HugeMed

VLM-02, VLM-03

Medical Image Processor

Instructions for Use

Model：VLM-02, VLM-03

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CE **2797**

INTRODUCTION

Thank you for purchasing the VLM-02,VLM-03 Medical 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-02,VLM-03
Date of manufacture:	See product labels
Service life:	3 years
Preparation/revision date:	2024-12-4
IFU version:	V2.0
Software release version:	V1
Product performance, structure and composition:	Power adapter, Power cable, USB cable, and HDMI cable
Intended purpose	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
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Website:	https://hugemed.net
EC REP	Shanghai International Holding Corp. GmbH(Europe) Address: Eiffestrasse 80,20537 Hamburg, Germany

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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 Medical 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.

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TABLE OF CONTENTS

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CHAPTER 1 SAFETY

1.1 Safety Information

This chapter lists the basic safety information that users must pay attention to and observe when using the 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.**

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

1.1.1 Hazard

There is no such safety risk.

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1.1.2 Warning

 Warnings

The Medical 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 Medical Image Processor 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 work properly and safely.

It cannot 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 installed or handled properly to protect the Medical Image Processor from falling, collision, intensive oscillation, or damage 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 used near the Medical Image Processor and its supporting products must meet the corresponding EMC requirements, otherwise the Medical 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.

Medical Image ProcessorRepairs or upgrades to the Medical 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.

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;

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1.1.3 Caution

Caution

The use environment and power supply for the Medical Image Processor must meet the requirements in *A Product Specification*.

1.1.4 Notice

Notice

- Please place the IFU near the Medical 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 Medical Image Processor you have purchased may not have certain configuration or functions.

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1.2 Labels and Identification

⚠	Warning	CE 2797	CE Mark
🧍	Type BF applied part	📖	Follow operating instructions
♻	Waste electrical and electronic equipment directive	MD	Medical device
EC REP	Authorized Representative in the European Community/ European Union	SN	Serial number
🏭	Manufacturer	📅	Date of manufacture
UDI	Unique device identifier	%	Humidity limitation
⊕•⊝	Atmosphere pressure limitation	🌡	Temperature limit
🍷	Fragile, handle with care	☂	Keep dry
↑↑	This way up	5	Stacking limit by five

CHAPTER 2 OVERVIEW

2.1 Product Introduction

2.1.1 Intended purpose

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**

- **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 Medical 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 Medical Image Processor must meet the requirements in** *A Product Specification*.

2.1.2 Contraindications

None

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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

Bus terminal
USB interface
HDMI interface
Charging port

Bus terminal
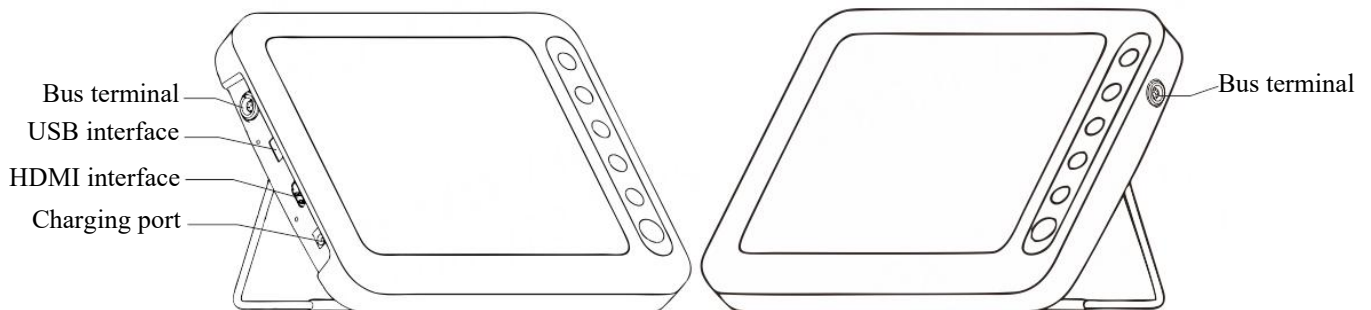
The plugs of the Medical Image Processor host and endoscopic wiring have alignment marks. When inserting, please pay attention to the matching of the green and blue circle interfaces between the endoscopy and the host.

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2.1.4 Screen display


```
┌─────────────────────────────────────┐
│                                      │
│                                      │
│   Real-time videos                   │
│                                      │
│                          ┌─────────────┐
│                          │ DD/MM/YYYY  │
│     ┌──────────────┐     │ HH/MM/SS    │
│     │ Power display│     └─────────────┘
└─────┴──────────────┴─────────────────┘
```
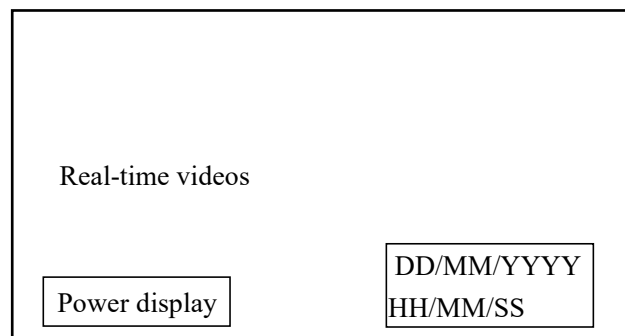
『**Figure 23**』 **display main interface**

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.

2.1.5 Clinical Benefits

Together with the compatible HugeMed endoscope tract provides visualization and inspection of hollow organs and cavities in the body.

2.1.6 Indication

Please refer to the Instructions for Use of the compatible HugeMed endoscope for information on the indications for use.

2.2 Battery

2.2.1 Overview

The Medical Image Processor has a built-in lithium ion battery (hereafter referred to as the "Battery"), which will be charged when the Medical Image Processor connects to the power adapter. When charging in the power-on state, the Medical 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.

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- 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 **Medical 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 **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%**), 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 Medical 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

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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 Medical 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 Medical Image Processor to the power adapter and charge it continuously to 100%;

2. Disconnect the power adapter from the Medical Image Processor and use the battery to supply power until the Medical Image Processor is powered off;

3. Reconnect the Medical 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 Medical Image Processor to the power adapter and charge it continuously for 4–6 h;

2. Disconnect the power adapter and let the Medical Image Processor run continuously until it is powered off due to excessively low battery level;

- If the time from the start of the Medical Image Processor to shutdown is 120 min or above, the battery is in good condition;

- If the time from the start of the Medical 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 Medical 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 Medical 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.**

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CHAPTER 3 USE AND MAINTENANCE

3.1 Installation and Use

⚠️**Warnings**

● 　　The software copyright of the Medical 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 Medical 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

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The use environment for the Medical Image Processor shall meet the requirements in *A.2 Environment Specification*.

The use environment for Medical 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 Medical Image Processor shall meet the requirements in *A.3 Power Supply Specification*.

⚠️**Warnings**

- **Please ensure that the Medical 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 Medical Image Processor failure**.

- **The appropriate power supply source must be chosen according to the setting of the supply voltage of the Medical Image Processor. Otherwise, it may cause serious damage to the Medical Image Processor.**

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CHAPTER 4 OPERATION INSTRUCTIONS OF MEDICAL IMAGE PROCESSOR

⚠ **Warnings**

- Before using the Medical Image Processor, the user must check its fittings and accessories to ensure that they work properly and safely.

- Please ensure that the Medical Image Processor works under the specified environmental and power conditions, otherwise it may lead to unexpected consequences such as Medical Image Processor failure.

- The appropriate power supply source must be chosen according to the setting of the supply voltage of the Medical Image Processor. Otherwise, it may cause serious damage to the Medical 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	⏻	⚙	▲	▼	AWB	❄/↵
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 ![power icon] to start the Medical 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 ![gear icon] button.

『**Figure 4-1**』**Boot LOGO interface**
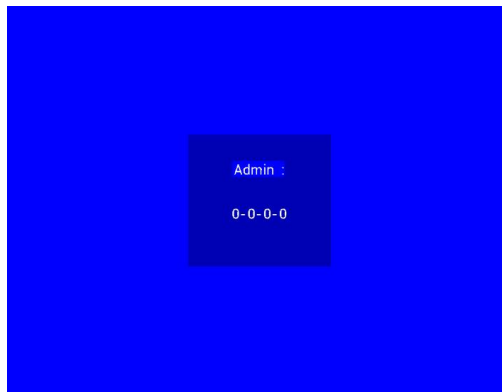
『**Figure 4-2**』**User login interface**

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』.
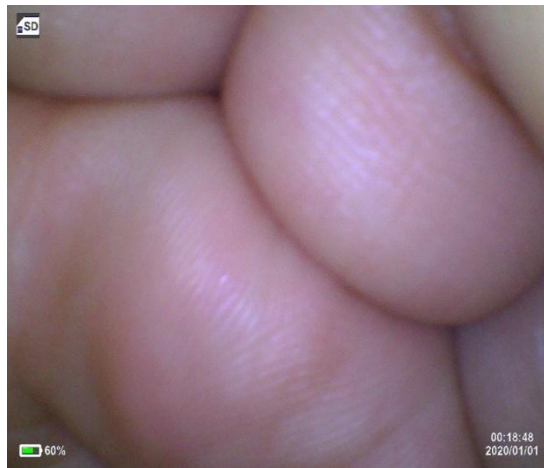
【Figure 4-4】 **Normal working interface**

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』.

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『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』.
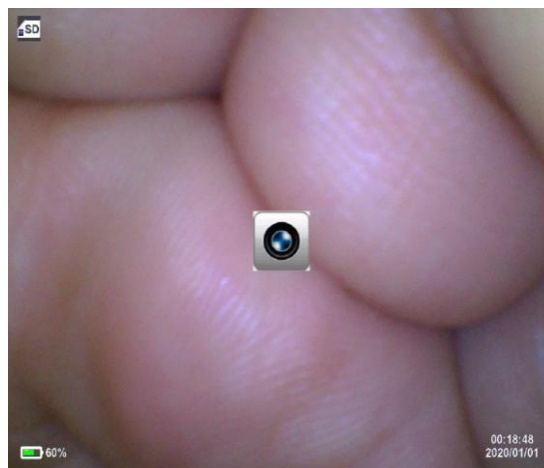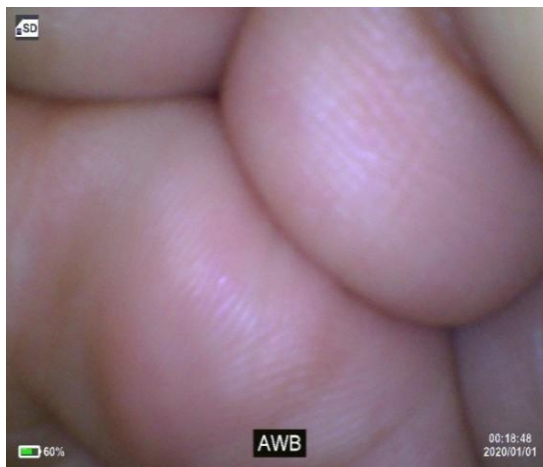

『Figure 4-7』　Photographing prompt interface

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』.
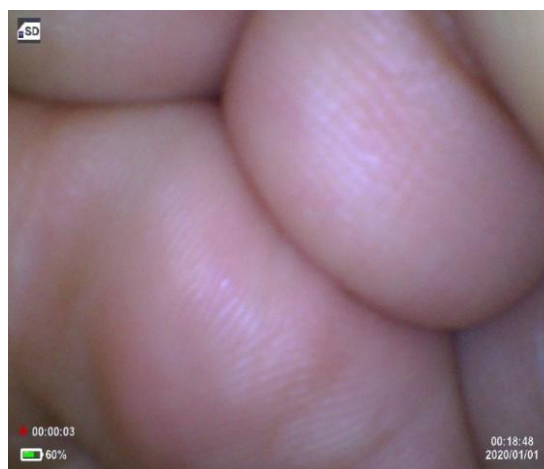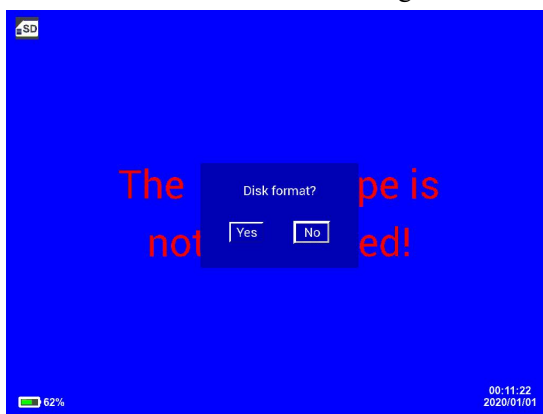

『Figure 4-8』 Recording prompt interface

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6) Press the function button ![AWB button] to enter the white balance interface.

〖Figure 4-9〗 White balance prompt interface

7) Press the function button ![freeze 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 ![menu button] to enter the system setting interface, as shown in 〖Figure 4-11〗, and press the button ![freeze button] to exit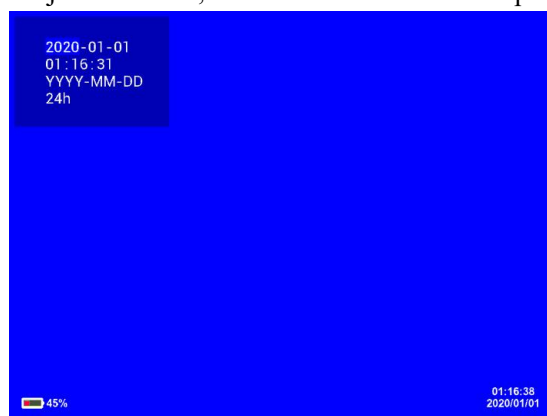 the system setting interface. Press the arrow buttons ▲ and ▼ to select, and press ![menu button] to enter the sub-interface, and ![freeze button] to return to the previous interface.

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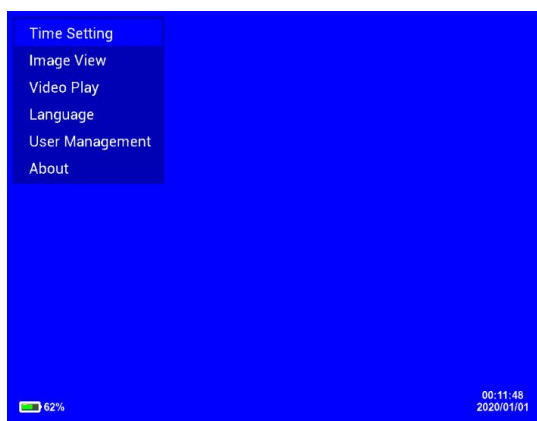
〖Figure 4-11〗System setting interface

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 (AWB) to delete the currently selected image file.
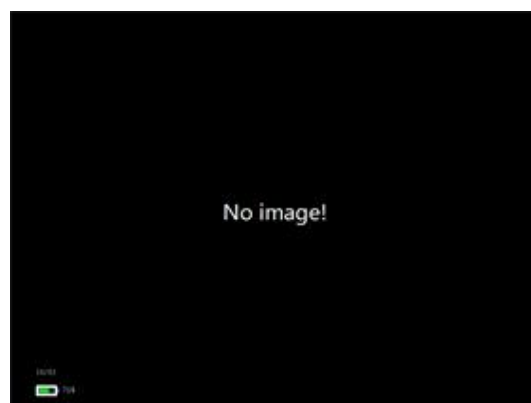
〖**Figure 4-13**〗 **Image browsing interface**

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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 (AWB) 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 (AWB) 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.

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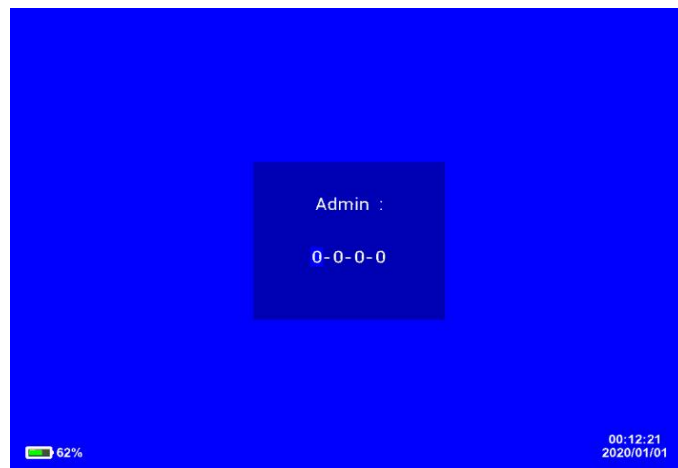
〖Figure 4-16〗 Administrator login interface

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

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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.
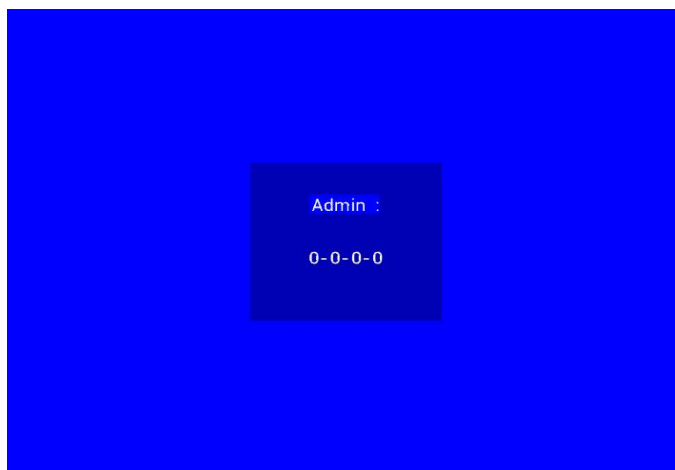
『Figure 4-18』 Administrator login interface

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

Brightness identification
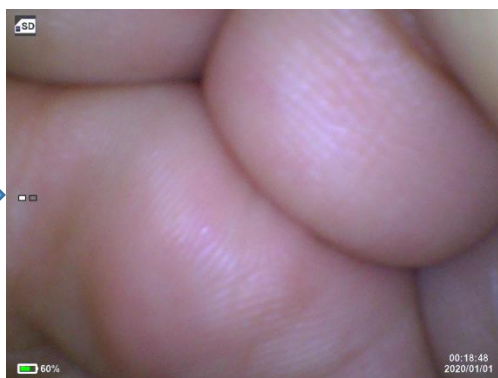
『Figure 4-19』 Brightness interface

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：

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4.2 Product Maintenance

4.2.1 Maintenance of the Medical Image Processor

⚠️**Warnings**

> **After using the Medical Image Processor, disconnect it from the power source, remove all accessories, and turn off the power.**
>
> **When disconnecting from the power adapter, pull the plug out of the socket.**

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

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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	30%–80%, non-condensing
Operating atmospheric pressure	80–106 kPa
Storage temperature	-10℃~45℃
Storage humidity	30%–80%, non-condensing
Storage atmospheric pressure	80–106 kPa
Transport temperature	-20℃~50℃
Transport humidity	20%–90%, non-condensing
Transport atmospheric pressure	80–106 kPa
Description of storage conditions	Well-ventilated room without corrosive gases

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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	Medical Image Processor	1	
2	Power cord	1	
3	Power adapter	1	
4	USB cable	1	
5	HDMI cable	1	
6	Instructions for Use Medical Image Processor	1	

A.5 Compatible Products

Single-use Bronchoscope
Single-use Rhinolaryngoscope
Single-use Cystoscope
Single-use Choledochoscope

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The way to access the electronic Instructions for use:

The url of VLM-02&VLM-03:

https://hugemed.net/Product/Medical-Image-Processor/Medical-Image-Processor-VLM-02

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B EMC

The Medical 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 Medical Image Processor and/or reduce the electromagnetic immunity of the Medical Image Processor.**

- **Do not use the Medical Image Processor adjacent to or stacked with other equipment. If necessary, the Medical Image Processor shall be closely observed to ensure that it functions properly in the configuration used.**

- **The EMC of the Medical 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 Medical 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 Medical 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 Medical Image Processor.**

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Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Medical 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 Medical 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 Medical 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 Medical 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,	0% U_T ;0.5 cycle	0% U_T ;0.5 cycle	Mains power quality

short 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	should be that of a typical commercial or hospital environment. If the user of the endoscopy Medical Image Processor requires continued operation during power mains interruptions, it is recommended that the endoscopy Medical 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.			

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<table>
<tr><th colspan="4">Guidance and Manufacturer's Declaration – Electromagnetic Immunity</th></tr>
<tr><td colspan="4">The Medical 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 rowspan="2">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</td>
<td>3 V (r.m.s. value)

6V</td>
<td rowspan="2">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>3 V/m
80 MHz–2.7 GHz</td>
<td>3 V/m</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 Medical Image</td></tr>
</table>

Processor is used exceeds the applicable RF compliance level above, the endoscopy Medical 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 Medical Image Processor.

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