medical 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:	Medical Image Processor
Product model:	MS-8
Date of manufacture: Service life: Preparation/revision date: Version of the Instructions for Use: Software release version:	See the product label 3 years March 8, 2024 1.0 V1
Product performance, structure and composition:	It consists of an Medical Image Processor and accessories, which include a power cord and a signal cable.
Intended use:	This product shall be used in conjunction with the medical electronic endoscope produced by the Company for displaying images of the in vivo operative region during endoscopic surgery.
Manufacturer:	Shenzhen HugeMed Medical Technical Development Co.,Ltd.
Legal Manufacturer Address: After-sales service company: Contact Details:	401, 501, Building 4, Haizhi Technology Park, Fortis, No. 17, Bulan Road, Xililang Community, Nanwan Street, Longgang District, Shenzhen, Guangdong, 518112, China Shenzhen HugeMed Medical Technical Development Co.,Ltd. Tel: +86-4006901290 E-mail: Info@hugemed.net
Website:	http://www.hugemed.net
EC REP	Shanghai International Holding Corp. GmbH(Europe) Address: Eiffestrasse 80,20537 Hamburg, Germany

Intellectual Property

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

HugeMed is the registered trademark of HugeMed.

Statement

HugeMed reserves all the rights for the final interpretation of the IFU.
HugeMed reserves the right to modify the IFU without prior notice. Modifications to the content of the IFU will be reflected in the latest version.
HugeMed shall not be held responsible for any software and equipment not provided by HugeMed or its distributors.

Only when all of the following requirements are met shall HugeMed 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 HugeMed;
- All replaced parts involved in repair and supporting accessories and consumables are genuine (original) parts of HugeMed or approved by HugeMed.
- The related electrical equipment complies with national standards and the requirements specified in the IFU;
- This product shall be operated according to the IFU.

Warranty and Repair Service

The standard warranty period for this product is one year.

If the warranty period in your sales contract with the seller is inconsistent with the above standard warranty period or unless otherwise agreed, please consult and confirm with HugeMed through the free service hotline at +86-4006901290. If it is not confirmed by HugeMed, please promptly negotiate and confirm with the seller.

The warranty period starts from the "Installation Date" filled in the Product Warranty Card attached to the product, which is the only proof for calculating the warranty period. To protect your rights and interests, please urge the installer to return the second page of the Product Warranty Card to HugeMed within 30 days from the date of installation. If the Product Warranty Card of the product you purchased is not returned to HugeMed in time, the warranty period will be extended for 45 days starting from the "Ex-warehouse Date" indicated on the product packaging box.

Within the warranty period, you may enjoy free after-sales services for the product. Please note that HugeMed will offer a fee-based repair service even within the warranty period if the product needs to be repaired due to the following reasons, and you need to pay for the repair and accessories:

- Artificial damage;
- Improper use;
- The grid voltage exceeds the voltage range specified for the product;
- Force majeure;
- Parts or accessories not approved by HugeMed are replaced or used, or repairs are conducted by personnel not authorized by HugeMed; and
- Other failure not arising from the product itself.

After the warranty period of the product expires, HugeMed may continue to provide fee-based repair services. If you fail to pay for or delay the payment for the repair service, HugeMed will temporarily suspend the repair service until you make the payment.

After-sales Service Unit

Customer Service Department of Shenzhen HugeMed Medical Technical Development Co.,Ltd.
Postcode: 518112
After - sales service hotline: +86-4006901290
Sales hotline: +86-4006901290
Official website: www.hugemed.net

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.**
- **In case repairs are needed, it is advisable to use the original parts.**

Forward

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 them may not apply to the product you have purchased. If you have any questions, please feel free to contact this Company.

These operation instructions contain precautions on how to operate the Medical Image Processor safely, correctly, and effectively. They help reduce failure, maintenance cost and downtime, 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.

Table of Contents

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 Medical 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.**

Caution

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

Note

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

1.1.1 Hazard

There is no such safety risk.

1.1.2 Warning

Warning

- **The Medical 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 Medical Image Processor, the user must check the Medical 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 Medical Image Processor and its supporting equipment shall be properly installed or carried to protect the Medical 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 Medical Image Processor and its supporting equipment, so the equipment in use near the Medical Image Processor and its supporting products must meet the corresponding EMC requirements, otherwise, electromagnetic interference may result in failure or collapse to the Medical 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 Medical 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 the local equipment supplier or the technical service center of HugeMed.**
- **Repairs or upgrades to the Medical Image Processor must be made by trained maintenance personnel authorized by the Company.**
- **Relevant local regulations or the hospital's regulations on waste disposal must be followed when handling the packaging materials.**
- **HugeMed shall not be held accountable for any personal injury and property damage because:**

- Equipment parts are not original parts of HugeMed;
- The IFU is lost;
- Installation, commissioning, revision, upgrading and repair are done by personnel not authorized by HugeMed.

- **HugeMed will not be responsible for any damage or incident arising from using consumables or accessories that are not of the specifications required by HugeMed.**
- **The main unit is prohibited from use while charging. HugeMed 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.**
- **To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.**

1.1.3 Caution

Caution

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

1.1.4 Note

Note

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

1.2 Labels and Identification

	Warning		CE Mark
	Type BF applied part		Follow operating instructions
	Waste electrical and electronic equipment directive		Medical device
	Authorized Representative in the European Community/ European Union		Serial number
	Manufacturer		Date of manufacture
	Unique device identifier		Humidity limitation
	Atmosphere pressure limitation		Temperature limit
	Fragile, handle with care		Keep dry
	This way up		Stacking limit by five

Chapter 2 Overview

2.1 Product Description

2.1.1 Intended use

This product shall be used in conjunction with the medical electronic endoscope produced by the Company for displaying images of the in vivo operative region during endoscopic surgery.

Warning

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

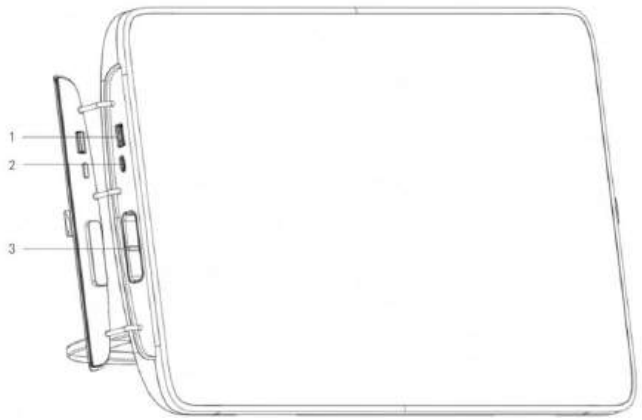
2.1.2 Structural Composition

It consists of an Medical Image Processor and accessories, which include a power cord and a signal cable.

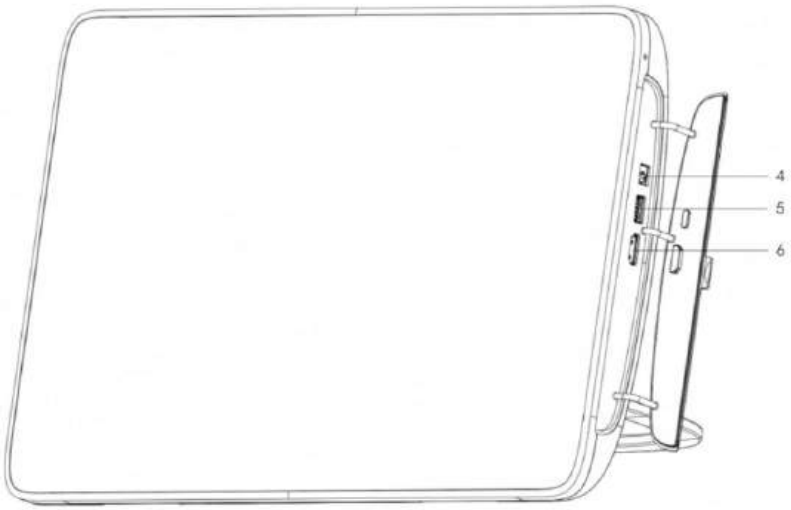
2.1.3 Contraindications

Used in conjunction with the electronic endoscope or laryngoscope of the Company, which is equivalent to the contraindications of endoscope or laryngoscope.

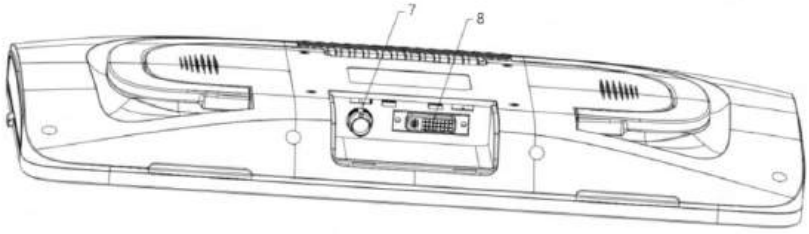
2.1.4 Product Structural Diagram



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

Note

- **Do not charge if the mains voltage fluctuates significantly.**
- **Warning: MS-8 cannot be used while charging.**
- **It takes 4–5 hours to charge the battery in full in case of running down of battery. 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 belongs to consumable part and, once exhausted and failed, must be replaced. If the battery supplies power for a too 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 Medical Image Processor, e.g. long-time backlight of the display screen.**
- **If the battery suffers from obvious damage (bulging, deformation, weeping) or the battery cannot store energy, it shall be replaced and reasonably recycled.**
- **If the battery is to be replaced, contact the distributor selling this product to you or the manufacturer.**
- **Replacement of battery can only be done by the technical service engineer of the Company!**

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:

- The battery performance must be checked once a year. Before the Medical Image Processor is subject to repair or the battery is suspected to be the failure source, the battery performance shall also be checked;
- Every 3 months of use (or storage) or when the running time of the Medical Image Processor becomes significantly short, the battery shall be fully charged and discharged

(the Medical 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, it shall be replaced and reasonably recycled. At the end of the product's service life, open the display unit and dispose of the battery and the display unit separately according to local regulations.

Warning

- **Do not disassemble the battery, put it into fire or make it short-circuited. 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 Medical Image Processor is owned by the Company, and no organization or individual is allowed to tamper, copy, or exchange it by any means or in any form without permission.**
- **The Medical Image Processor main unit must be connected to the endoscope or laryngoscope manufactured by HugeMed. HugeMed shall assume no responsibility for any damage or incident caused by connecting to endoscopes not manufactured by HugeMed.**
- **When the Medical Image Processor main unit is connected to energized endoscopes or endoscope accessories not manufactured by HugeMed, leakage currents of patients may be increased.**
- **When the endoscope connected to the Medical Image Processor main unit loses its function, it shall be removed from the patient immediately and disconnected from the Medical 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.**

3.1.1 Unpacking and Inspection

Before unpacking, please carefully check the packing box to determine whether the product is damaged during transportation. Notify the carrier or this Company immediately if any damage is found.

If the package is intact, please unpack the it correctly, carefully take out the Medical 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 the After-Sales Service Department of this Company.

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 the distributor selling this product to you or the manufacturer as soon as possible.**

3.1.2 Charging Requirements

The Medical 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 Medical Image Processor from the adapter, pull the plug out of the socket.**

3.1.3 Environment Requirements

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

The use environment of the Medical 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 earthed power supply.**
- **When disconnecting the device from the power supply, the plug must be pulled out of**

the wall socket.When disconnecting the Medical 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 Medical 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 Medical Image Processor failure.**

3.1.5 Endoscopic Connection

Note

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

(1) Check whether the endoscope is intact in appearance;

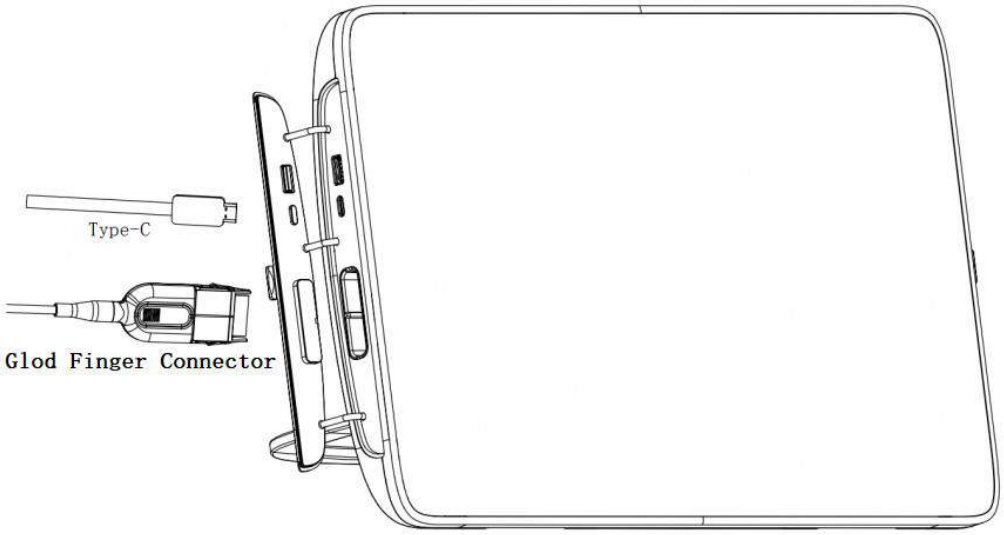
(2) Check the IFU attached to the main unit and prepare to connect the endoscope.

(3) Connect the Medical Image Processor main unit to the endoscope.

(4) Press the Power button to start the main unit.

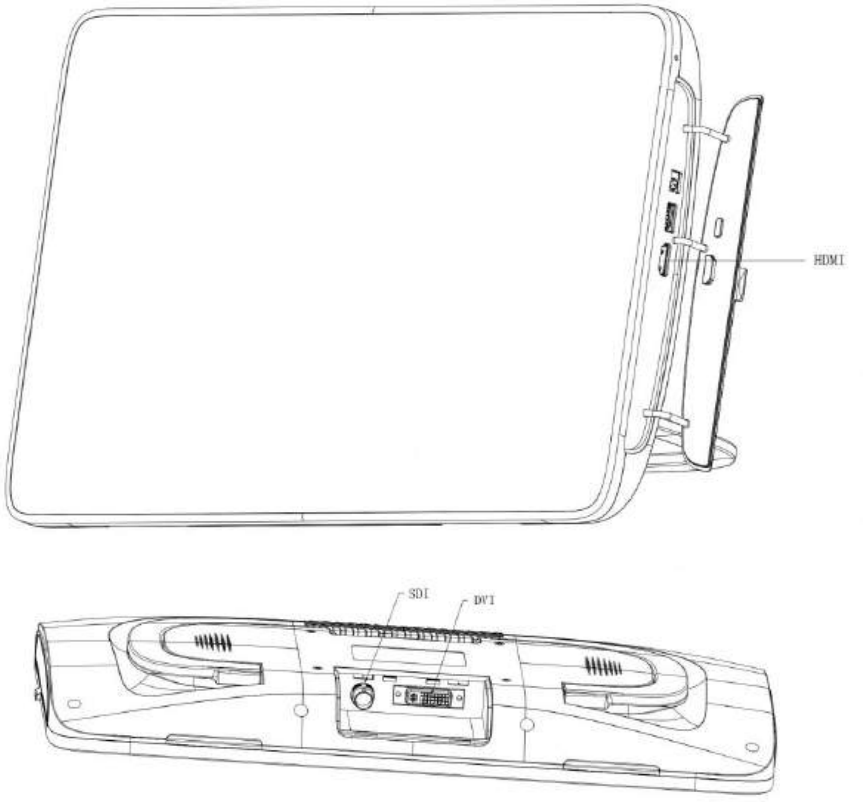
Note

- **The plugs for the wiring of the Medical 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 Medical Image Processor to the monitor with a signal connecting line.

3.2 Care and Maintenance

Warning

- **Disconnect the Medical Image Processor from any main power supply, remove all connectors, and ensure that the Medical 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 Medical 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).

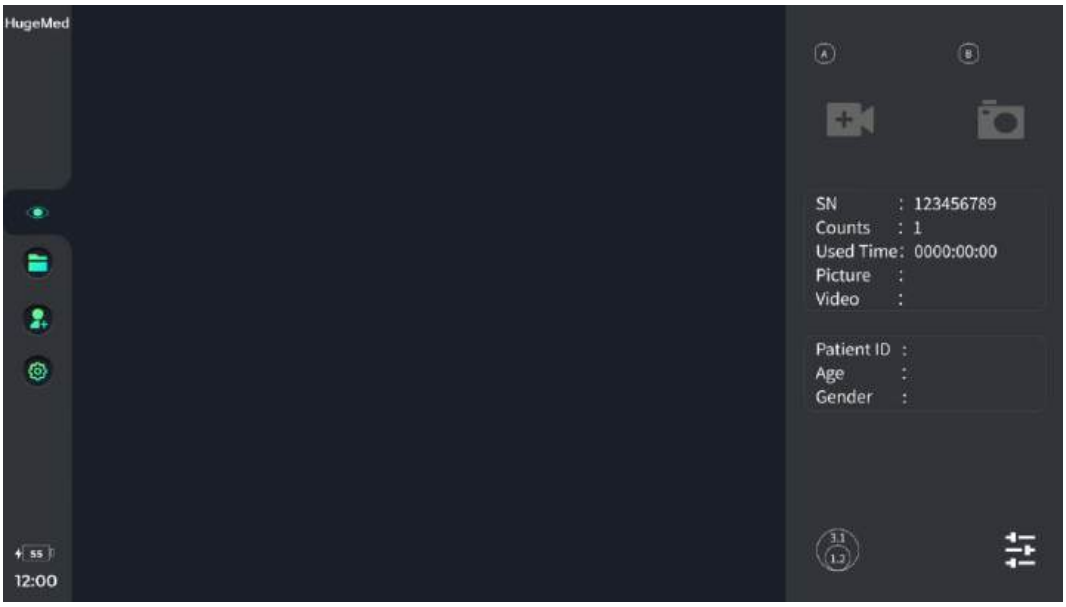
Remark: The default user name of Admin is admin, and the default password is 00000000;

(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 A or B 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.

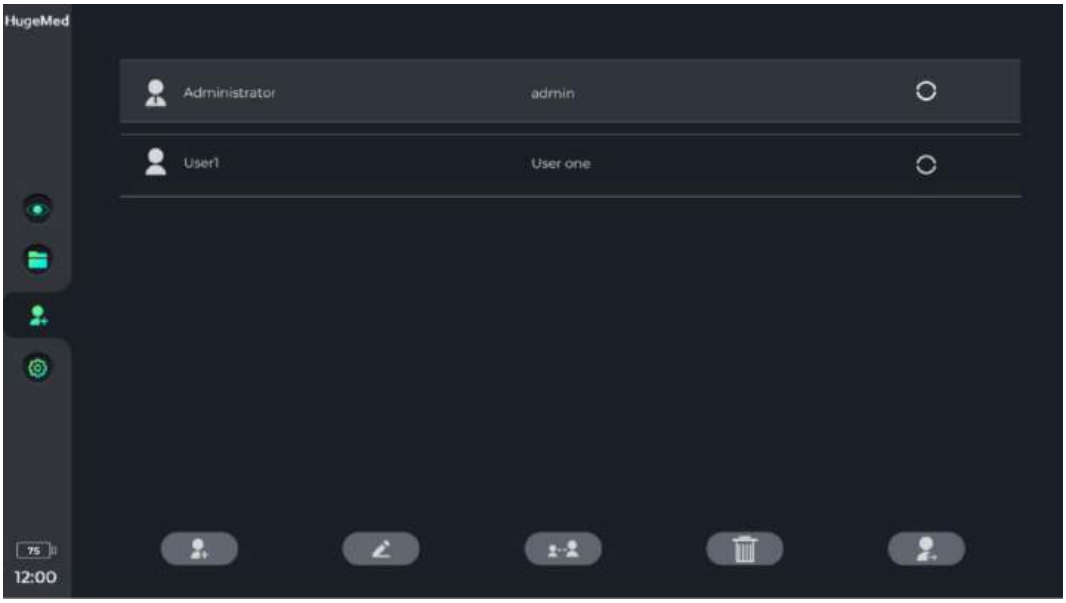
[Fig. 4-5] File Export Pop-up Window

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

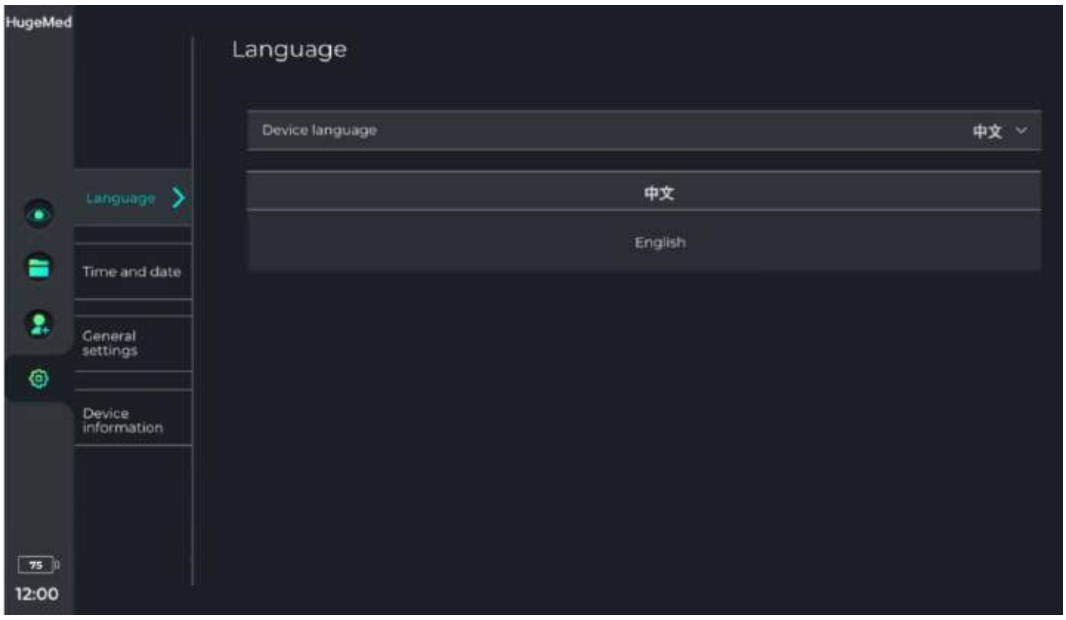
(4) Delete user: Log in as Admin, select the user, and click . Click in the pop-up window Confirm Delete to delete the selected user.

(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 enable, all the user can access other user's folder. When it is disable, only admin can access other 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: Click the button to check whether there is an upgrade file in the USB flash drive, and click the file to upgrade the system after the administrator certification.

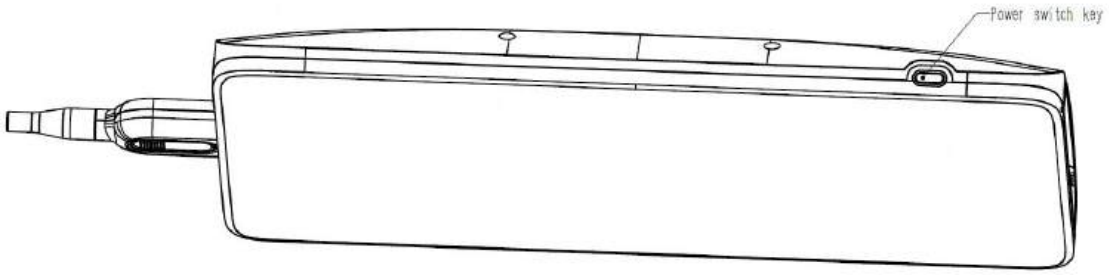
(4) Device information: Enter the Device Information page to view the information on the main unit machine and lens body.

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 I, Type BF applied part
Operating environment Temperature Relative humidity Atmospheric pressure	 5–40℃ 30%–80%RH, non-condensing 80-106kPa
Storage Temperature Relative humidity Atmospheric pressure	 -10～45℃ 30～80% RH, non-condensing 80-106kPa
Transportation Temperature Relative humidity Atmospheric pressure	 -20～50℃ 20～90% RH, non-condensing 80-106kPa
HDMI port	HMDI
SDI port	SDI
DVI port	DVI
USB port	USB

4.3 Compatible Products

Reusable Ureterorenoscope
Single-use Bronchoscope
Single-use Rhinolaryngoscope
Single-use Cystoscope
Single-use Choledochoscope
Single-use Ureterorenoscope
Video Laryngoscope

Chapter 5 Appendix

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

VLM-03

Medical Image Processor

Instructions for Use

INTRODUCTION

Thank you for purchasing the VLM-03 image processor.

Please read the Instructions for Use (IFU) carefully prior to use for proper use of the product.

Please keep the IFU for future reference.

Product name:	Medical Image Processor
Product model/specification:	VLM-03
Date of manufacture:	See product labels
Service life:	3 years
Preparation/revision date:	Dec，20，2023
IFU version:	V1.0
Software release version:	V1
Product performance, structure and composition:	Power adapter, Power cable, USB cable, and HDMI cable
Scope of application:	This product shall be used in conjunction with the medical electronic endoscope produced by the Company for displaying images of the in vivo operative region during endoscopic surgery.
Name of registrant/manufacturer:	Shenzhen HugeMed Medical Technical Development Co., Ltd.
After-sales service provider:	Shenzhen HugeMed Medical Technical Development Co., Ltd.
Site address:	401, 501, Building 4, Haizhi Technology Park, Fortis, No. 17, Bulan Road, Xialilang Community, Nanwan Street, Longgang District, Shenzhen, Guangdong, 518112, China
Contact:	Tel: +86-755-22275866 E-mail: service@hugemed.net
Website:	http://www.hugemed.net

FOREWARD

Introduction

The Instructions for Use (hereinafter referred to as "IFU") detail the purpose, functions and operation of the product. Prior to use of 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 describe this product in its most complete configuration, and some of them may not apply to the product you have purchased. If you have any questions, please feel free to contact the Company.

These operation instructions contain precautions on how to operate the image processor safely, correctly and effectively. They help reduce failures, maintenance costs and downtime, and improve the reliability and service life of the instrument. It can be used not only as an operating manual, but also as a reference manual. Therefore, the 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 population

The IFU are 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.

Conventions

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

TABLE OF CONTENTS

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.**

Caution

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

Notice

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

1.1.1 Hazard

There is no such safety risk.

1.1.2 Warning

Warnings

- **The image processor shall be used in conjunction with our endoscope, and can only be used by professional clinicians, medical electrical specialists or trained clinical medical staff in a designated situation.**
- **The responsible surgeon must be responsible for 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.**
- **Please read the IFU of the image processor carefully before using it for the first time.**
- **Before using the image processor, the user must check the image processor and its accessories to ensure that they work properly and safely.**
- **It cannot 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 installed or handled properly to protect the image processor from falling, collision, intensive oscillation, or damage due to other external mechanical forces.**
- **The electromagnetic field may affect the performance of the image processor and its supporting equipment, so the equipment used near the image processor and its supporting products must meet the corresponding EMC requirements, otherwise the image processor may fail or collapse due to electromagnetic interference. Mobile phones, X-ray or MRI equipment are all possible sources of interference, and they all emit high levels of electromagnetic radiation.**
- **All other equipment, for example, some similar digital interference devices, when connected to an image processor, must meet relevant requirements in the standards (e.g. requirements in GB 4943 for digital processing devices and requirements in GB 9706 for electrical devices). In addition, when other equipment is connected, involving the signal input or output of the equipment, the structure of such other equipment must comply with the system structure as required by GB 9706.1. 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 the local equipment supplier or the technical service center of HugeMed.**
- **Repairs or upgrades to the image processor must be made by the maintenance personnel trained and authorized by the Company.**
- **Relevant local regulations or the hospital's regulations on waste disposal must be followed when handling the packaging materials.**

- **HugeMed shall not be held accountable for any personal injury and property damage due to:**
  - Equipment parts are not original parts of HugeMed;
  - The IFU are lost;
  - Installation, commissioning, revision, upgrading and repair are done by personnel not authorized by HugeMed.
- **HugeMed is not responsible for any damage or event caused by using consumables or accessories not supplied by HugeMed.**

1.1.3 Caution

 **Caution**

The use environment and power supply for the image processor must meet the requirements in *A Product Specification*.

1.1.4 Notice

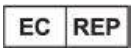
Notice

- **Please place the IFU near the image processor so that they can be easily and promptly accessed when required.**
- **The IFU introduce this product in its most complete configuration and functions, and the image processor you have purchased may not have certain configuration or functions.**

1.2 Labels and Identification


Caution


Type BF applied part



EC Authorized Representative

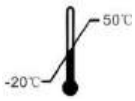

Consult instructions for use or consult electronic instructions for use


Manufacturer

Serial number

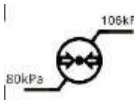

Date of manufacture


Waste electrical and electronic equipment directive



Temperature limit (-20ºC – 50ºC)

Humidity limitation (20%–90%)



Atmospheric pressure limitation (80kPa–106 kPa)


Keep dry


Fragile,
handle with care

Stacking limit by 5


This way up


CE Mark

RX Only

Medical Device

CHAPTER 2 OVERVIEW

2.1 Product Introduction

2.1.1 Scope of application

This product shall be used in conjunction with the medical electronic endoscope produced by the Company for zooming in images of the in vivo operative region during endoscopic surgery.

 **Warning**

- **This product should be used by professional clinicians, medical electrical specialists or trained clinical medical personnel in a designated situation. Personnel using this product should be adequately trained. No operation should be performed by unauthorized or untrained personnel.**
- **Before using the image processor, the user must check its fittings and accessories to ensure that they work properly and safely.**

 **Caution**

- **The use environment and power supply for the image processor must meet the requirements in** *A Product Specification*.

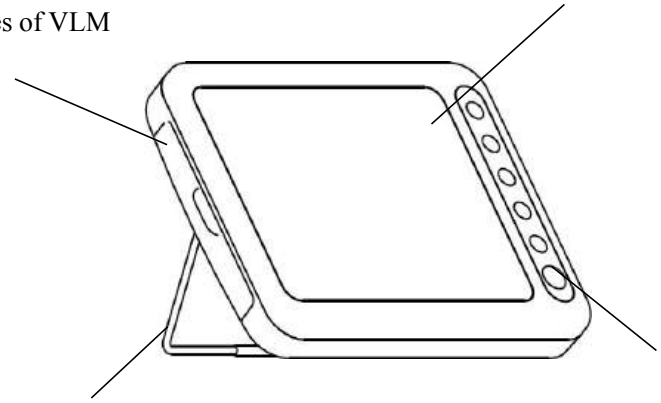
2.1.2 Contraindications

None

2.1.3 Product structural diagram

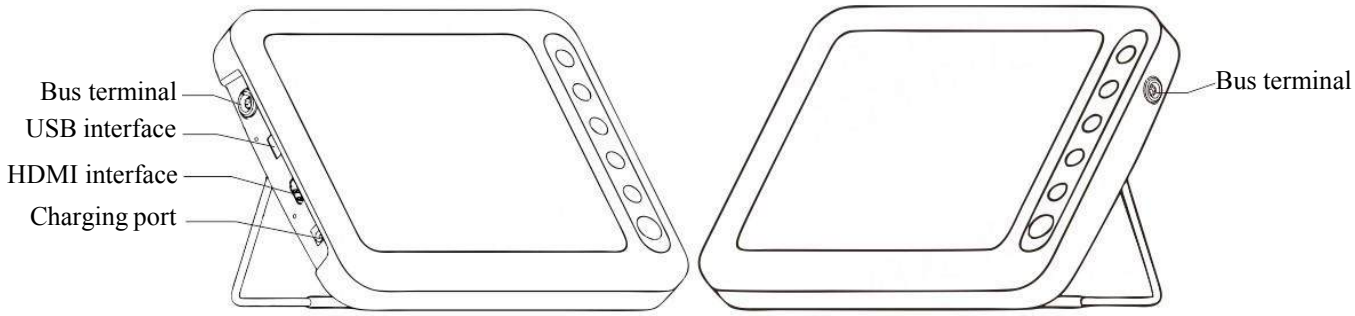
Dust plug:
Protects the power interface and various data transfer interfaces of VLM

Display screen:
Displays the images transmitted by the endoscope



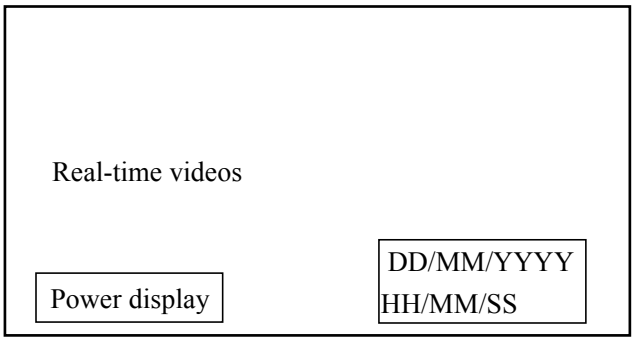
Buttons:
Six operable physical buttons

Metal holder:
Stably places on a robust platform



The plugs of the image processor host and endoscopic wiring have alignment marks. When inserting, please pay attention to the matching of the green and blue circle interfaces between the endoscopy and the host.

2.1.4 Screen display



『Figure 23』display main interface

1. During normal operation, the screen displays real-time video in full screen, the live time is displayed in the lower right corner, and battery level is displayed in the lower left corner;
2. When the battery level falls below 20%, a "Low battery level" prompt will pop up in the top left corner of the screen;
3. When the battery level falls below 10%, a "Battery exhausted" prompt will pop up in the top left corner of the screen;
4. When photographing or taking a video, a photo or video prompt appears in the upper right corner of the screen. When photographing, the photographing prompt pops up; when taking a video, the video prompt keeps flashing.

2.2 Battery

2.2.1 Overview

The image processor has a built-in lithium ion battery (hereafter referred to as the "Battery"), which will be charged when the image processor connects to the power adapter. When charging in the power-on state, the image processor will enter the charging mode, in which operation is also allowed.

Power supply by battery can only be maintained for some time. A low battery level alarm will be triggered at least 30 min before running down of battery, during which the prompts are displayed.

Notice

- **Do not charge if the mains voltage fluctuates significantly.**
- **It takes 4-6 hours to charge the battery in full in case of running down of battery.**
- **If this product will not be used for a long time, please charge and discharge the battery at 3-month intervals to avoid battery damage.**
- **The battery belongs to consumable parts and, once exhausted and failed, must be replaced.**
- **If the battery is to be replaced, contact the distributor who sold this product to you or the manufacturer.**
- **Do not keep the device working while the battery is being charged.**
- **Replacement of battery can only be done by the technical service engineer of the Company!**

2.2.2 Guidance for battery use

The service life of the battery depends on the frequency of use and the operating environment. If used and maintained properly, its service life is about 3 years; Otherwise, its service life may be shorter. The battery shall be replaced every 3 years.

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

- The battery performance must be checked once a year. Before the **image processor** is subject to repairing or the battery is suspected the fault source, the battery performance shall also be checked;
- 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%**), so as to ensure storage of the battery with energy.
- It is recommended not to work during charging.

Warnings

- **Use only the battery specified by the manufacturer.**
- **If the battery shows signs of damage or leakage, replace it immediately.**
- **Do not apply a faulty battery to this image processor.**
- **The used battery can be sent back to the distributor who sold this product to you or the manufacturer, and can also be disposed of according to applicable laws and regulations.**

2.2.3 Battery maintenance

2.2.3.1 Optimization of battery performance

When using the battery for the first time, it shall be optimized. A complete optimization cycle is: continuously charging the battery until full, then discharging it until the image processor is powered off, and then continuously charging the battery until full. During the use of the battery, it shall be optimized regularly to prolong its service life as much as possible.

Notice

- **With the passage of time and the use of the battery, the actual storage capacity of the battery will be reduced. During optimization, if you find that the power supply time of the battery becomes significantly short, please replace the battery.**

Please follow the following steps for optimization:

1. Connect the image processor to the power adapter and charge it continuously to 100%;
2. Disconnect the power adapter from the image processor and use the battery to supply power until the image processor is powered off;
3. Reconnect the image processor to the power adapter and charge it continuously to 100% again;
4. Optimization of the battery is complete.

2.2.3.2 Check of battery performance

The performance of the battery may decline over time, so the battery performance shall be checked regularly.

The following steps shall be followed when checking the battery performance:

1. Connect the image processor to the power adapter and charge it continuously for 4–6 h;
2. Disconnect the power adapter and let the image processor run continuously until it is powered off due to excessively low battery level;

- If the time from the start of the image processor to shutdown is 120 min or above, the battery is in good condition;
- If the time from the start of the image processor to shutdown ranges 30–120 min, the battery is close to the end of its service life;
  - If the time from the start of the image processor to shutdown is less than 30 min, the battery has reached the end of its service life and needs to be replaced.

3. After checking the battery, the battery must be recharged for future use.

Notice

- **If the power supply time after the battery is fully charged is too short, the battery 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 suffers from obvious damage (bulging, deformation, and weeping) or the battery cannot store energy, it shall be replaced and reasonably recycled.**

2.2.4 Battery recycling

If the battery suffers from obvious damage (bulging, deformation, and weeping) or the battery capacity is exhausted, it shall be replaced and reasonably recycled. When disposing of waste battery, corresponding laws and regulations shall be followed.

Warnings

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

CHAPTER 3 USE AND MAINTENANCE

3.1 Installation and Use

Warnings

- **The software copyright of the image processor is owned by our Company, and no organization or individual is allowed to tamper, copy or exchange it by any means or in any form without permission.**

3.1.1 Open package inspection

Before unpacking, please carefully check the packing box to determine whether the product is damaged during transportation. Notify the carrier or the Company immediately if any damage is noted.

If the package is intact, please unpack the package using the correct method, carefully take out the image processor and other components from the packing box, and count them 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 the After-Sales Service Department of the Company.

Warnings

- **The user shall place the packaging materials out of the reach of children. Relevant local regulations or the hospital's regulations on waste disposal must be followed when handling the packaging materials.**

Notice

- **Please keep the packing box and packaging materials for future transportation or storage.**
- **If you open the package and find that some fittings are missing, please contact the distributor who sold this product to you or the manufacturer as soon as possible.**

3.1.2 Environmental requirements

The use environment for the image processor shall meet the requirements in ***A.2 Environment Specification***.

The use environment for image processor shall be free of noise, vibration, dust, corrosive or flammable and explosive substances.

3.1.3 Power requirements

The power supply for the image processor shall meet the requirements in ***A.3 Power Supply Specification***.

 **Warnings**

- **Please ensure that the image processor works 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**.
- **The appropriate power supply source must be chosen according to the setting of the supply voltage of the image processor. Otherwise, it may cause serious damage to the image processor.**

CHAPTER 4 OPERATION INSTRUCTIONS OF IMAGE PROCESSOR

Warnings

- **Before using the image processor, the user must check its fittings and accessories to ensure that they work properly and safely.**
- **Please ensure that the image processor works under the specified environmental and power conditions, otherwise it may lead to unexpected consequences such as image processor failure.**
- **The appropriate power supply source must be chosen according to the setting of the supply voltage of the image processor. Otherwise, it may cause serious damage to the image processor.**

4.1 Operation of Display Screen

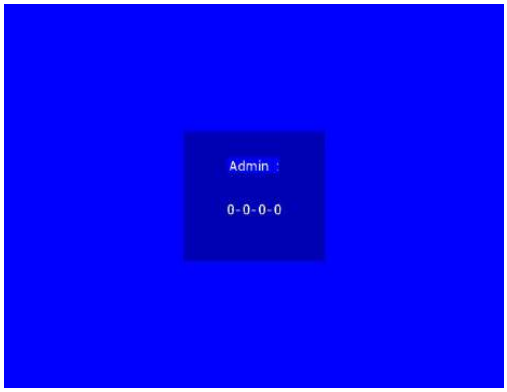
4.1.1 Function button

Buttons	Power Button	Menu Button	Selection Button	Selection Button	Function Button	Function Button
Identification						
Function	Switch on/off the device	1. Enter the setting interface. 2. Confirm the selection. 3. Save the settings.	Select upwards	Select downwards	White balance	1. Freeze 2. Back

4.1.2 Working interface

Press the power button to start the image processor, then the company logo will be displayed statically, as shown in『Figure 4-1』. After 3 seconds, it will automatically enter the user login interface as shown in『Figure 4-2』. Enter the administrator password or user password (all the initial passwords are 0000, and the administrator password and user password can be changed in the user management interface), and press the button.

『Figure 4-1』Boot LOGO interface



『Figure 4-2』User login interface

After user login, enter the working interface, namely the working interface when the endoscope is not connected as shown in『Figure 4-3』.

『Figure 4-3』Working interface when the endoscope is not connected

1) After the endoscope is connected, the screen will display the real-time video in full screen, with the real-time date and time in the lower right corner, and the battery symbol in the lower right corner, as shown in『Figure 4-4』.

『Figure 4-4』Normal working interface

2) When the battery level is lower than 20%, a "Low battery level" prompt will pop up in the upper right corner, as shown in the low battery level interface in 『Figure 4-5』.

『Figure 4-5』Low battery level interface

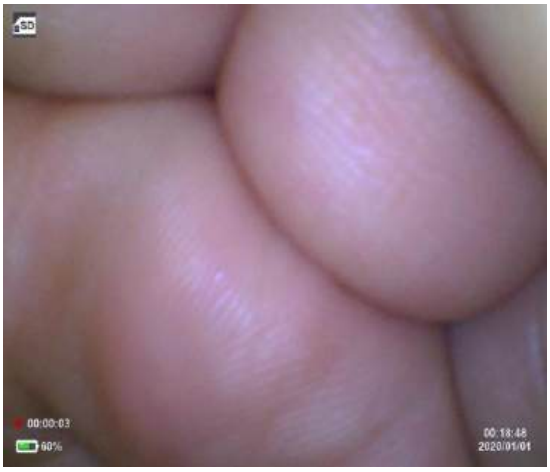
3) When the battery level is lower than 10%, a "Battery exhausted" prompt will pop up in the upper right corner, as shown in the battery exhausted interface in『Figure 4-6』.

『Figure 4-6』Battery exhausted interface

4) When photographing, a photographing prompt will pop up in the center of the screen, as shown in the photographing prompt interface in『Figure 4-7』.

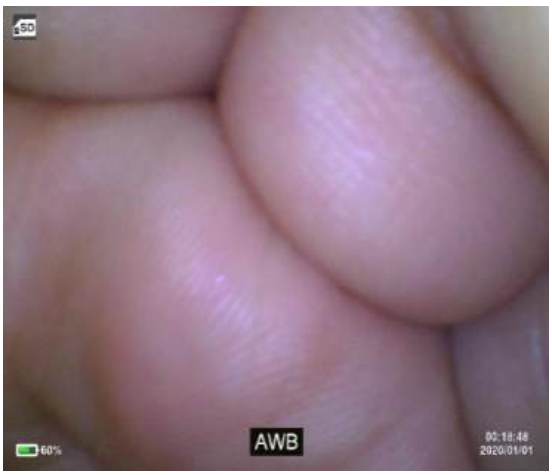
『Figure 4-7』 Photographing prompt interface

5) When recording, a recording prompt and the real-time recording duration will show in the lower left corner of the screen, as shown in『Figure 4-8』.



『Figure 4-8』Recording prompt interface

6) Press the function button  to enter the white balance interface.



『Figure 4-9』White balance prompt interface

7) Press the function button  to enter the graphics freeze interface.

8) Press the arrow button  to enter the disk formatting interface.

『Figure 4-10』Disk formatting prompt interface

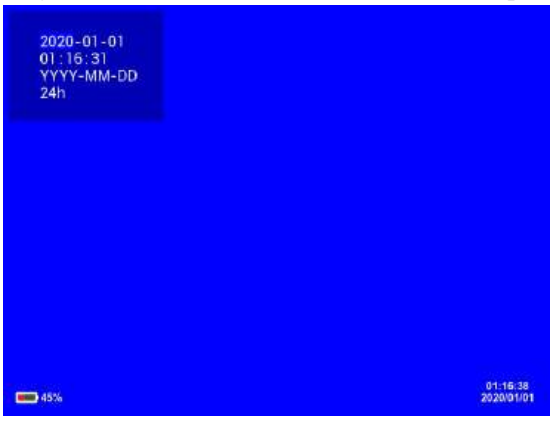
4.1.3 System setting

Press the menu button  to enter the system setting interface, as shown in『Figure 4-11』, and press the button  to exit the system setting interface. Press the arrow buttons  and  to select, and press  to enter the sub-interface, and  to return to the previous interface.

『Figure 4-11』System setting interface

4.1.3.1 Time setting

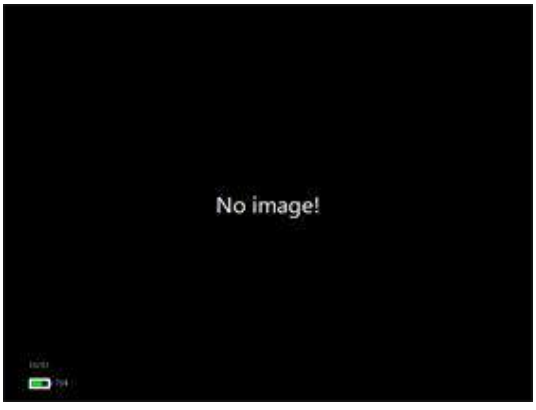
Press the button to switch among Year, Month, Day, Hour, Minute and Second, the arrow buttons and to adjust the value, and to return to the previous interface.



『Figure 4-12』Time setting interface

4.1.3.2 Image browsing

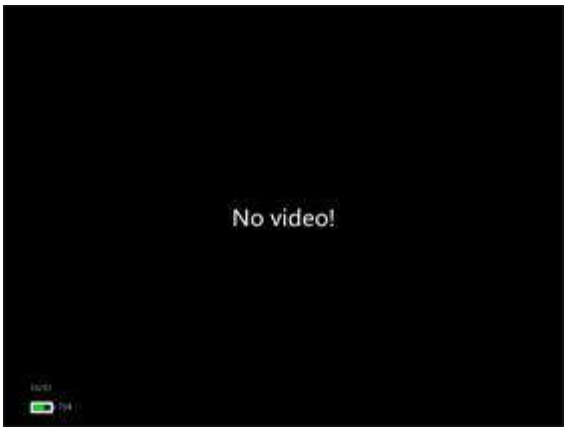
Press the arrow buttons and to switch photos, press the button to return, and long press the button to delete the currently selected image file.



『Figure 4-13』Image browsing interface

4.1.3.3 Video playback

Press the arrow buttons ▲ and ▼ to switch the video, press the button ⚙ to confirm and play the video and press it again to switch between pause and play, press the button ✱/↵ to return, and long press the button ⚙ to delete the currently selected video file.



『Figure 4-14』 Video playback interface

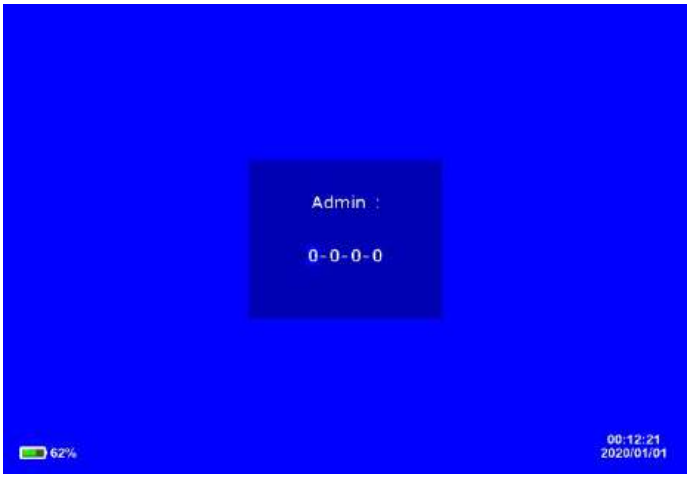
4.1.3.4 Language setting

Press the arrow buttons ▲ and ▼ to select language, and press the button ⚙ to confirm.

『Figure 4-15』Language setting interface

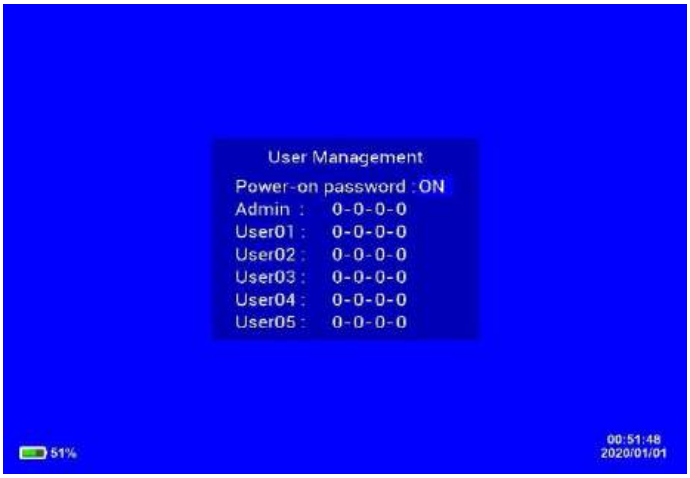
4.1.3.5 User management

1） The administrator password is needed for entering the user management interface. Press the button to switch options, press the arrow buttons and to change the value (0–9), and then press the button to enter the user management interface.



『Figure 4-16』Administrator login interface

2） After entering the user management interface, press the button to switch options, press the arrow buttons and to change the value, and then press the button to save the settings and exit; if you want to cancel the settings, press the button to return to the menu interface.

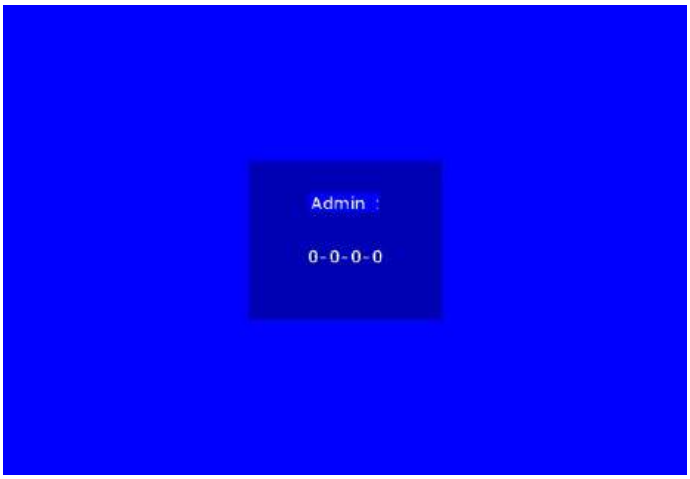


『Figure 4-17』 Password setting interface

4.1.4 Data copy

After connecting to the PC through the USB interface, the image or video data saved in this machine can be read and copied on the PC.

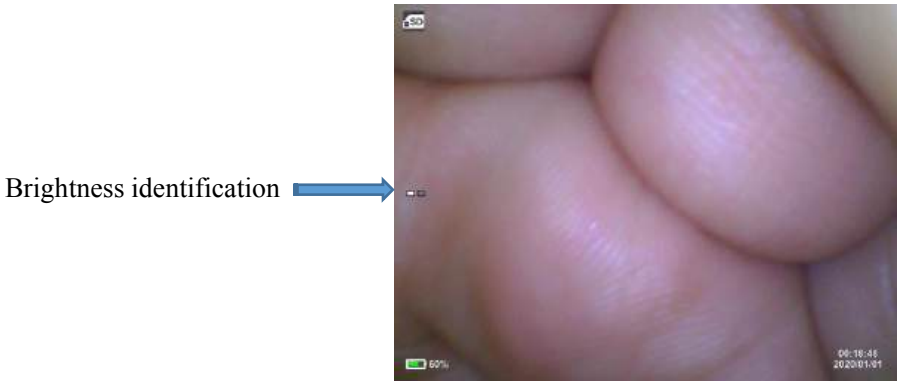
1） Connect the device to the PC through the USB cable, the administrator password input interface will pop up on the screen, and only after the administrator password is entered can the data be read on the PC.



『Figure 4-18』Administrator login interface

2） After entering the administrator password, the user can read the image and video data saved in this machine on the PC.

4.1.5 Brightness adjustment



『Figure 4-19』Brightness interface

Press “▲” key to adjust the brightness of the endoscopy，The brightness adjustment is divided into three levels: maximum brightness, middle brightness, and no brightness, corresponding to the brightness identification:： , , .

4.2 Product Maintenance

4.2.1 Maintenance of the image processor

Warnings

After using the Image Processor, disconnect it from the power source, remove allaccessories, and turn off the power.

When disconnecting from the power adapter, pull the plug out of the socket.

The Image Processor shall be wiped with wet gauze or alcohol gauze before and after use, and then wiped and disinfected with 75% medicinal alcohol.

A Product Specification

A.1 Safety Specification

A.1.1 Classified as Class II equipment with internal power supply by type of anti-electric shock

A.1.2 Classified as Type BF applied part by shock-proof degree

A.1.3 EMC is classified as Group 1 Class A by CISPR 11 .

A.1.4 Rated voltage, frequency and power

Power adapter input: 100–240 V～, 50/60 Hz, 1.5 A Max

Power adapter output: DC 12 V, 3.5 A

Display host external input: DC 12 V, 3.5 A

Internal power supply: DC 7.2 V, lithium-ion battery

A.1.5 Non-permanently installed equipment

A.1.6 Classified by the degree of safety when used in the presence of flammable anesthetic gas mixed with air, or flammable anesthetic gas mixed with oxygen or nitrous oxide: Equipment that cannot be used in the presence of flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide.

A.1.7 Classified by operation mode: Continuous operation.

A.2 Environmental Specification

Parameter	Specification
Operating temperature	5–40ºC
Operating humidity	20%–80%, non-condensing
Operating atmospheric pressure	86–106 kPa
Storage and transport temperature	0–45ºC
Storage and transport humidity	30%–95%, non-condensing
Storage and transport atmospheric pressure	70–106 kPa
Description of storage conditions	Well-ventilated room without corrosive gases

A.3 Power Specification

Parameter	Specification
Power adapter	
Input voltage	100–240 V～
Input current	1.5 A Max
Input frequency	50/60 Hz
Output voltage	DC 12 V
Output current	3.5 A
Battery	
Number of batteries	1
Battery type	Battery pack
Nominal battery voltage	DC 7.2 V
Battery capacity	≥6400 mAh

A.4 List of Accessories

If you find that the following items are inconsistent with this information, please contact the manufacturer.

S/N	Component Name	Quantity	Remarks
1	image processor	1	
2	Power cord	1	
3	Power adapter	1	
4	USB cable	1	
5	HDMI cable	1	
6	Instructions for Use Image Processor	1	

B EMC

The image processor complies with the

IEC60601-1-2:2014+A1:2020/EN60601-1-2:2015+A1:2021 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

Notice

- **Use of accessories, sensors and cables other than those specified may increase the electromagnetic emissions of the image processor and/or reduce the electromagnetic immunity of the image processor.**
- **Do not use the image processor adjacent to or stacked with other equipment. If necessary, the image processor shall be closely observed to ensure that it functions properly in the configuration used.**
- **The EMC of the image processor needs to be specially protected, and it needs to be installed and repaired in an environment that meets the following EMC information.**
- **Avoid simultaneously using the image processor and MRI (Magnetic Resonance Imaging) or similar equipment, otherwise equipment failure or equipment breakdown may occur due to electromagnetic interference.**
- **Even if other equipment complies with CISPR emission requirements, it may cause interference with the image processor.**
- **When the input signal amplitude is lower than the minimum amplitude specified in the technical specifications, it may result in inaccurate measurement.**
- **Portable and mobile RF communication equipment can affect the performance of the image processor.**

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The image processor is intended for use in the electromagnetic environment specified below, and the purchaser or user should assure that it is used in such an environment:		
Emission Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	The image processor uses RF energy only for its internal function. Therefore, its RF emissions are very low, and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The image processor is suitable for use in non-domestic establishments and those not directly connected to the public low-voltage power supply network used for domestic purposes.
Harmonic emissions IEC/EN 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC/EN 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The image processor is intended for use in the electromagnetic environment specified below, and the purchaser or user should assure that it is used in such an environment:			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge IEC/EN 61000-4-2	±8 KV contact discharge ±15 kV air discharge	±8 KV contact discharge ±15kV air discharge	Floors should be wooden, concrete, or ceramic tile; if floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC/EN 61000-4-4	±2 KV for power supply lines	±2 KV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short	0% U_T ;0.5 cycle	0% U_T ;0.5 cycle	Mains power quality should be that of a

interruptions and voltage variations on power input lines IEC/EN 61000-4-11	At 0°,45°,90°，135°,180°,225°,270°and315° 0% U_T ;1 cycles and 70% U_T ; 25and30 cycles Single phase:at 0° 0% U_T ； 250and300 cycles	At 0°,45°,90°，135°,180°,225°,270°and315° 0% U_T ;1 cycles and 70% U_T ; 25and30 cycles Single phase:at 0° 0% U_T ； 250and300 cycles	typical commercial or hospital environment. If the user of the endoscopy image processor requires continued operation during power mains interruptions, it is recommended that the endoscopy image processor be powered from an uninterruptible power supply or a battery.
Power frequency magnetic field IEC/EN 61000-4-8	30A/m	30A/m,50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the alternative current mains voltage prior to application of the test level.			

<table>
<tr><th colspan="4">Guidance and Manufacturer's Declaration – Electromagnetic Immunity</th></tr>
<tr><td colspan="4">The image processor is intended for use in the electromagnetic environment specified below, and the purchaser or user should assure that it is used in such an environment:</td></tr>
<tr><th>Immunity Test</th><th>IEC 60601 Test Level</th><th>Compliance Level</th><th>Electromagnetic Environment – Guidance</th></tr>
<tr><td>Conducted RF
IEC/EN 61000-4-6

Radiated RF
IEC/EN 61000-4-3</td><td>3 V (r.m.s. value)
150 kHz–80 MHz

6V in ISM and amateur radio bands between 0,15MHz and 80MHz

3 V/m
80 MHz–2.7 GHz</td><td>3 V
(r.m.s. value)

6V

3 V/m</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the endoscopy image process including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance

$d = 1.2\sqrt{P}$

$d = 1.2\sqrt{P}$ 80 MHz～800 MHz
$d = 2.3\sqrt{P}$ 800 MHz～2.5 GHz
Where:

P — Maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer;

d — Recommended separation distance in meters (m) [b].
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [c] should be less than the compliance level in each frequency range. [d]
Interference may occur in the vicinity of equipment marked with the following symbol:  </td></tr>
<tr><td colspan="4">Notes:
1. At 80 MHz and 800 MHz, the higher frequency range applies.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects, and human body.</td></tr>
<tr><td colspan="4">a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength of the site where the endoscopy image processor</td></tr>
</table>

is used exceeds the applicable RF compliance level above, the endoscopy image processor should be observed to verify normal operation. If any abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the endoscopy image processor.

b) Over the frequency range 150 kHz–80 MHz, field strengths should be less than 3 V/m.

HUV-02

User's Manual of Medical Image Processor

Description

Thank you for purchasing the Medical Image Processor HUV-02.

Before using this product, please read the User's Manual carefully for correct use.

Please keep the User's Manual properly for reference.

Product name:	Medical Image Processor
Product model:	HUV-02
Date of manufacture:	See product label
Service life:	3 years
Date of preparation/revision:	February 28, 2023
Manual version:	1.0
Software release version:	V1

Performance, structure, and composition of product:	The product consists of an Medical Image Processor host and accessories. The accessories include power lines, equipotential lines, and signal lines.
Application scope of product:	The product is used in conjunction with a display and an electronic endoscope produced by our company, which is used to process and transmit images captured by the electronic endoscope to the display.
Name of registrant/manufacturer:	Shenzhen HugeMed Medical Technical Development Co., Ltd.
Domicile/production address:	401, 501, Building 4, Haizhi Technology Park, Fortis, No. 17, Bulan Road, Xialilang Community, Nanwan Street, Longgang District, Shenzhen, Guangdong, 518112, China
After-sales service provider:	Shenzhen HugeMed Medical Technical Development Co., Ltd.
Contact information:	Tel: 0755-22275866 Email: service@hugemed.net
Website:	http://www. hugemed. net

Intellectual property

The intellectual property of the User's Manual and its corresponding products belong to Shenzhen HugeMed Medical Technical Development Co., Ltd. (hereinafter referred to as "HugeMed").

Statement

HugeMed reserves the right of final interpretation of the Manual.

HugeMed has the right to modify the content of the Manual without prior notice. The modifications to the content of the Manual will be reflected in the new version.

HugeMed assumes no responsibility for software and equipment provided by non-HugeMed organizations or distributors.

HugeMed is responsible for the safety, reliability, and performance of the products only if all of the following requirements are met, namely:

- Assembly, expansion, readjustment, improvement, and maintenance must be carried out by professionals approved by HugeMed;
- All components to be replaced involved in maintenance as well as supporting accessories and consumables are original or approved by HugeMed;
- The relevant electrical equipment meets the requirements of national standards and the User's Manual;
- The relevant operation conforms to the national standards and the requirements of the User's Manual;

Warranty and repair

The standard warranty period of this product is one year,. The main accessories include power cord, USB flash disk and grounding wire. During the warranty period, the product may enjoy free after-sales services; But please note that if the product needs to be repaired due to the following reasons even during the warranty period, HugeMed will provide a fee-based repair service, and you will need to pay for the repair and accessories:

- Man-made damage;
- Improper operation;
- The grid voltage exceeds the range specified for the product;
- Irresistible natural calamities;
- Replace or use any parts and accessories not approved by HugeMed or assign any person for repair without HugeMed's authorization;
- Other failures not caused by the product itself.

After-sales service company

After-sales service company: Customer Service Department of Shenzhen HugeMed Medical Technical Development Co., Ltd.

After-sales address: 415,416-1, 516-1, Building 2, No. 1, Mawu Road, Baoan Community, Yuanshan Street, Longgang District, Shenzhen, Guangdong , 518115, China

Post code: 518024

After-sales hotline: +86 755 22275833

Sales hotline: +86 755 22275833

Official website: www.hugemed.net

Warnings

- **This product should be used by professional clinicians, medical electrical experts, or trained clinical medical workers in designated situations. Personnel using this product shall receive adequate training. Any unauthorized or untrained personnel shall not perform any operation.**
- **Potential accidents can only be prevented by careful work!**
- **Routine instrument cleaning and maintenance are necessary.**
- **In case of repair, original parts should be used.**

Introduction

Description

The User's Manual (hereinafter referred to as the "Manual") details the purpose, function, and operation of the product. Before using this product, please read and understand the Manual carefully to ensure the correct use of this product and the safety of patients and operators.

The Manual introduces this product based on the most complete configurations. Some content may not be applicable to the product you purchase. If you have any questions, please contact us.

These operating instructions include cautions on how to operate the Medical Image Processor safely, correctly, and effectively. They help reduce faults, maintenance costs and downtime, and improve the reliability and service life of the instrument. It can be used not only as an operating manual, but also as a reference manual for reference. So this operating instruction manual must be placed next to the equipment and readily accessible.

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

Applicable objects

The Manual is only suitable for use by trained clinical medical workers.

Illustration

All illustrations provided in the Manual are for reference only, and the settings or data in the illustrations may not be completely consistent with the actual display of the product.

Usual practice

- In the Manual, ***bold italics*** are used to indicate quoted chapters.
- In the Manual, terms such as danger, warning, and caution are used to indicate danger information and its severity.

Contents

Chapter 1 Safety

1.1 Safety information

This chapter lists the basic safety information that users must be aware of and comply with when using the Medical Image Processor. Other safety information that is the same as, similar to, or related to specific operations will appear in each chapter.

⚠Danger

Indicates an imminent danger, which, if not avoided, may result in death, serious personal injury, or property loss.

⚠Warnings

Indicates a potentially hazardous or unsafe operation, which, if not avoided, may result in death, serious injury, or property loss.

⚠Caution

Indicates a potential hazardous or unsafe operation, which, if not avoided, may result in minor personal injury, product fault, damage, or property loss.

Attention

Highlights important cautions and provides instructions or explanations for better use of the product.

1.1.1 Danger

No safety risk of this type.

1.1.2 Warnings

⚠Warnings

- **The Medical Image Processor is used in conjunction with our endoscope and can only be used by professional clinicians, medical electrical experts, or trained clinical medical workers in designated situations.**
- **The responsible doctor must be responsible for the operating procedures and technical applications of the equipment! According to the actual application conditions, the trained doctor (the responsible doctor) has the right to decide how to use the equipment adequately.**
- **Please read the Manual carefully before using it for the first time.**
- **Before using the Medical Image Processor, the user must check the Medical Image Processor and its accessories to ensure that they can work normally and safely.**
- **Do not use it in an environment with flammable or explosive materials to prevent fire or explosion.**
- **Please properly install or carry the Medical Image Processor and its supporting equipment to prevent the Medical Image Processor from falling, colliding, strong vibration or being damaged by other external mechanical forces.**
- **Electromagnetic fields can affect the performance of the Medical Image Processor and its supporting equipment. Therefore, equipment used near the Medical Image Processor and its supporting products must meet corresponding EMC requirements, otherwise electromagnetic interference may cause faults or crashes of the Medical Image Processor. Mobile phones, X-ray or MRI devices are all possible sources of interference, and they all emit high-intensity electromagnetic radiation.**
- **The maintenance or upgrade of the Medical Image Processor must be performed by maintenance personnel trained and authorized by the Company.**
- **When handling packaging materials, it is necessary to comply with the relevant local regulations or the hospital's waste disposal system.**
- **HugeMed is not responsible for personal injury or property loss caused by:**
  - **The equipment parts are not original parts of HugeMed;**
  - **The User's Manual is missing;**
  - **Installation, commissioning, modification, upgrading, and maintenance are performed by personnel authorized by non-HugeMed organizations.**
- **HugeMed shall not be responsible for any damage or incident caused by the use of consumables or accessories of non-HugeMed organizations.**

1.1.3 Caution

⚠Caution

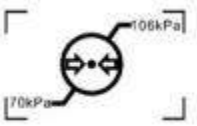
- **The use environment and power supply of the Medical Image Processor must meet the requirements of *A Product Specifications*.**

1.1.4 Attention

Attention

- **Please place the Manual near the Medical Image Processor for easy and timely reference when needed.**
- **The Manual introduces this product based on the most complete configurations and functions. The Medical Image Processor you purchased may not have certain configurations or functions.**

1.2 Label identification

	Consult the user manual		Application components for BF type
	Attention/Caution/Warning	~	AC voltage
	Disposal by using an environmentally friendly method	EC REP	EC Authorized Representative
CE	CE marking	MD	Medical medice
SN	Serial number		Date of manufacture
	Manufacturer		Product service life
	The humidity limit range for transportation packaging is 30%~95%		The environmental pressure limit range for transportation packaging is 70~106kPa
	The temperature limit range for transportation packaging is 0~45ºC		A maximum of 5 layers for identical packaging can be stacked
	During transportation, the packaging should be kept upright		The packaging should be protected from rain during transportation
	If there are fragile items inside the packaging, handle with care		

Chapter 2 Overview

2.1 Product introduction

2.1.1 Scope of application

The product is used in conjunction with a display and an electronic endoscope produced by our company, which is used to process and transmit images captured by the electronic endoscope to the display.

⚠Warnings

- **This product should be used by professional clinicians, medical electrical experts, or trained clinical medical workers in designated situations. Personnel using this product shall receive adequate training. Any unauthorized or untrained personnel shall not perform any operation.**
- **Before using the Medical Image Processor, the user must check its accessories to ensure that they can work normally and safely.**

⚠Caution

- **The use environment and power supply of the Medical Image Processor must meet the requirements of *A Product Specifications*.**

2.1.2 Structural composition

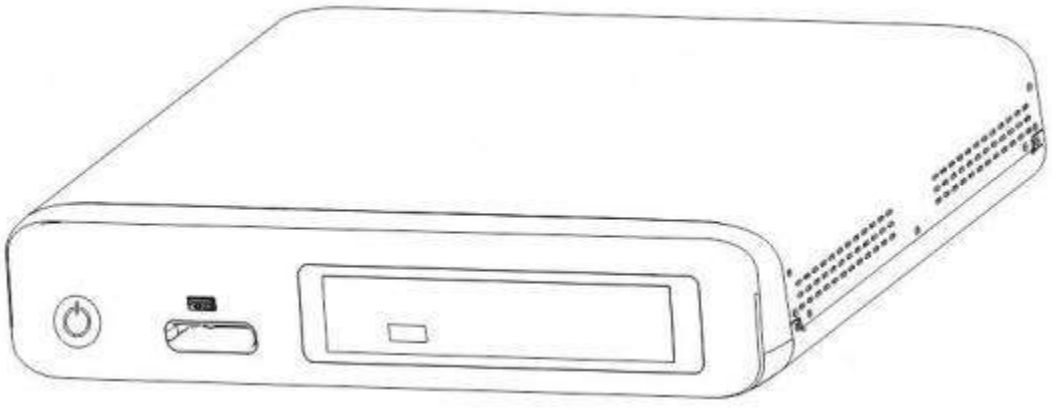
The product consists of an Medical Image Processor and accessories, including power lines, equipotential lines, signal lines.

2.1.3 Contraindications

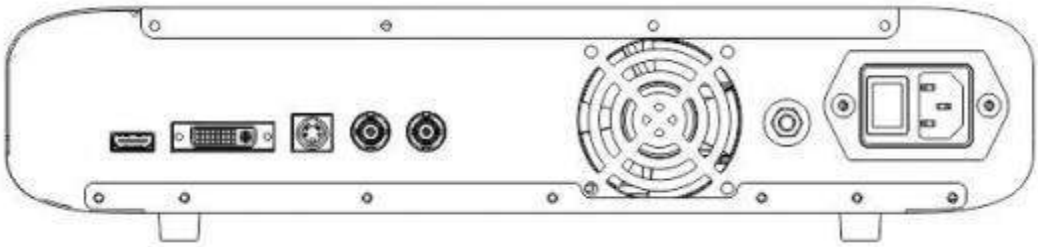
When used in conjunction with our company's electronic endoscope, it is equivalent to the contraindications of the endoscope.

2.1.4 Product structural diagram

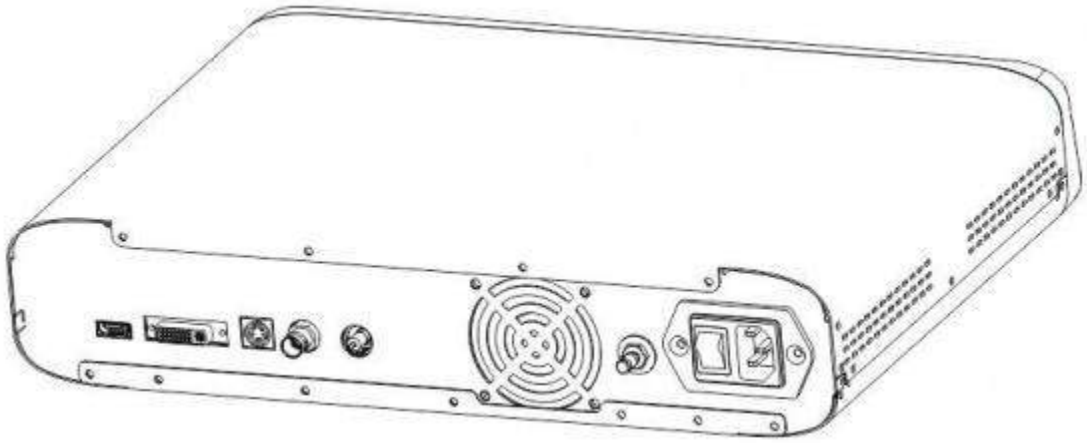
2.1.4.1 Right front view of host HUV-02



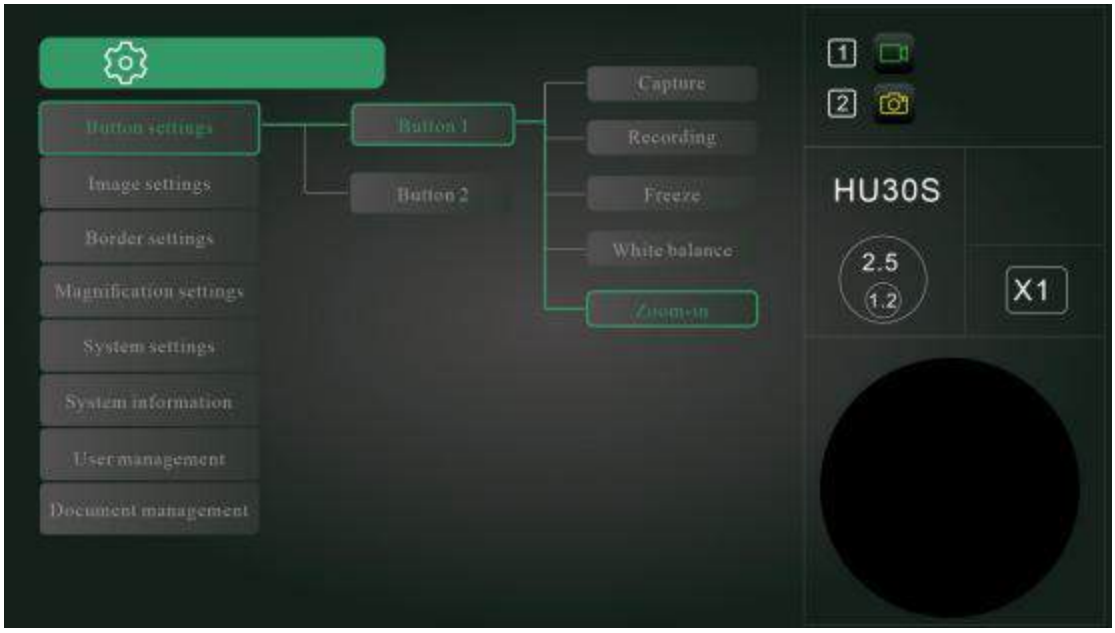
2.1.4.2 Rear view of the host HUV-02



2.1.4.3 Rear left view of Host HUV-02



2.1.5 System main menu interface



Main menu functions

First-level menu	Second-level menu	Third-level menu
Button settings	Button 1	Select capture, video, freeze, white balance, zoom - in, with video as default
	Button 2	Select capture, video, freeze, white

		balance, zoom - in, with video as default
Image settings	Light source	Select D65, LED1, M0, with D65 as default
	Color temperature	Select among-2~2 , with 0 as default
	Saturation	Red saturation 0~100, with 65 as default; Green saturation 0~100, with 65 as default; Blue saturation 0~100, with 66 as default;
	Light extinction	Select Average or Peak , with Average as default
	Sharpness	Select among 0~15 , with 1 as default
	Noise reduction	Select among 0~3, with 3 as default
	Gamma	Select among 0~15, with 12 as default
	Video source	Camera head
	CVBS format	Select between PAL and NTSC, with PAL as default
	Video format settings	Select between AVI and Mp4, with AVI as default
Border settings	Optional	/
Magnification settings	Optional	/
System setting	Language	Select among Chinese, English, French, German, Spanish, Portuguese, Norwegian, Swedish, Finnish, Italian, and Russian, with English as default
	Time/Date	Time can be set and you can choose between 24-hour and 12-hour system, with 24-hour system as default
	Date format selection	You can choose among yyyy-mm-dd, mm-dd-yyyy, and dd-mm-yyyy. With yyyy-mm-dd as default
System information	Displays: product model,name of software, software release version,software full version, and storage space information	/
User management	Password: On/Off	/
	Endoscope management: Displays connected endoscope	

	information, including: Endoscope body model, Endoscope body SN, Inner diameter/outer diameter, number of insertions, accumulated usage time	
	User management: Users are classified as administrators and ordinary users with different operating privileges. At startup, the user must select the user and enter the login password. Administrator: Account login, real-time imaging, recording, photo-taking, white balance, freezing, image adjustment, parameter setting, data copying, management of ordinary user privileges, can add, delete sub-accounts, and modify sub-account passwords. Ordinary users: Account login, real-time imaging, recording, photo-taking, white balance, freezing, image adjustment, parameter setting, data copying, and password modification under their own account. There is one administrator and five users by default. The initial password for the administrator (admin) is root, and 1234 for the user.	
Document management	View image	Enter the View Image interface
	View video	Enter the View video interface

Chapter 3 Utilization and Maintenance

3.1 Installation and Utilization

⚠Warnings

- **The software copyright of the Medical Image Processor belongs to our company. No organization or individual may modify, copy, or exchange it in any way or form without permission.**
- **The host HUV-02 must be connected to an endoscope produced by HugeMed. HugeMed will not be responsible for any damage or incidents caused by connection to an endoscope not produced by HugeMed.**
- **When host HUV-02 is connected to an endoscope or accessory with energy produced by a non-HugeMed manufacturer, the patient is more likely to be subject to current leakage.**
- **When the endoscopic equipment connected to host HUV-02 have malfunctions, the endoscope should be immediately removed from the patient's body and disconnected from the host HUV-02.**
- **Do not use the high-frequency electric surgical equipment with this product. Otherwise, it may cause harm to the patient or damage to the instrument.**

3.1.1 Unpacking inspection

Before opening the box, please carefully inspect the packaging to determine if the product has been damaged during transportation. If any damage is found, please immediately contact the carrier or our company.

If the packaging is intact, unpack it correctly, carefully remove the Medical Image Processor and other components from the box, and check them one by one according to the packing list. Check if the product has any mechanical damage and if all parts are complete. If you have any questions, please immediately contact our company's after-sales service department.

⚠Warnings

- **The user should keep the packaging materials out of reach of children. When handling packaging materials, it is necessary to comply with the relevant local regulations or the hospital's waste disposal system.**

Attention

- **Please keep the packaging box and packaging materials properly for future transportation or storage.**
- **If you find any missing parts when opening the package, please contact the distributor or manufacturer who sold you this product as soon as possible.**

3.1.2 Environmental requirements

The use environment of the Medical Image Processor should meet the requirements of ***A.2 Environmental Specifications***.

The use environment of the Medical Image Processor should also avoid the existence of noise, vibration, dust, corrosive, flammable, explosive materials, etc.

3.1.3 Power requirements

The power supply used by the Medical Image Processor should meet the requirements of***A.3 Power Specifications***.

⚠Warnings

- **Please ensure that the Medical Image Processor works under the specified environmental and power requirements, otherwise, it will not be able to meet the technical specifications claimed in the *A product specifications* and may result in unexpected consequences such as Medical Image Processor failure.**
- **A suitable power supply must be chosen according to the power voltage setting of the Medical Image Processor. Otherwise, it may cause serious damage to the equipment.**

3.1.4 Endoscope connection

Attention

- **The host HUV-02 must be connected to endoscopes produced by HugeMed. HugeMed will not be responsible for any damages or incidents caused by its connection to non-HugeMed endoscopes**

(1) Check the appearance of the signal cable to ensure it is intact;

(2) Refer to the user manual attached to the host and prepare to connect the endoscope.

(3) Connect the endoscope to the host HUV-02;

(4) Press the power button to start the host.

Attention

- **The host HUV-02 and the endoscope plug both have anti-mistake design. When inserting them, pay attention to the direction of the connector. Do not forcefully insert the connection. Forcing it when it is not in the correct position can damage the plug.**
- **When disconnecting the connection between the host and the endoscope, pull the endoscope plug out in the opposite direction along which it was inserted.**

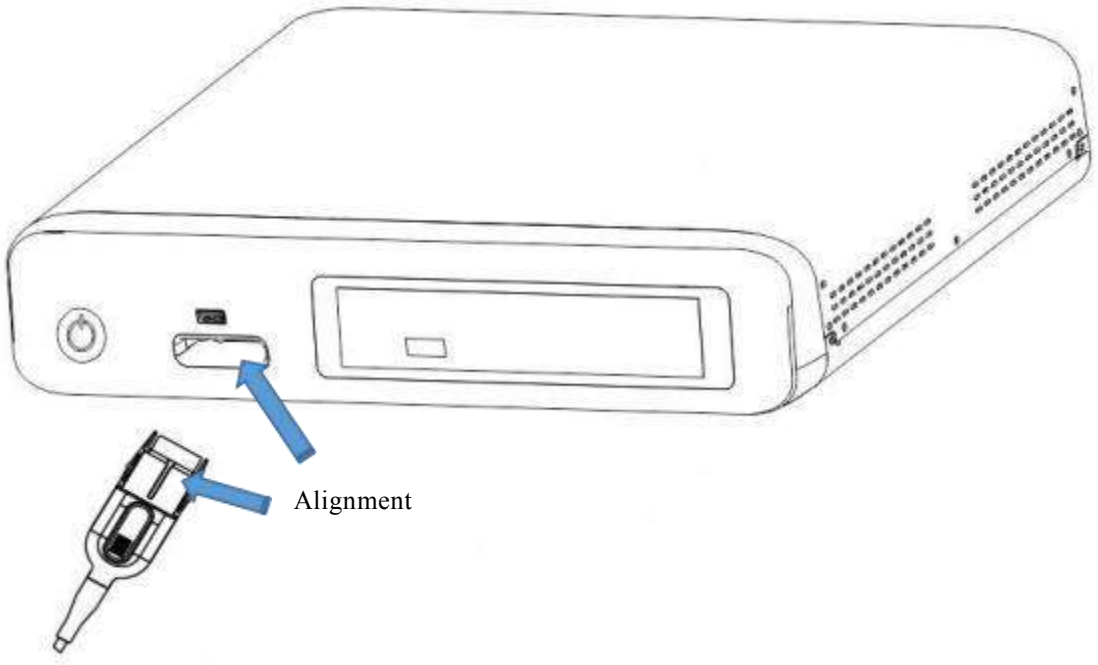


Figure 3-1 Host HUV-02 Connection Diagram

3.1.5 Monitor (display device) connection

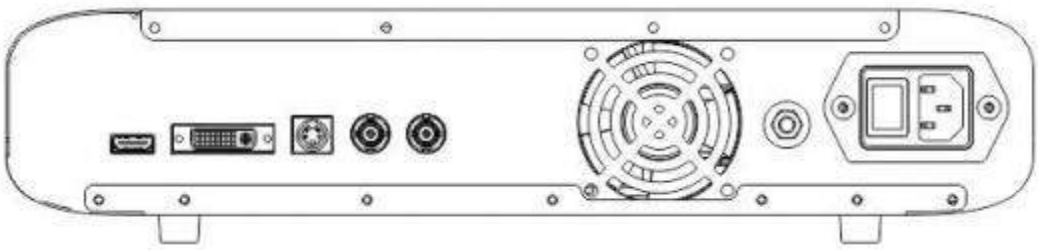


Figure 3-2 HUV-02 Back Interface Diagram

Choose the corresponding signal cable according to different interfaces, and connect it to the processor interface and monitor according to the interface structure of the connection cable.

Attention

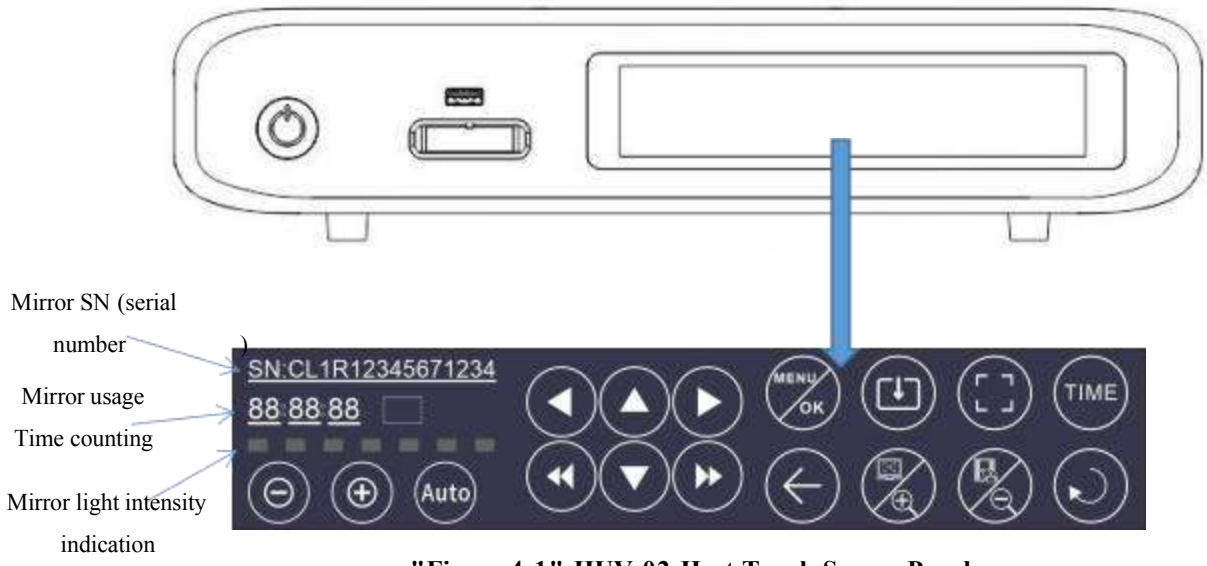
☞ **To disconnect the signal cable, pull it out in the opposite direction of insertion.**

Chapter 4 HUV-02 Operation Guide

4.1 HUV-02 Host System Operation

4.1.1 Function keys

Keys	Power button	Light intensity key	Light intensity key	Light intensity key	Left key	Right key
Identification						
Function	Turn on/off device	Manually adjust to reduce light intensity	Manually adjust to increase light intensity	Enter automatic adjustment, adjust light intensity to maximum; exit automatic adjustment	Move left/reduce value/access settings interface, return to the previous menu	Move right/increase value/access settings interface, enter the next level menu
Keys	Up key	Down key	MENU/OK key	Back key	Fast rewind key	Fast forward key
Identification						
Function	Move up to switch options	Move down to switch options	Menu key/Confirm selection input; pop up soft keyboard	Save and return/Return	Video playback interface, fast rewind	Video playback interface, fast forward
Keys	Zoom in key	Zoom out key	Select key	Download key	Rotate key	Time key
Identification						
Function	Main interface, image white balance; Picture view interface, picture zoom in	Main interface recording; Picture view interface, picture zoom out	Select picture/video; Full screen/list browsing interface switching	Picture/Video download	Grid/list browsing interface switching, clockwise rotation of the picture by 90°	Grid interface, set filtering time; Video playback interface, switch speed



"Figure 4-1" HUV-02 Host Touch Screen Panel

(1) The light intensity setting range is from 0 to 7 levels, with the initial default set to level 5. The light intensity adjustment is divided into two modes: manual adjustment and default adjustment.

(2) Manual adjustment: Press the "⊕" key to increase the light output of the corresponding endoscope handle, and press the "⊖" key to decrease the light output of the corresponding endoscope handle.

(3) Automatic adjustment: Press the "Auto" key to start automatic adjustment of the illumination intensity, and adjust the illumination intensity to level 7 and lock it. At this time, it is not possible to adjust the light intensity by pressing the "⊕, ⊖" key. Press "Auto" again to switch back to manual adjustment of the illumination intensity.

4.1.2 User login interface

(1) Press the power button ⏻ to start HUV-02. The power button will light up and automatically enter the user login interface, as shown in Figure 4-2.

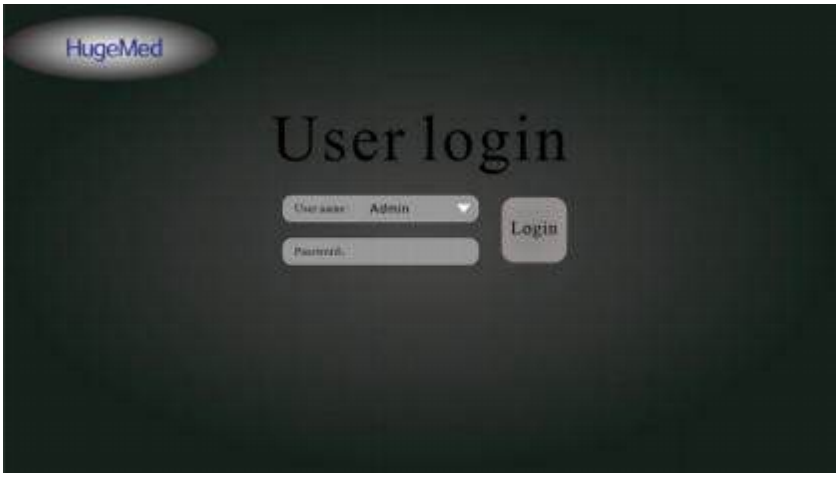


Figure 4-2 User Login Interface

(2) Press the "MENU/OK" button to select the user. After selecting the user, press "②" again to save and exit.

(3) Press the "▼" button to select the "Password" field, then press the "②" button, and the interface will pop up a soft keyboard. Use the "Up, Down, Left, Right" keys to move the cursor, and press "MENU/OK" to enter the numerical value.

(4) Value deletion: Select the "⌫" key on the soft keyboard and press the "②" key to delete the last entered digit.

(5) Soft keyboard exit: Select the "↵" key on the soft keyboard, then press the "②" key to exit the soft keyboard; or press the "←" key to directly exit the soft keyboard.

After exiting the soft keyboard, select the "login" field with the "▼" key, and then press the "②" key to enter the main interface. (6) Note: The initial password for the admin user is "root", and the initial password for the user1/2/3/4/5 users is "1234".

4.1.3 Patient information entry interface

Cancel entry interface: In the initial state, the cursor has selected the "cancel" option. Press "②" to cancel and exit the patient information entry.

Figure 4-3 Patient Information Input

Setup of entry interface: If you need to enter patient information, follow these steps:

(1) Move the cursor from the initial "Cancel" option to the "ID" box by pressing the "▲" key, and enter a combination of numbers or letters or both by pressing the "②" key on the soft keyboard. Press "②" to complete the ID information entry;

(2) Press the "←" key to exit the soft keyboard ID input, then press the "▼" key to select the "age" box, press "②" to pop up the soft keyboard, enter "age" information, and press "②" to confirm the age.

(3) Press the "" key to exit the "age" input soft keyboard, then press the "" key to select the "gender" field, and select the gender using the " , keys.

(4) Use the "、" keys to select "Input" or "Cancel," then press "" to save and exit the patient information input interface.

4.1.4 Main screen interface

(1) After completing the patient information entry, enter the main screen interface, as shown in Figure 4-4.

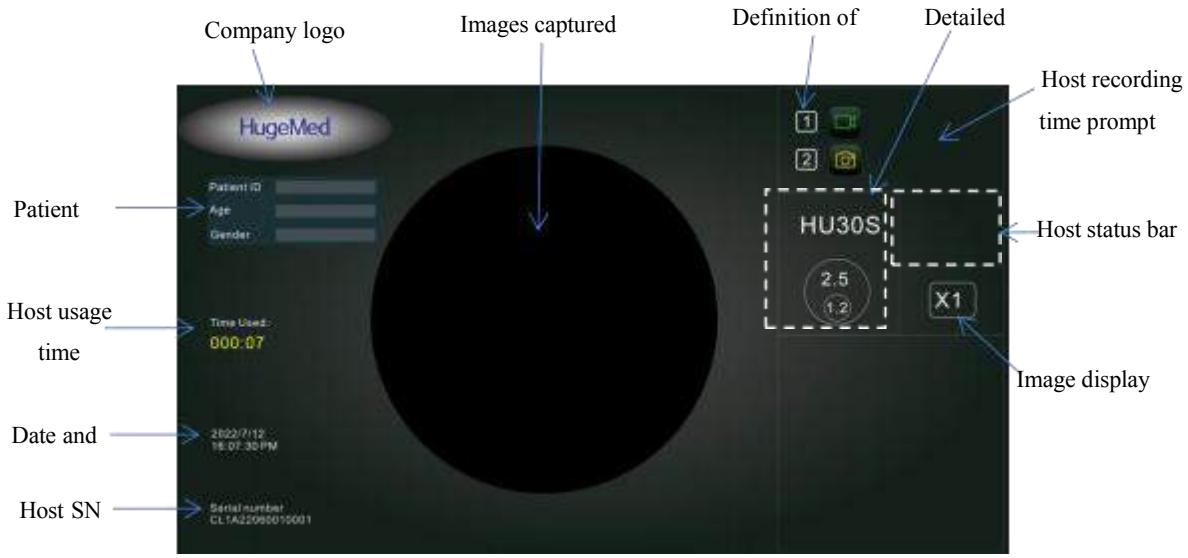


Figure 4-4 Main Screen Interface

(2) The system's main interface displays the following information: company logo, patient information, host operating time, date and time, camera SN, camera capture image, definition of endoscope buttons, detailed information of the endoscope, main device recording time prompt, main device status reminder, and image display magnification.

(3) On this interface, press the "" key to start recording by the host, and press the "" key for the host to perform image white balance.

(4) If the camera is not connected, the prompt message "The camera lens is not connected." will be displayed at the top of the interface. If the camera is properly connected, the message "The camera lens has been inserted." will be displayed at the top of the interface, and the prompt message will automatically disappear after 3 seconds.

4.1.5 Setting menu interface

Press the "" button on the main interface to enter the menu settings interface, and press the "" button to exit the menu settings interface.

4.1.5.1 Button settings

(1) After entering the button settings, press "" or "" to enter the second or third level menu. In the third-level menu, press "" or " " or " " to save settings and return to the previous level menu. In the same level menu, press " , " to switch options.

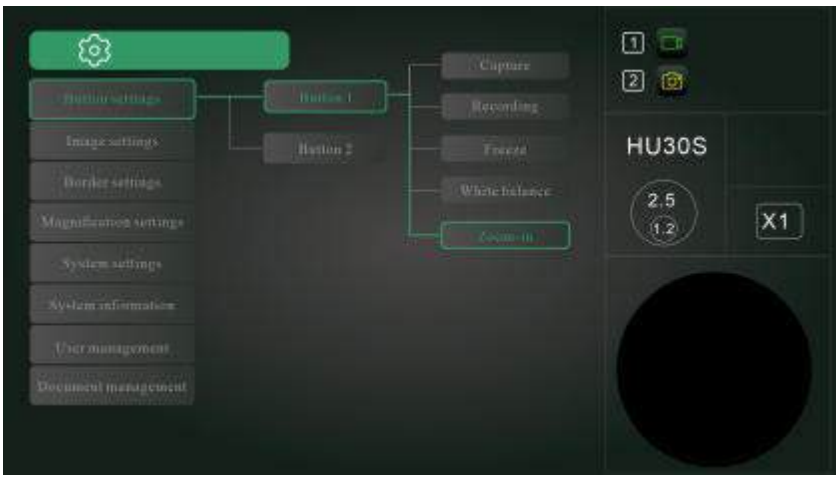


Figure 4-5 Button Setting Interface

(2) Second-level menu button 1: You can choose to take a photo, record a video, freeze the screen, adjust white balance, or zoom in. The initial option is taking a photo;

(3) Second-level menu button 2: You can choose to take a photo, record a video, freeze the screen, adjust white balance, or zoom in. The initial option is recording a video.

4.1.5.2 Image settings

(1) After entering the image setting - light source setting, press the "② or ▶" key to enter the next level menu, press "▲, ▼" to switch options, and press "② or ← or ④" to save the settings and return to the previous level menu;

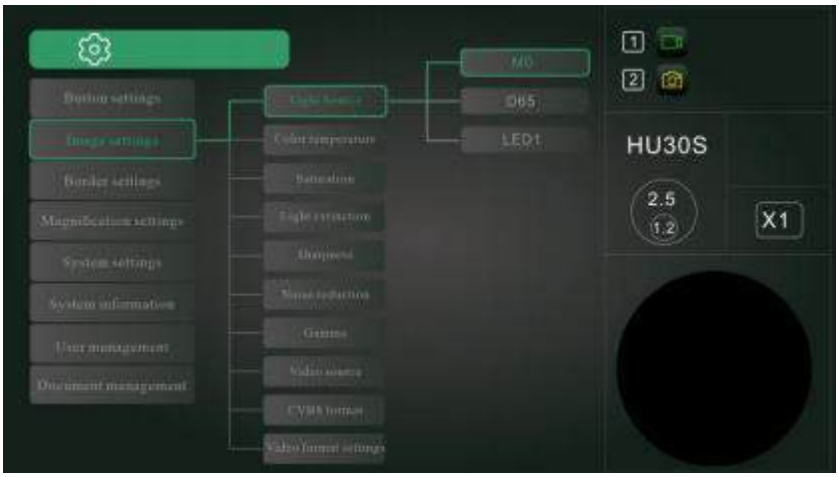


Figure 4-6 Light Source Setting Interface

(2) After entering the image setting - color temperature setting, press the "MENU/OK or ▶" key to enter the next level menu, press "▲, ▼" to change the value, press "② or ← or ④" to save the settings and return to the previous level menu;

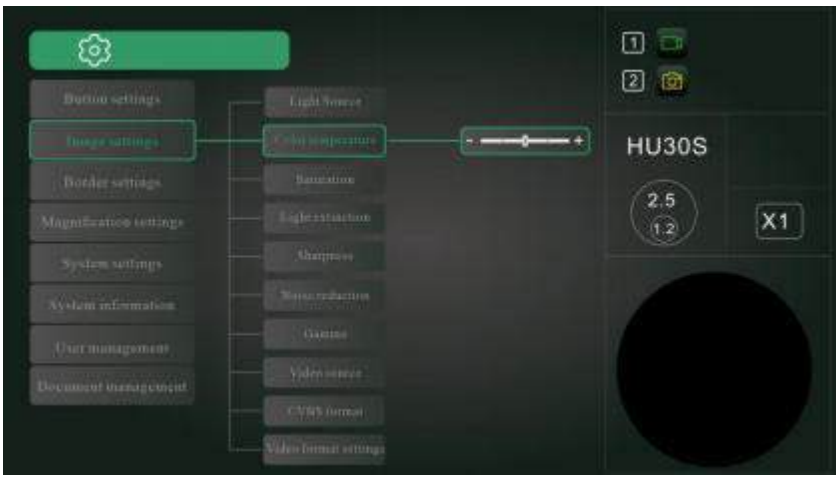


Figure 4-7 Color Temperature Setting Interface

(3) After entering the image setting - saturation setting, press the "② or ▶" key to enter the next level menu, press "▲, ▼" to switch options, press "④, ▶" keys for parameter setting, finally press "② or ←" to save the settings and return to the previous level menu;

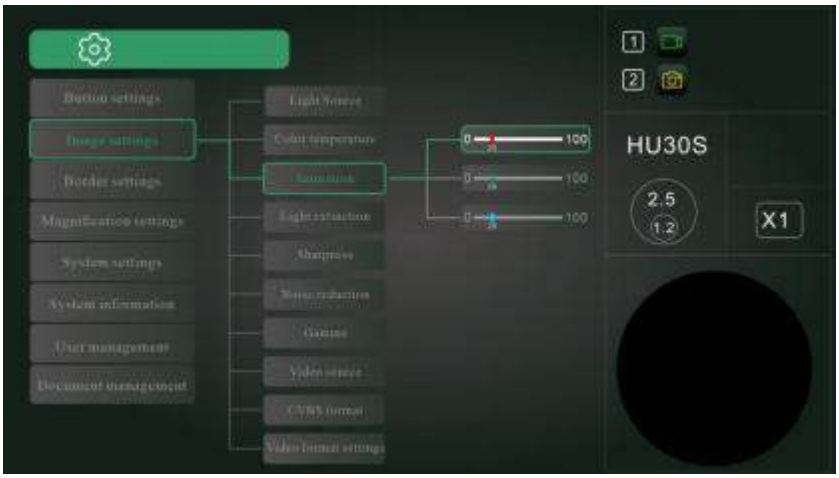


Figure 4-8 Saturation Setting Interface

(4) Enter the image setting - light extinction setting, press the "MENU/OK or ▶" key to enter the next level menu, press "▲ or ▼" to switch options, and press "② or ← or ④" to save settings and return to the previous level menu;

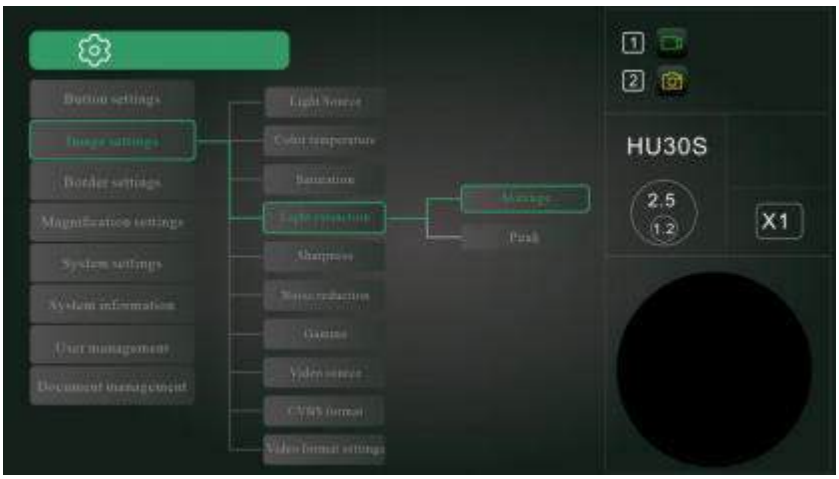


Figure 4-9 Light extinction Setting Interface

(5) Enter the image setting-sharpness setting, press the "② or ▶" key to enter the next level menu, press "▲, ▼" to change the value, and press "② or ← or ④" to save settings and return to the previous level menu;

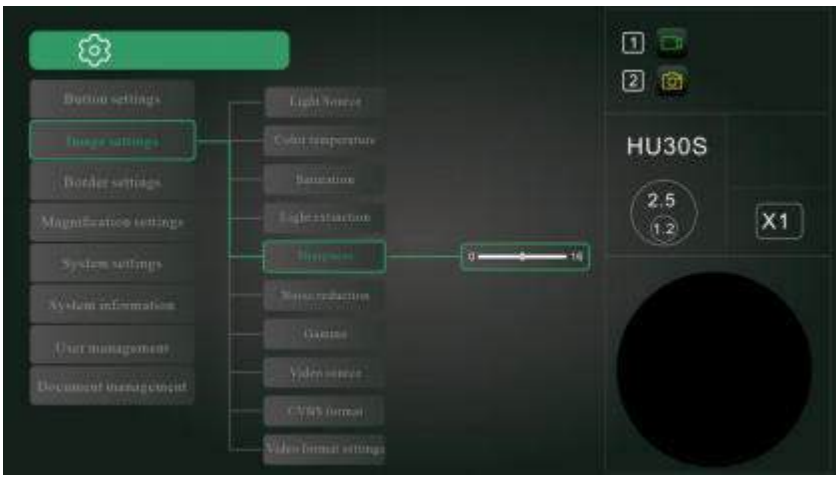


Figure 4-10 Sharpness Setting Interface

(6) After entering the image settings - noise reduction settings, press the "MENU/OK or ▶" key to enter the next level menu, press "▲ or ▼" to change the values, and press "② or ← or ④" to save the settings and return to the previous menu;

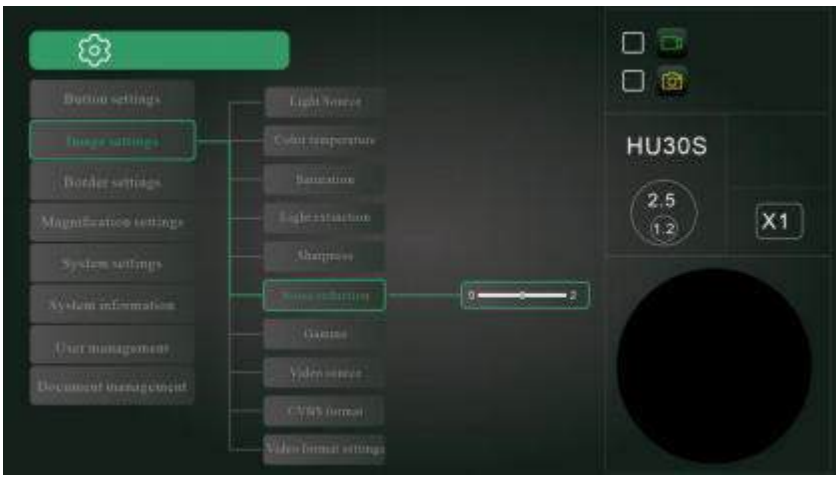
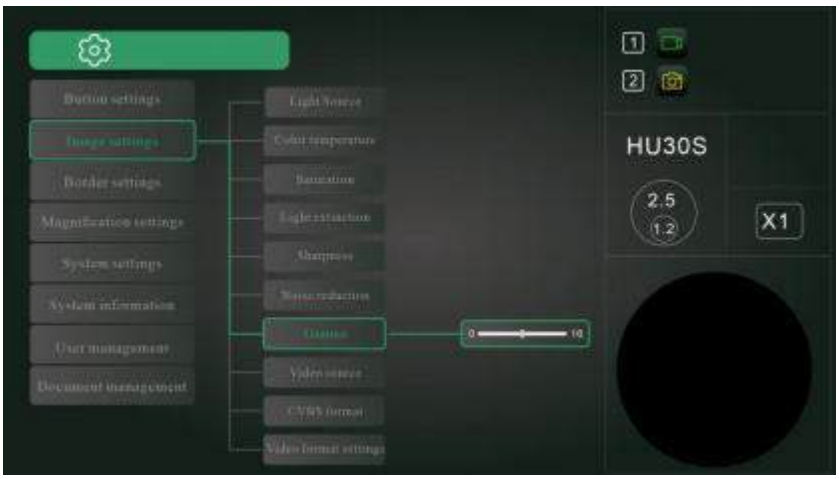


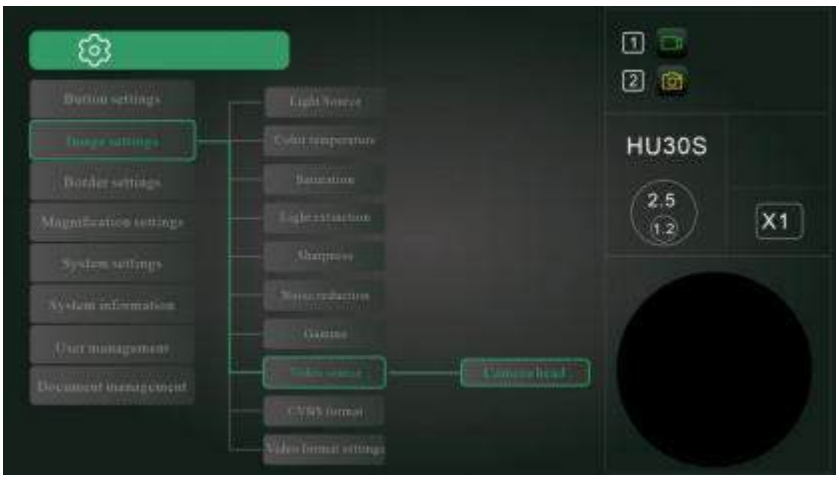
Figure 4-11 Noise Reduction Setting Interface

(7) After entering the image settings - gamma settings, press the "② or ▶" key to enter the next level menu, press "▲ or ▼" to change the values, and press "② or ← or ④" to save the settings and return to the previous menu;



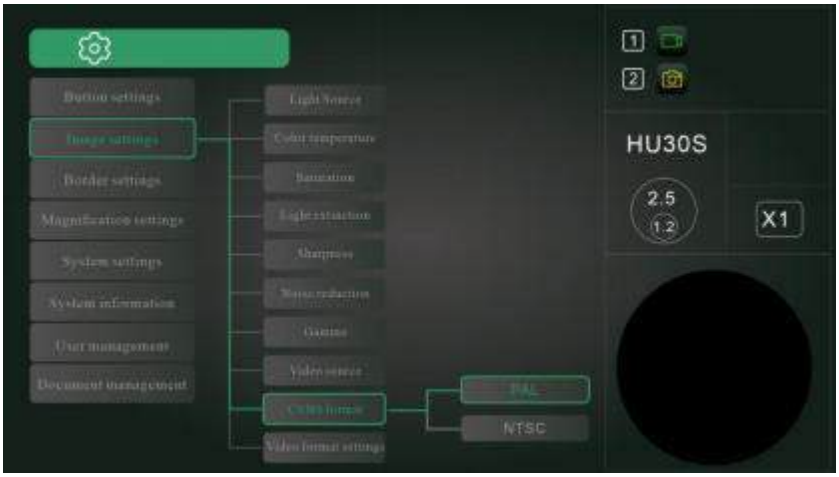
[Figure 4-12] Gamma Setting Interface

(8) After entering the image setting - video source setting, press the "MENU/OK or ▶" key to enter the next level menu, and press the "② or ← or ◀" key to return to the previous level menu;



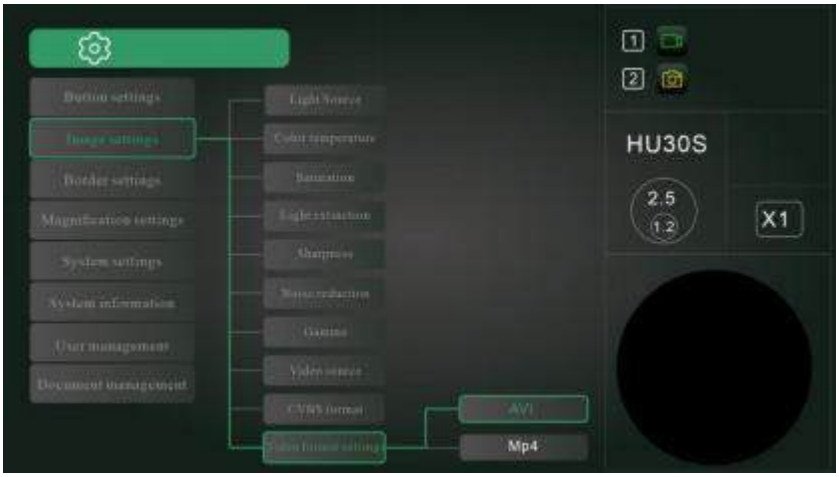
[Figure 4-13] Video Source Setting Interface

(9) After entering the image setting - CVBS format setting, press the "② or ▶" key to enter the next level menu, press the "▲ and ▼" keys to switch options, and press the "MENU/OK or ← or ④" key to save settings and return to the previous level menu;



[Figure 4-14] CVBS Format Setting Interface

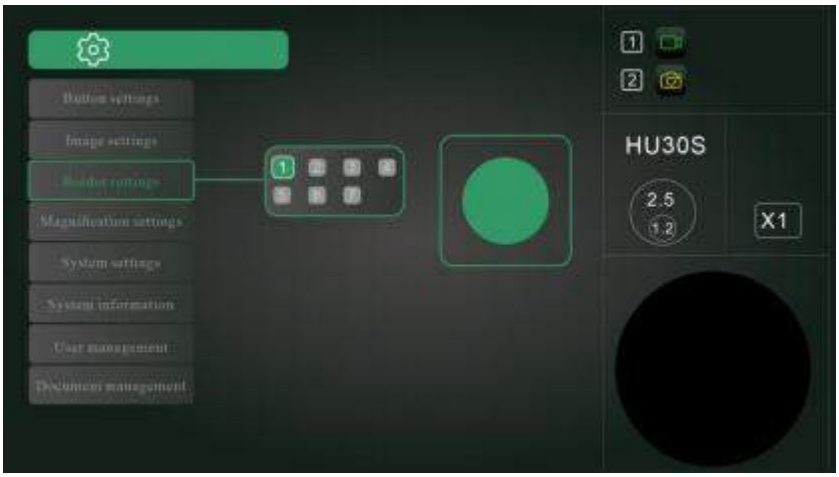
(10) After entering the image setting - video format setting, press the "② or ▶" key to enter the next level menu, press the "▲ and ▼" keys to switch options (with AVI, MP4 available), and press the "② or ← or ④" key to save the settings and return to the previous level menu.



[Figure 4-15] Video Format Setting Interface

4.1.6 Border settings

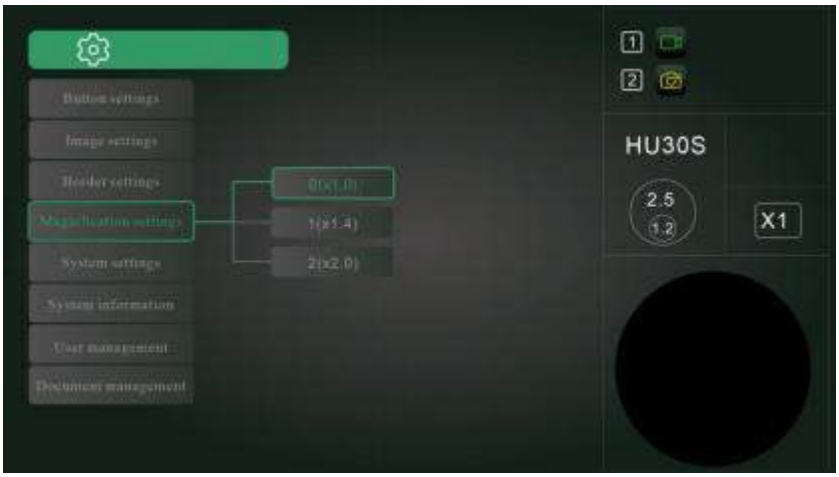
After entering the border setting, press the "② or ▶" key to enter the next level menu, press the "▲ and ▼ and ④ and ▶" keys to switch options, and press the "←" key to save settings and return to the previous level menu.



[Figure 4-16] Border Setting Interface

4.1.7 Magnification Setting

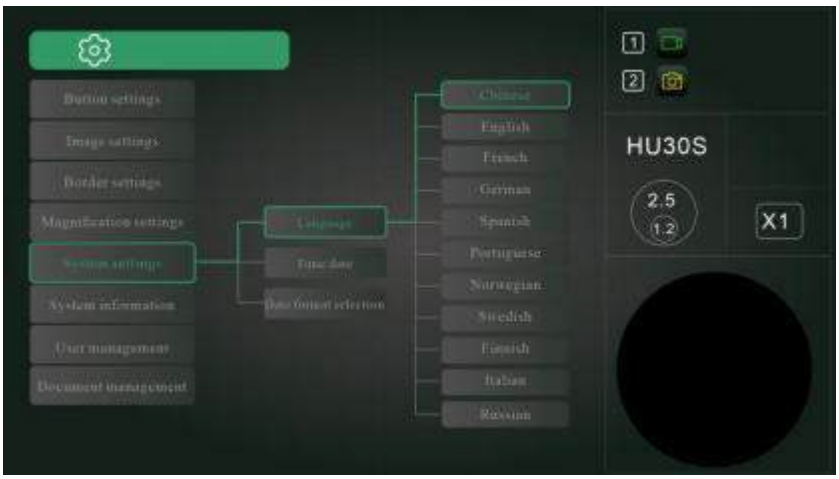
After entering the Magnification Setting, press the "② or ▶" key to enter the next level menu, press the "▲ and ▼" keys to switch options, and press the "MENU/OK or ← or ④" key to save settings and return to the previous level menu.



[Figure 4-17] Magnification Setting Setting Interface

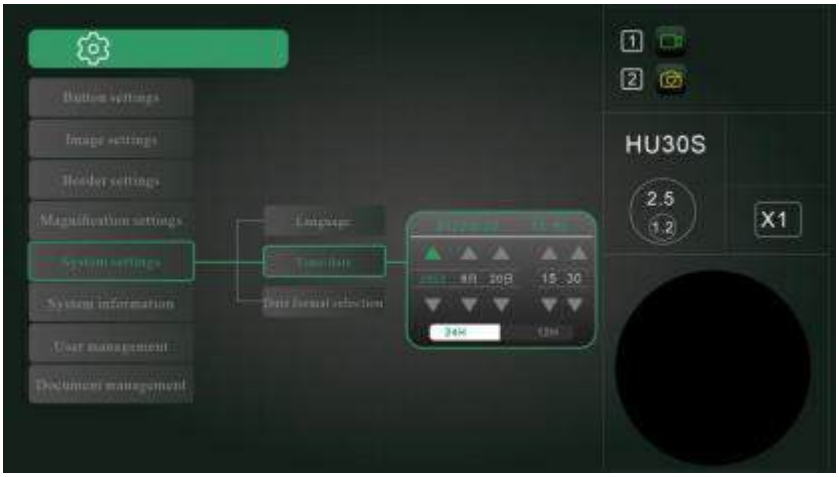
4.1.8 System Setting

(1) After entering the system setting - language setting, press the "② or " key to enter the next level menu, press the "▲ and ▼" keys to switch options, and press the "MENU/OK or ← or " key to save settings and return to the previous level menu;



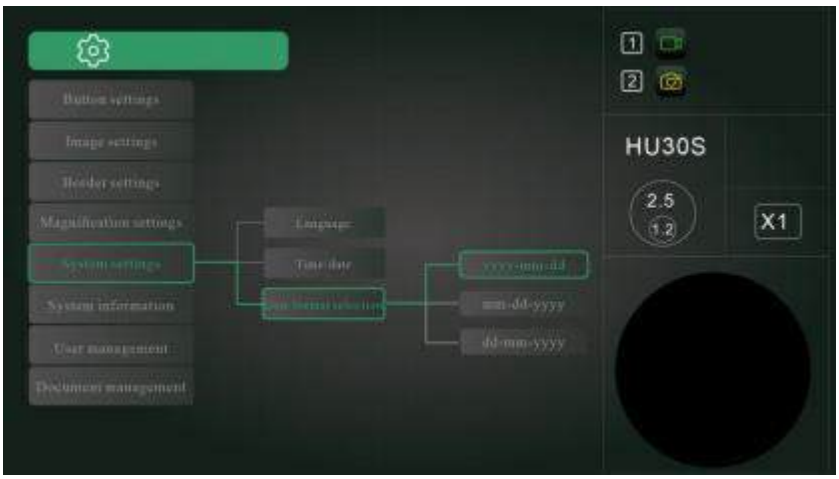
[Figure 4-18] Language Setting Interface

(2) After entering the system setting - time and date setting, press the "② or ▶" key to enter the next level menu, press the "◀ and ▶" keys to switch options, press the "▲ and ▼" keys to alter the values, press the "▲ and ▼ and ②" keys to toggle between 24H/12H, and press the "←" key to save settings and return to the previous level menu;



[Figure 4-19] Time and Date Setting Interface

(3) After entering the system setting - date format setting, press the "② or ▶" key to enter the next level menu, press the "▲ and ▼" keys to switch options, and press the "② or ← or ④" key to save settings and return to the previous level menu;



[Figure 4-20] Date Format Setting Interface

4.1.9 System Information

After selecting the system information option, the system information window will automatically pop up, displaying the following information: product model, software name, software release version, full version of software, and storage space information.

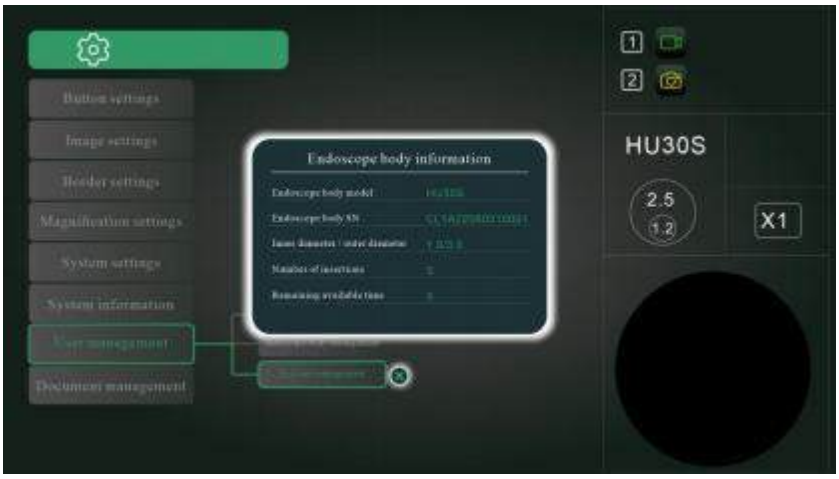
[Figure 4-21] System Information Displaying Interface

4.1.10 User management

(1) After entering the user administration - password setting, press the "② or ▶" key to enter the next level menu, press the "MENU/OK" key to set the switch, and press the "← or ④" key to save settings and return to the previous level menu;

[Figure 4-22] Startup Password Setting Interface

(2) After entering the user administration setting, select the "endoscope body" option and press the "②" key to have the endoscope information window pop up, and then press the "←" key to close the window and return to the previous level menu, with the endoscope management window displaying the following information: endoscope model, endoscope SN, inner/outer diameter, insertion times and cumulative usage time.



[Figure 4-23] Endoscope Management Interface

(3) After entering the user administration setting, select the "account management" option and press the "②" key to have the account management window pop up, and then press the "←" key to close the window and return to the previous level menu;

[Figure 4-24] Account Management Interface

(4) Logging in with an administrator account, the user have the authority to delete, add sub-accounts (as shown in Figures 4-25 and 4-26), modify sub-account passwords and administrator passwords (as shown in Figures 4-27); logging in with sub-accounts, the user can only modify/save the login account password.

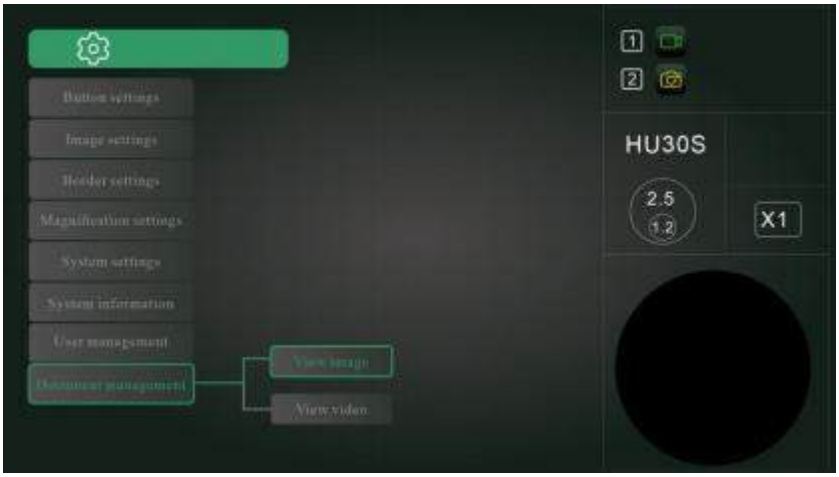
[Figure 4-25] Deleting Sub-account

[Figure 4-26] Adding Sub-account

[Figure 4-27] Modifying Account Passwords

4.1.11 Document management

After entering the Document management setting, press the "▲" and "▼" keys the switch options, and press the "②" key to enter the image or View video interface.

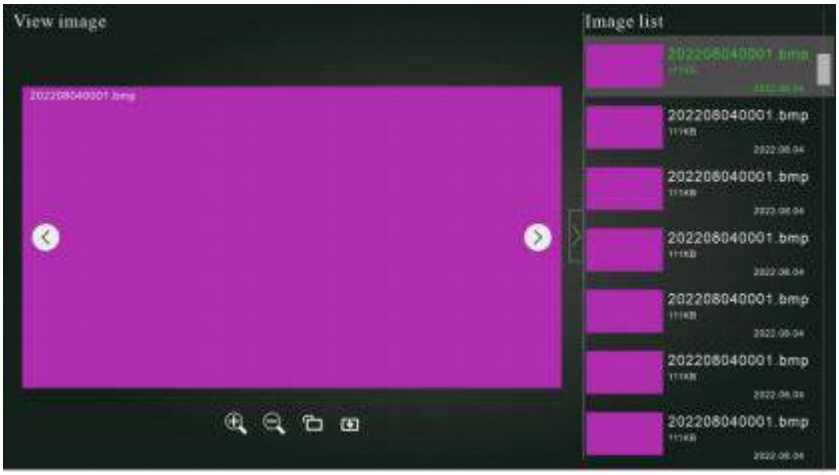


[Figure 4-28] Document management Interface

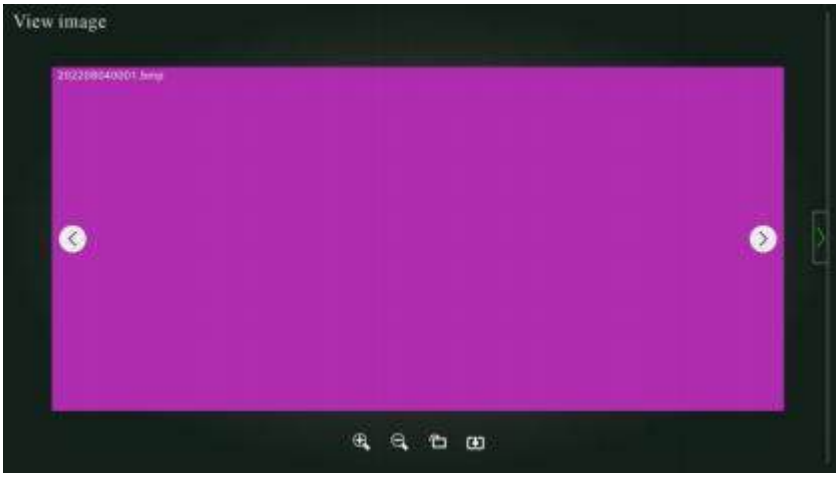
4.1.11.1 View Image

(1) In the grid browsing interface, press the "②" key to enter the list browsing interface, and in that interface, press the "⛶" key to enter the full screen browsing interface.

(2) [Figure 4-29] Grid Browsing Interface



[Figure 4-30] List Browsing Interface

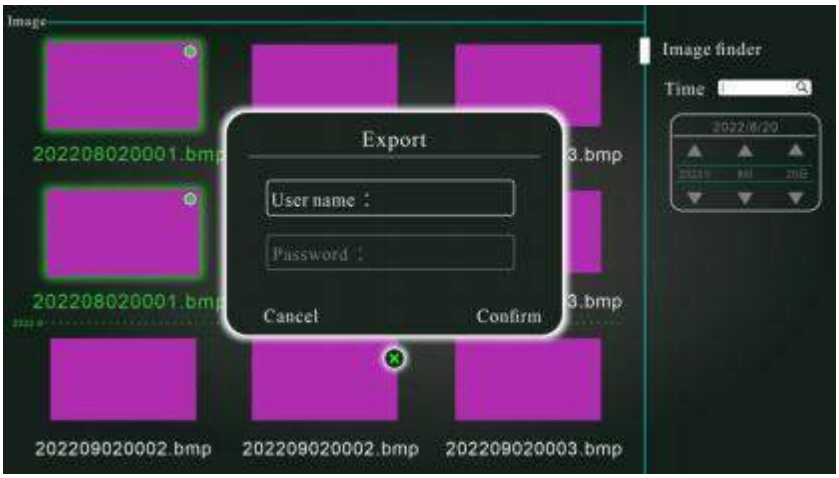


[Figure 4-31] Full Screen Browsing Interface

（2） In the grid browsing interface, press the "TIME" key to enter the image search mode, and then set the filtering time using the "▲", "▼", "④", and "▶" keys, and finally press the "↻" key to complete the image filtering.

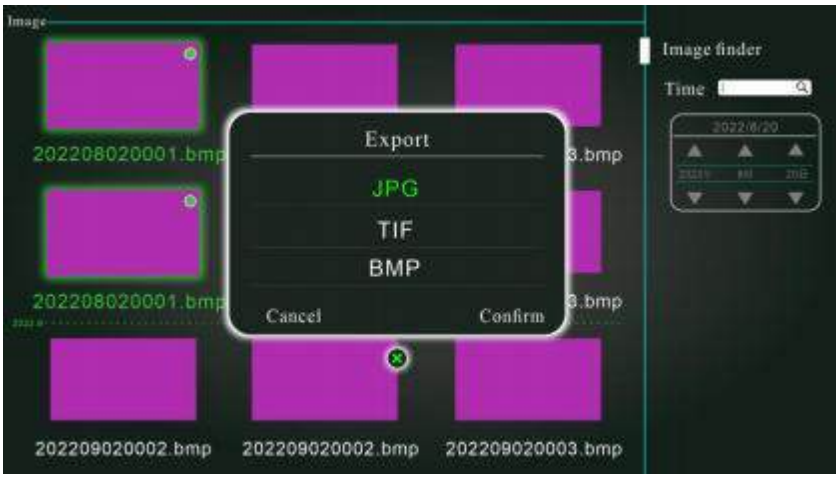
（3） In the grid browsing interface, press the "⛶" key to select the image to be downloaded, press the

"  " key to download the image, and then the "Image Export" window will pop up, and select the username, enter the password through the soft keyboard, and finally select "Confirm" with the cursor to enter the "Image Export" image format selection pop-up window.



[Figure 4-32] Image Export User Login Example Figure

（4） In the image export dialogue bar, select the image format (with JPG, TIF, BMP available) by pressing the "  " and "  " keys, and then press the "  " and "  " keys to select "Confirm"; after the export progress reaches 100%, press the "  " key to complete the image export.



[Figure 4-33] Image Export Format Selection Example Figure

（5） In the list browsing interface or full screen browsing interface, press the "  " key to switch to the previous image, and press the "  " key to switch to the next image; press the "  " key to enlarge the image, press the "  " key to shrink the image, and press the "  " key to rotate the image clockwise by 90°.

Instruction:

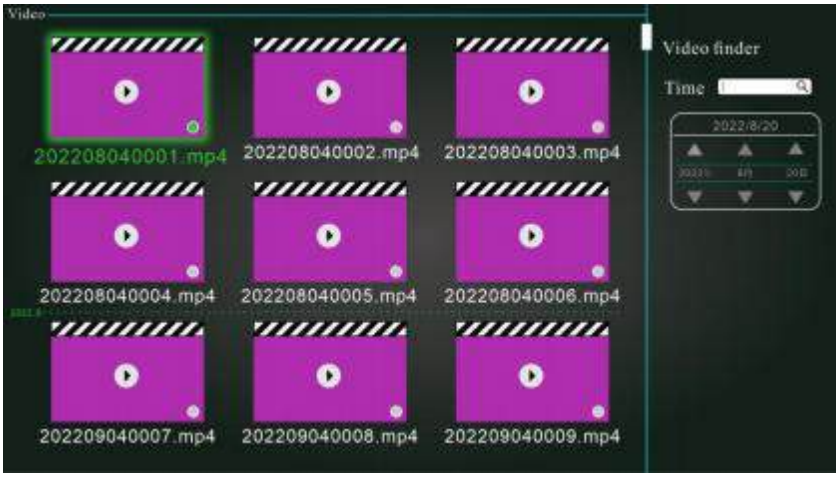
1. When exporting, the username and password entered are the same as the username and password entered when logging in.

2. After entering the incorrect password, all input information will be cleared and a new input is required.

3. Before exporting images, the USB drive must be inserted into the USB interface of the host.

4.1.11.2 View video

(1) In the grid browsing interface, press the "②" key to enter the full screen browsing interface, and press the "⛶" key to enter the list browsing interface.



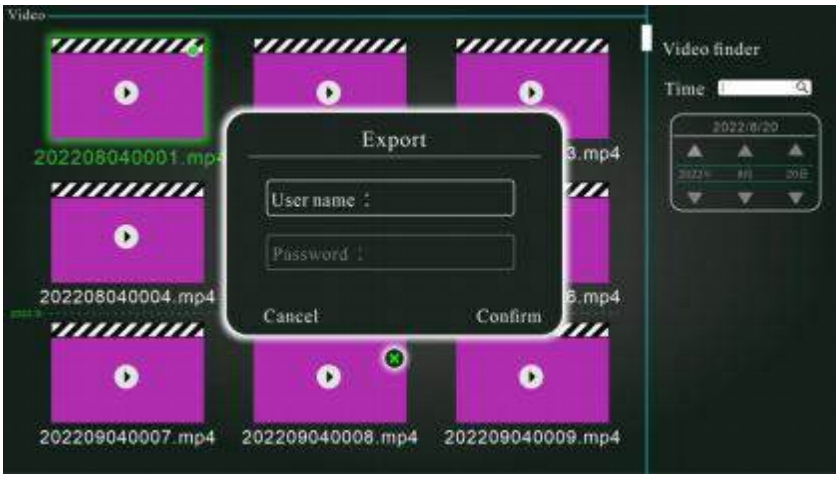
[Figure 4-34] Grid Browsing Interface

[Figure 4-35] List Browsing Interface

[Figure 4-36] Full Screen Browsing Interface

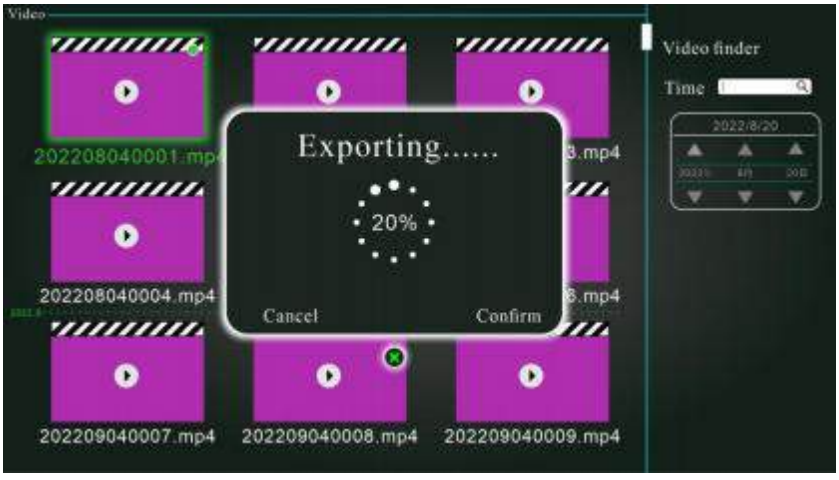
(2) In the grid browsing interface, press the "TIME" key to enter the video search mode, and then set the filtering time using the "▲", "▼", "④", and "▶" keys, and finally press the "↩" key to complete the video filtering.

(3) In the grid browsing interface, press the "⛶" key to select the video to be downloaded, press the "⬇" key to download the video, and then the "Video Export" window will pop up, and press the "MENU/OK" to have the username option pop up, **and finally press the "MENU/OK" key to confirm.** Press the "▼" key to enter the password box, press the "②" key to enter the password through the soft keyboard, and then press the "←" key to exit the soft keyboard.



[Figure 4-37] Video Export User Login Example Figure

(4) Select the "Confirm" option with the cursor, and then press the "MENU/OK" key to have the video export progress window pop up; after the export progress reaches 100%, press the "②" key to complete the video export.



[Figure 4-38] Video Exporting Progress Example Figure

(5) In the list browsing interface or full screen browsing interface, press the "  " key to switch to the previous video, and press the "  " key to switch to the next video; press the "  " key to fast rewind the video, press the "  " key to fast forward the video, and press the " 

" key to alter the video playing speed.

Instruction:

1. When exporting, the username and password entered are the same as the username and password entered when logging in.

2. After entering the incorrect password, all input information will be cleared and a new input is required.

3. Before exporting videos, the USB drive must be inserted into the USB interface of the host.

4.1.12 HUV-02 Technical Parameter

Display Default Resolution	 1920*1080
Screen Ratio	16：9
Image Export	1920*1080
Start Time	≤17s
Storage Mode	FAT32 Format Built-in Memory Card
Capacity Power requirements	 100-240V～50/60HZ 1A
Electric Shock Proof	Class I, BF Application Part
Operation Environment Temperature	 0-40℃ (50-90℉)
Relative Humidity	30-85%
Atmos	70-106kPa
Altitude	≤2000m
Preservation and Transportation Temperature	 0-45℃ (32-113℉)
Relative Humidity	30-95%
Overall Dimensions Length	 377±5mm
Width	280±5mm
Height	85±5mm
Weight	3kg
USB Connection	USB3.0
HDMI Connection	1.3
DVI Connection	1.0
S-video Connection	/
CVBS Connection	/
SDI Connection	3G-SDI

⚠Warnings

- **To avoid the risk of electric shock, the equipment can only be connected to a power supply with grounding protection.**
- **When disconnecting the device from the power supply, the plug must be unplugged from the wall socket.**

4.1.13 HUV-02 Cleaning and Disinfection

Using neutral enzymes to clean the surface

A.1 EMC

HUV-02 complies with the domestic IEC 60601-1-2: 2014 Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests

Cautions

- **Using accessories, sensors and cables outside the specified range may increase the electromagnetic emission of HUV-02 and/or reduce the electromagnetic immunity of HUV-02.**
- **Do not use HUV-02 close to or stack it with other equipment. When necessary, HUV-02 should be closely observed to ensure that it can operate normally in the configuration used.**
- **Special protection against EMC of HUV-02 is required, and installation and maintenance are required in an environment that is consistent the following EMC information.**
- **Avoid using HUV-02 and MRI (Magnetic Resonance Imaging) or similar equipment at the same time, otherwise equipment failure or equipment breakdown may occur due to electromagnetic interference.**
- **Even if other equipment meets the emission requirements of CISPR, it may cause interference to HUV-02.**
- **When the input signal amplitude is lower than the minimum specified in the technical specifications, the measurement may be inaccurate.**
- **Portable and mobile RF communication equipment may affect the performance of Medical Image Processor of the medical electronic endoscope.**

Guideline and statement of the manufacturer - electromagnetic emission		
HUV-02 is expected to be used in the following electromagnetic environment, and the purchaser or user should ensure that it is used in this electromagnetic environment:		
Emission test	**Compliance**	**Electromagnetic environment - guideline**
RF emissions CISPR 11	Group 1	HUV-02 uses RF energy only for its internal functions. Therefore, its radio-frequency emissions are very low and it is almost impossible to cause interference to nearby electronic equipment.
RF emissions CISPR11	Class A	HUV-02 is suitable for use in all facilities that are not domestic and not directly connected to the residential public low-voltage power supply network for

Harmonic emissions lEC 61000-3-2	Not applicable	domestic use.
Voltage fluctuations / flicker emissions lEC 61000-3-3	Not applicable	

Guideline and statement of the manufacturer - Electromagnetic immunity			
HUV-02 is expected to be used in the following electromagnetic environment, and the purchaser or user should ensure that it is used in this electromagnetic environment:			
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment - guideline**
Electrostatic discharge (ESD) lEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Floors shall be wood, concrete or tile. If floors are covered with synthetic material, the relative humidity shall be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2kV, for the power line	±2kV, for the power line	The grid power supply should have the quality used in a typical commercial or hospital environment
Surge lEC 61000-4-5	±1 kV line to line ±2 kV line to ground	±1 kV line to line ±2 kV line to ground	The grid power supply should have the quality used in a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines	<5% U_T for 0.5 cycle (> 95% dip on U_T) 40 % U_T for 5 cycles (60% dip on U_T)	<5% U_T for 0.5 cycle (> 95% dip on U_T) 40 % U_T for 5 cycles (60% dip on U_T) 70 % U_T for 25	The grid power supply should have the quality used in a typical commercial or hospital environment If

IEC 61000-4- 11.	70 % U_T for 25 cycles (30% dip on U_T) <5 % U_T for 5s (> 95% dip on U_T)	cycles (30% dip on U_T) <5 % U_T for 5s (> 95% dip on U_T)	the user of HUV-03 requires continuous operation during the power interruption, it is recommended that the Medical Image Processor of the medical electronic endoscopes use an uninterrupted power supply or battery power supply
Power frequency (50/60 Hz) magnetic field lEC 61000-4-8	3A/m	3A/m,50/60Hz	Power frequency magnetic field shall have the horizontal characteristics of power frequency magnetic field of typical places in typical commercial or hospital environment.
Note: U_T refers to the AC network voltage before applying the test voltage			

Guideline and statement of the manufacturer - Electromagnetic immunity			
HUV-02 is expected to be used in the following electromagnetic environment, and the purchaser or user should ensure that it is used in this electromagnetic environment:			
Immunity test	**IEC 60601-1-2 test level**	**Complian ce level**	**Electromagnetic environment - guideline**

			Portable and mobile RF communication equipment should not be used closer to any part of the Medical Image Processor of the medical electronic endoscope than the recommended isolation distance, including cables. This distance shall be calculated by the formula corresponding to the frequency of the transmitter. **Recommended isolation distance** $d = 1.2\sqrt{P}$
Conducted RF lEC 61000-4-6 Radiated RF lEC 61000-4-3	3 V(Effective value） 150 kHz~80 MHz 3 V/m 80 MHz~2.5 GHz	3 V (Effective value) 3 V/m	$d = 1.2\sqrt{P}$ *80 MHz~800 MHz* $d = 2.3\sqrt{P}$ *800 MHz~2.5 GHz* Wherein: P — Subject to the maximum rated output power of the transmitter provided by the transmitter manufacturer, in watts (W); *d— Recommended isolation distance b, in meters (m)* [b]. The field strength of the fixed radio frequency transmitter is determined by surveying the electromagnetic field [c], which should be lower than the compliance level in each frequency range d. Interference may occur in the vicinity of equipment marked with the following symbols. 

Note: 1. The higher frequency band formula is used on 80MHz and 800MHz frequency. 2. These guidelines may be not suitable for all circumstances, and the electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human body.
a) Fixed transmitters, such as: Field strengths from fixed transmitters, such as base situations of wireless (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment of fixed radio frequency transmitter, the electromagnetic field survey shall be considered. If the measured field strength of HUV-02 is higher than the above applicable RF compliance level, HUV-02 should be observed to verify its normal operation. If abnormal performance is observed, supplementary measures may be necessary, such as readjusting the direction or position of HUV-02. b) In the entire frequency range of 150KHz-80MHz, the field strength should be lower than 3 V/m.

Recommended isolation distance between portable and mobile RF communication equipment and HUV-02

HUV-02 is expected to be used in an electromagnetic environment with controlled radio frequency radiation disturbance. According to the maximum rated output power of the communication equipment, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile radio frequency communication equipment (transmitter) and the HUV-02 as recommended below.

Maximum rated output power of the transmitter W	**Isolation distances corresponding to different frequencies of transmitters /m**		
	150 kHz ~ 80 MHz $d = 1.2\sqrt{P}$	**80 MHz ~ 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz ~ 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For the transmitter's maximum rated output power not listed in the above table, the recommended isolation distance d , in meters (m), can be determined by the equation in the corresponding transmitter frequency column, where P represents the maximum rated output power provided by the transmitter manufacturer, in watts (W).

Note:

1. At 80 MHz and 800 MHz, the equation with a higher frequency range should be used.

2. These guidelines may be not suitable for all circumstances, and the electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human body.

A.2 Applied Standards

The Medical Image Processor conforms with:

IEC/EN 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

IEC/EN 60601-1-2 Medical electrical equipment – Part 1-2 General requirements for safety –

Collateral standard: Electromagnetic compatibility - Requirements for test.

The power supply conforms with:

IEC/EN 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.