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User's Manual
Digital Video Monitor

DVM-D1&DVM-D2

Rx only

Caution: Federal law restricts this device to be sold by or on the order of a physician.

- ◆For use by trained clinicians/physicians only.
- ◆For in-hospital use.
- ◆For use with Vathin endoscope.
- ◆Before use, thoroughly review this manual.
- ◆Please keep all instruction manuals in a safe, accessible place.
- ◆If you have any questions or comments about this manual, contact Vathin Medical.

Hunan Vathin Medical Instrument Co., Ltd.

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1. Important Information - Read Before Use

Please read these safety instructions carefully before using the Digital Video Monitor. The instruction for use may be updated without further notice. Copies of the current version are available upon request. Please note that no clinical procedure is explained or discussed in this manual. The product is to be operated only by a physician who has received clinical endoscopy training. Therefore, no clinical endoscopy procedure is explained or discussed in this manual. This manual only provides the basic operations and preventive measures for the Digital Video Monitor.

Before initial use of the Digital Video Monitor, it is essential for operators to have received sufficient training in clinical endoscopic techniques and to be familiar with the intended use, warnings, cautions and contraindications mentioned in these instructions.

If, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority.

This Instruction for Use only applies to the Vathin Digital Video Monitor. See relevant manuals for other products from Vathin Medical.

1.1. Intended Use

The equipment is specially designed to be used with Vathin medical endoscopes and other auxiliary equipment for the purposes of endoscopic diagnosis, treatment and video observation. Never use the product for any purposes other than those stated in this manual.

1.2. Contraindication

The product itself has no contraindications. If a doctor with appropriate qualifications believes that the use of this product will bring danger to the user, the product should not be used.

1.3. Repair and Refit

The product does not contain any user-repairable components. Never disassemble or refit or attempt to repair the product, which may cause injury to the patient or operator, damage to the product and/or failure to achieve the intended purpose. The product can be repaired only by the person authorized by Hunan Vathin Medical Instrument Co., Ltd.

1.4. Keywords

The following keywords are used throughout this manual:

Warning

Indicates a potentially hazardous situation, which, if not avoided, may result in death or serious injury.

Caution

Indicates a potentially hazardous situation, which, if not avoided, may result in minor or moderate injury. It may also be used to warn of unsafe practices or potential damage to the product.

Note

Indicates other useful information.

1.5. Warnings and Cautions

Failure to observe these warnings or precautions may result in injury to the patient or damage to the product. Hunan Vathin Medical Instrument Co., Ltd. is not responsible for any system damage or patient injury caused by the improper use of the product.

Warning

- As a BF-type application component, the endoscope connected to the product must not be directly applied to the heart. The leakage current at the BF-type application component may be very dangerous, and may cause ventricular fibrillation or severely affect the patient's heart function. Always observe the following two points.
- —Do not apply the endoscope connected with the product onto the heart or any area near the heart.
- —Do not use endoscope treatment accessories or other endoscopes on or near the heart to make it contact the endoscope connected to the product.
- Do not install or use the product under the following conditions:
- — High oxygen concentration
- — Presence of oxidants (such as nitrous oxide) or flammable anesthetics in the atmosphere
- Do not use the product in an MRI environment.
- Do not use the product during the defibrillation process.
- The product can only be connected to a medical equipment that has been qualified as per IEC 60601-1.
- RJ45, HDMI, USB, SDI, Remote, D-SUB9 interfaces are functional interfaces and are prohibited from connecting to hazardous voltages in external circuits.

Warning

- To avoid the risk of electric shock, do not simultaneously touch the power socket, the docking connector or the bracket of the product when handling with the patients.
- To minimize the risk of contamination, always clean and disinfect the product as specified in Chapter 7 after each use.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the DVM-D1, including cables specified by the Vathin Medical. Otherwise, degradation of the performance of this equipment may result..
- Always observe the following precautions; otherwise, patients or medical personnel may be in danger.

  —When using the product to examine patients, always prevent the metal parts of the endoscope or its accessories from touching any metal part of other components of the system.

  —Keep all the electrical equipment away from any liquid.
- Wear suitable protective filtering spectacles when the laser is use. Otherwise, eye damage may occur.
- When the lithium battery needs to be replaced, it needs to be returned to the manufacturer and replaced by professional personnel, otherwise it will cause certain risks

Caution

- Always prepare an applicable and immediately available standby system to ensure that treatment procedure can be continued in the event of equipment failure.
- Always use the spare parts provided by Vathin Medical. Never refit any spare part.
- Always keep the product dry during preparation, usage and storage.
- The real-time imaging of the product may be affected by the use of high-frequency tools inside the connected endoscope. This phenomenon is not a malfunction. In such a case, just wait a few seconds to reset the image.
- The product is not intended to be repaired. In case that the product becomes defective, it should be discarded.

Note

Please note that your organization is responsible for the following areas, which should be

- implemented according to your local policy:
- Network setup
- Ensuring availability and confidentiality of the network
- Ensuring confidentiality and integrity of physical devices
- Management of the Digital Video Monitor user profiles
- Maintenance of user passwords
- Monitoring and audit of the Digital Video Monitor
- Complete data erasure before disposal of the Digital Video Monitor

Note

Expected environment network configuration Suggestions

Wireless:

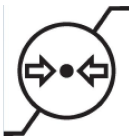
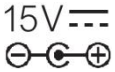
- Modify the default "SSID" of the AP device, and disable the SSID broadcast identifier to prevent unauthorized unfamiliar devices from searching and attempting to connect. wifi password must meet more than 12 characters, covering letter case, numbers, special characters.
- Set WPA-XXX security encryption to prevent brute-force password cracking. Add a MAC address whitelist, enable MAC address filtering, manually add the MAC addresses of authorized wireless devices, and deny connections to devices with unauthorized MAC addresses.

LAN:

- You are advised to add MAC address authentication to the user network or use the static address assignment mode for network connections

2. Symbols

Symbols	Expression	Symbols	Expression
CE	CE marking of conformity		Waste Bin symbol,indicating that waste mustbe collected according tolocal regulation and collection schemes fordisposal of electronic andelectrical waste (WEEE)

	General warning sign		Manufacturer
	Refer to instruction manual		Date of manufacture, followed by YYYY-MM-DD
Rx only	Indicates that the product can be used only with a prescription from a U.S. physician as required by the appropriate regulations of USA		Serial number
	Authorized representative in the European Community/European Union		Keep dry
	Humidity limitation		Temperature limitation
	Atmospheric pressure limitation		Keep away from sunlight
	Catalog number. Indicates the manufacturer's catalog number so that the medical device can be identifie		Type BF Applied Part
	UL Recognized Component Mark for Canada and the United States		Input voltage: 15V DC
	Universal serial bus Ports		wireless local area networks Port
	Only for indoor use		Tested to comply with FCC Standards-medical Equipment
	Fragile, handle with care		Model number
	Medical device		Unique device identifier
	Protective earth (ground)		Direct current

3. System

The product is designed as the system controller of an endoscopic image observation system to

display, record endoscopic images. Certain functions described below can only be enabled when the necessary equipment is connected to the product. For information about the compatible endoscope and other equipment, please refer to their Instruction for Use.

3.1. Digital Video Monitor

No.	Model	Specification of endoscope port
1	DVM-D1	1*26-pin, 2*14-pin
2	DVM-D2	1*26-pin, 2*16-pin

3.2. Compatible Endoscopes

The Digital Video Monitor has been designed to be used in conjunction with the Vathin endoscope and medical monitor. The compatible equipment is listed below.

No.	Model	Compatible endoscopes	Model
1.	DVM-D1 DVM-D2	**Single-use Flexible Video Bronchoscope**	BCV1-C2, BCV1-02, BCV1-KS2, BCV1-KS3-L, BCV1-M2, BCV1-S2, BCV1-W2
2.		**Single-use Flexible Ureteroscope**	US-S170, US-S180, US-E170, US-E180
3.		**Single-use Flexible Video Bronchoscope**	BC-S1E00-L, BC-S1H00-L, BC-S1J00-L, BC-S1E00, BC-S1H00, BC-S1J00
4.		**Single-use Flexible Bronchoscope**	BC-E1C11, BC-E1C12, BC-E1E10, BC-E1E11, BC-E1E12, BC E1H10, BC-E1H11, BC-E1H12, BC-E1C10
5.		**Single-use Flexible Cystoscope**	CY-S2G01, CY-E2E00, CY-E2E01, CY-S2E00, CY-S2E01, CY E2F00, CY-E2F01, CY-S2F00, CY-S2F01, CY-E2G00, CY-E2G01, CY-S2G00, CY-E2F01R, CY-E2E01R, CY-E2G01R

3.3. Compatible Monitor

Item	Recommended parameter
Screen brightness	≥ 400 cd/m²
Color gamut	≥72% NTSC
Resolution	≥1920*1080

Monitoring technology	Bright LED backlight technology
Input signal type	DVI-D or HDMI or SDI
Contrast	≥ 1000/1

4. Checking the Package Contents

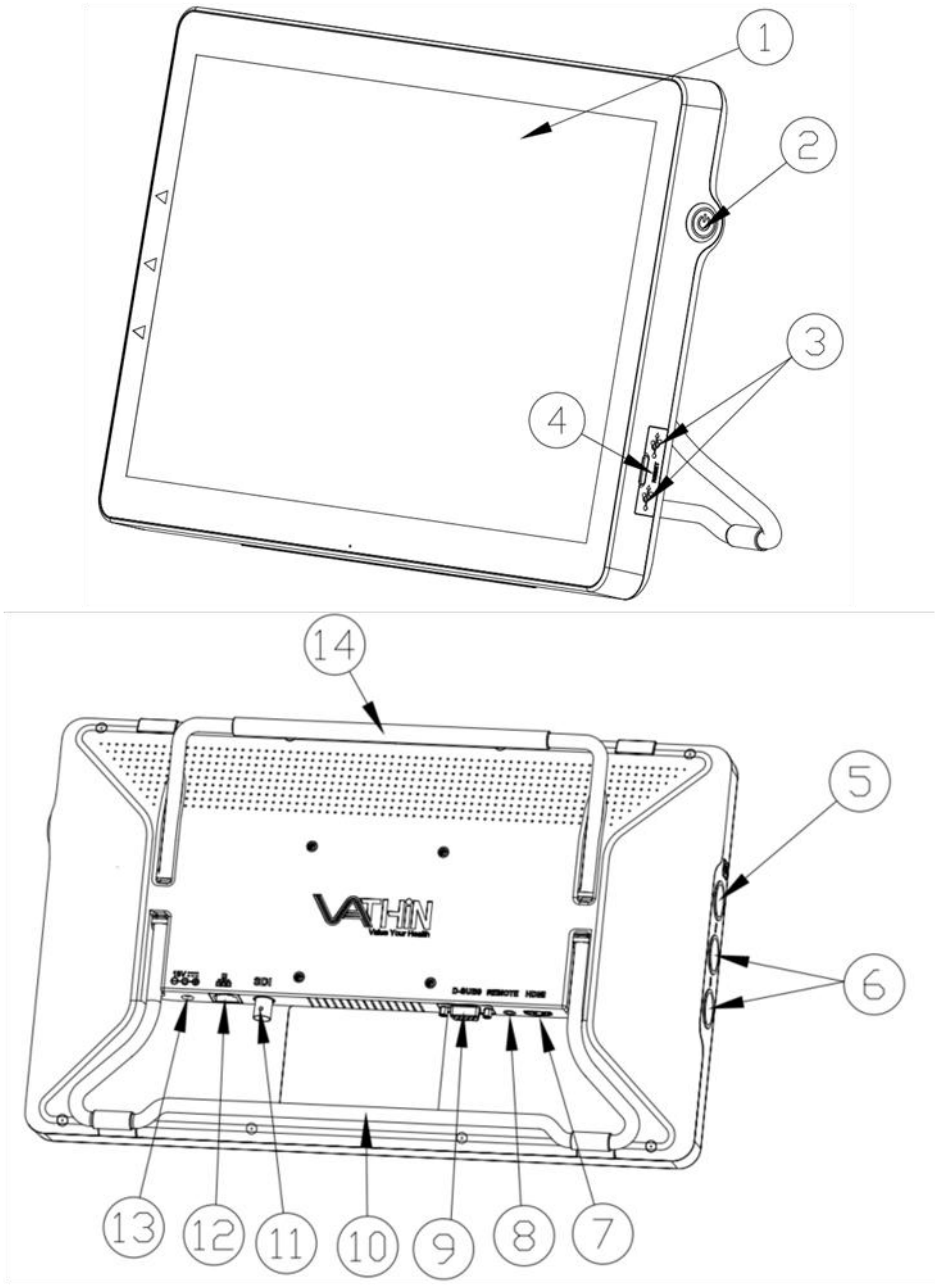
4.1. Package Contents

Open the product packaging to ensure that all components are included, including any optional components ordered. Optional components that have not been ordered will not be provided.. Check all items in the package with the components shown below. Check each item for damage. Please contact Vathin Medical if any component is missing or damaged.

Items	**Quantities**	**Pictures**
DVM-D1 Digital Video Monitor	1 pc	
Monitor cable (HDMI-DVI)	1 pc	
Power cable	1 pc	
Power adapter (Type: HPU63A-106, manufacturer:Sinpro Electronics Co.,Ltd)	1 pc	
D-SUB9 cable	1 pc	
Remote cable	1 pc	
SDI cable	1 pc	

HDMI cable	1 pc	
Endoscope connection cable A	1pc	
Endoscope connection cable B	1pc	
User's manual	1 pc	
Multilingual User's Manual（CD）(optional)	1 pc	
Reset pin	1 pc	
U Disk (optional)	1 pc	

4.2. Structure and Function



No.	Part	Menu Functions
1	Display	Displays the image after the endoscope is connected; touch screen.
2	Power button	Press and hold to turn on the product, and press to turn off the product.
3	USB interface 3.0	Connect external devices, such as USB stick here.
4	Reset button	Insert a pin and press the reset button in the hole to restore to factory settings. *It is recommended to use a Ø 1mm and 10mm long pin.

5	Video endoscope interface (26-pin)	Insert the video endoscope cable here to connect the video endoscope to the product.
6	Video endoscope interface (14-pin for DVM-D1, 16-pin for DVM-D2)	Insert the video endoscope cable here to connect the video endoscope to the product.
7	HDMI interface	Connect an external high-definition monitor for display expansion here.
8	Remote interface	Connect to a digital video recorder or digital filing system to control the recording of images and videos
9	D-SUB9 interface	Connect to a digital video recorder digital filing system to control the recording of images and videos
10	Stand 1	Supports the product on a plane surface or auxiliary handling.
11	SDI interface	Connect an external high-definition monitor for display expansion here.
12	RJ45 interface	Connect the Local Area Network via network cable here.
13	Power socket	Receives 15 VDC input, and provides the power supply for the entire system.
14	Stand 2	Supports the product on a plane surface or auxiliary handling.

5. Preparation and Operation

When using the product for the first time, please refer to this User Manual and install the product according to the following steps.

Warning

- Do not let the power cable become wet; otherwise, electric shock may be caused.
- Do not prepare, inspect or use the product with wet hands.
- Do not bend, pull or twist the power cable; otherwise, electric shock, equipment damage or fire may be caused.
- The product can be operated only according to the requirements given in "Operating Environment", "Storage and Transportation Environment" of Chapter 9. Technical Specification; Otherwise, malfunction, impaired safety and/or equipment damage may be caused.
- Do not place any equipment on top of the product; otherwise, the product may be damaged.
- Do not install the product near any strong electromagnetic radiation source (e.g. microwave therapy equipment, shortwave therapy equipment, and MRI); otherwise, the product may malfunction.
- Before each procedure, inspect the Digital Video Monitor as instructed below. Inspect other equipment to be used with this Digital Video Monitor as instructed in their respective instruction manuals. If any irregularity is observed, do not use the Digital Video Monitor.

⚠ ***Caution***

- Do not use any sharp object to operate the touch screen of the product; otherwise, the screen may be damaged.
- Never apply excessive force to the connector; otherwise, the product may be damaged.

5.1. Preparation and Inspection

⚠ ***Warning***

- To power supply problems, a power supply with medical certification specified in the manual is required. When the power supply needs to be connected, only the type and manufacturer as stated in the packing list is allowed. Otherwise, operator or patient injury may occur.
- To avoid the risk of electric shock, only the appropriate approved medical electrical equipment are allowed to be connected to the product.
- The product can only be connected to a medical display screen that has been qualified as per IEC 60601-1.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Do not use the product in case of any damage to it or any unacceptable item in the functional inspection. Otherwise, operator/patient injury may occur.

1. Prepare Digital Video Monitor, power cable, power adapter, cables and device used together. Carefully check the product and all the components for damage (and wear). Never use the product in case of any damage.

2. Prepare and inspect the endoscope and other accompanying equipment according to their user manual.

5.2. Installing the Digital Video Monitor

⚠ ***Warning***

- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth. Electric shock and/or fire may be caused if the product is not properly grounded.
- All the system components shall be powered off before connecting them. Only appropriate cables can be used for the product; Otherwise, the product may be damaged or malfunction.
- Before connecting the endoscope to the Digital Video Monitor , ensure that the Digital Video Monitor is completely dry. Otherwise, it may cause electric shock or equipment damage.
- The equipment is installed on a VESA 75 standard rack. It is recommended to choose the screws

on the Vathin medical trolley or the recommended screws for installation. The recommended screw specifications are: screws with a maximum depth of 6mm

- Ensure sufficient power capacity and stable power supply before use. Severe fluctuations in power supply must be regulated using a power regulator or UPS power supply.
- If the loss of power leads to an unacceptable risk, the equipment should be connected to a suitable external power source.

⚠ ***Caution***

- Always place the power cable in a place where it is unlikely to be stepped on. Do not place any objects on the power cable.
- Do not install the device in a place where it is difficult to disconnect from the power supply.

Before using this product for the first time, please refer to the product manual and follow the steps below to install the product.

5.2.1 Open the stand of Digital Video Monitor and place it on a stable plane. Do not place the Digital Video Monitor in a place where it is difficult to operate the disconnection device from the mains.

If necessary, connect the supplied Wi-Fi /LAN antenna to the Digital Video Monitor. Go to Appendix 3. Cybersecurity and ensure that the use of the Digital Video Monitor's software and connectivity is aligned with your organization's policies.

5.2.2 Connect the power cable to the power adapter and connect the power adapter to the power port of the the Digital Video Monitor.

5.2.3 Connect the power cable to supply mains with protective earth. The power supply should be stable. In case of severe fluctuations in the power supply, a power regulator or UPS power supply should be used for adjustment purposes.

5.2.4 Connect the Digital Video Monitor to a medical display or digital video recorder or digital filing system as needed.The digital filing system is a digital video recorder or hospital image storage workstation (such as HIS, PACS system), which can be connected to the endoscopic image processor through HDMI cable, SDI cable, or HDMI to DVI cable.

5.2.5 Connect the endoscope to the Digital Video Monitor by inserting the endoscope connector into the endoscope socket properly as indicated by the arrow.

5.3. Switching On and Setup

⚠ ***Warning***

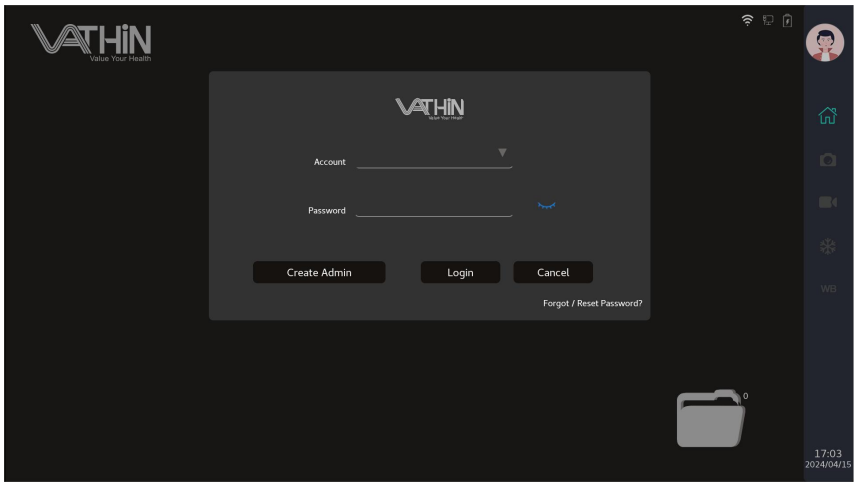
- When the device is turned on and the battery level is normal, the power switch indicator light is green; When the device battery level is low, the power switch indicator light turns orange.

- On the left side of the device's main interface, there is a battery level prompt message. When the battery level is low, please use the power adapter to power up in a timely manner to prevent the device from powering down during use.

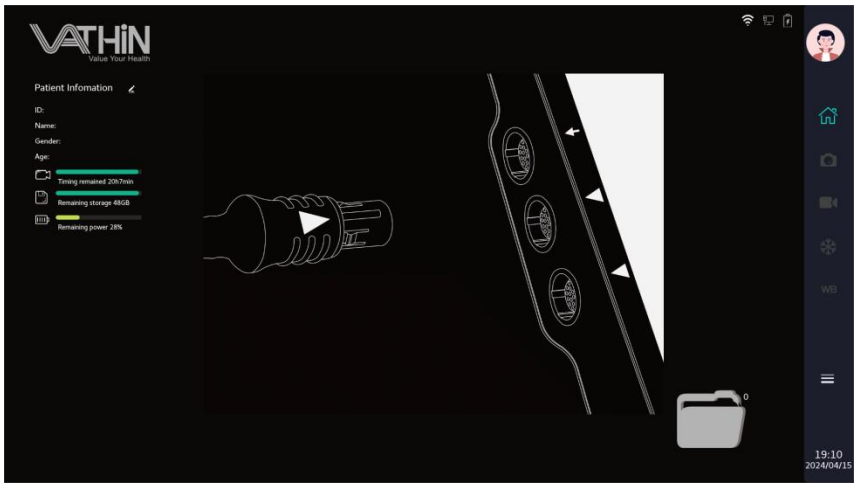
Note

- For access to some key functions your need to enter the user password. Initial user password of the product is vathin. Plear reset the user password during the firts login. Otherwise it may cause patient data leakage.
- If you forget your administrator account or password while using the Digital Video Monitor, please contact your local distributor or Vathin Medical for account and password initialization.
- In emergency situations, real-time images can be viewed without logging in, but other operations beyond previewing real-time images are not allowed.
- If an endoscope is not connected, the icons of photographing and recording on the screen are gray and unavailable.

5.3.1 Press and hold the power button to turn on the device. The system enters the login interface and clicks the "Cancel" button to enter tourist mode.



5.3.2 If the endoscope is not inserted, the screen will display the following animated image of endoscope insertion and removal, and the shortcut icons under the main interface will be grayed out and in an unusable state.

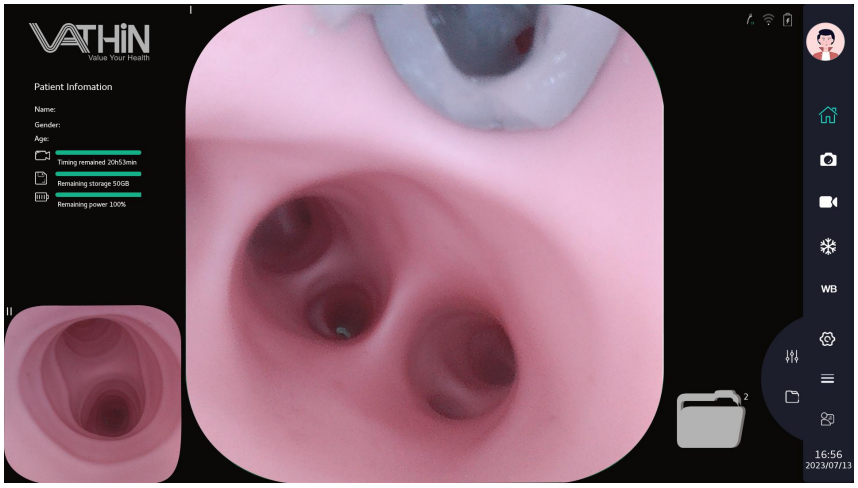


5.3.4 After logging into the account, the real-time image will be displayed. Icons on screen turn green and their functions are available.

5.3.5 If the Digital Video Monitor is functioning without connecting the power supply, check the battery level of the equipment, and charge it when the battery is low.

5.3.6 Set the image parameters of the Digital Video Monitor according to Chapter 6.4 image parameter adjustment interface.

5.3.7 Set the parameters of the Digital Video Monitor according to Chapter 6.5 System Settings Menu.



5.4. Inspecting the System

Warning

- If any irregularity is observed during inspection, do not use the Digital Video Monitor. Damage or irregularity may compromise patient or user safety and may result in more severe equipment damage.

⚠ ***Caution***

- Before each use or after changing settings, check to ensure that the image observed through the endoscope is a real-time image and that the image orientation is correct.
- This product supports dual endoscope image display. Before use, check and confirm that the observed image is the current captured image of the endoscope.

5.4.1. Inspect the basic functions of the equipment, including photo capture, recording, freezing, and manual white balance functions. Please refer to Chapter 6.2.1 for photo capture,Chapter 6.2.2 for recording, Chapter 6.2.3 for freezing, and Chapter 6.2.4 for manual white balance operation.

5.4.2. Inspect the endoscope function according to the instruction for use of the endoscope.

5.4.3. Before each use, check to ensure the view observed through the display provided a live image, has the correct image orientation, and is the image collected by the corresponding endoscope.

5.5. Operating the Digital Video Monitor

⚠ ***Warning***

- When advancing or withdrawing a Vathin endoscope, always watch real-time image of the corresponding endoscope on the monitor.
- This device supports dual endoscope image display. When displaying dual endoscope images, the image in the lower left corner of the screen is for reference only and should not be used for clinical diagnosis and treatment, otherwise it may cause damage to the patient.

5.5.1 Enter patient information: Enter patient information according to Chapter 6.3.

5.5.2 Adjust the white balance: Adjust the white balance according to Chapter 6.2.4.

5.5.3 Perform examination: related function of the Digital Video Monitor please refer to Chapter 6 Function.

5.5.4 Case record report: Manage case reports according to 6.3 as needed.

5.6. After Use

5.6.1 Disconnect the Vathin endoscope from the product. For information on how to dispose of the Vathin endoscope, refer to its user manual.

5.6.2 Press the power button to turn off the product. Remove the mains plug from the wall outlet to disconnect Digital Video Monitor from mains. Disconnect the accessories from the Digital Video Monitor.

5.6.3 Clean and disinfect the product according to Chapter 7 Cleaning and Disinfection.

6. Menu Functions

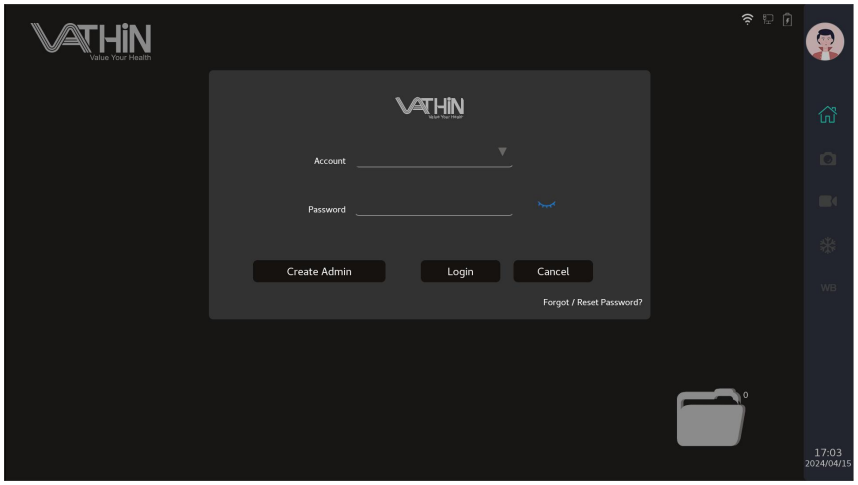
Note

- This product sets up user account management and authority management, and related functions are only open to users with authority. This product manual does not describe the authority of each user, and the authority of each user is subject to the actual authority provided by this product.
- Each device can only have one administrator account set up,Administrator account has more permissions
- Changing the administrator password requires super administrator privileges. Please keep your account password safe

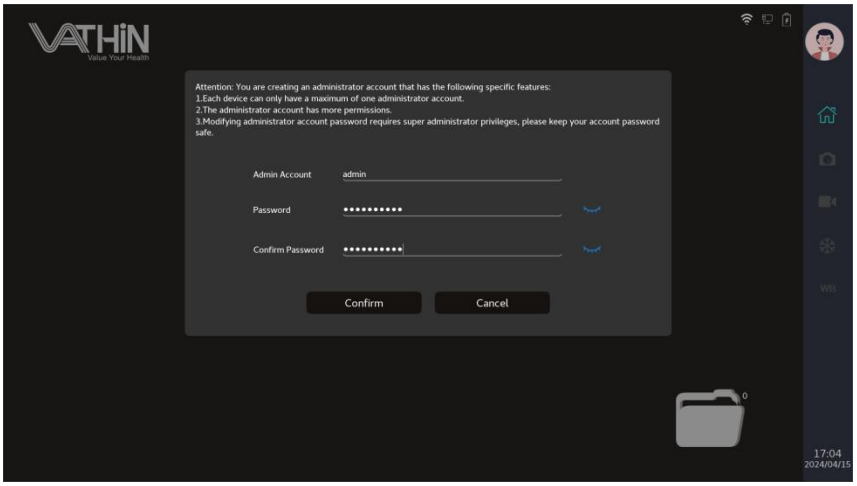
6.1. Login interface

6.1.1 When using this device, clicking the cancel button or the blank area around the login interface allows you to enter tourist mode and perform basic image viewing functions, but you cannot make any modifications to the settings information

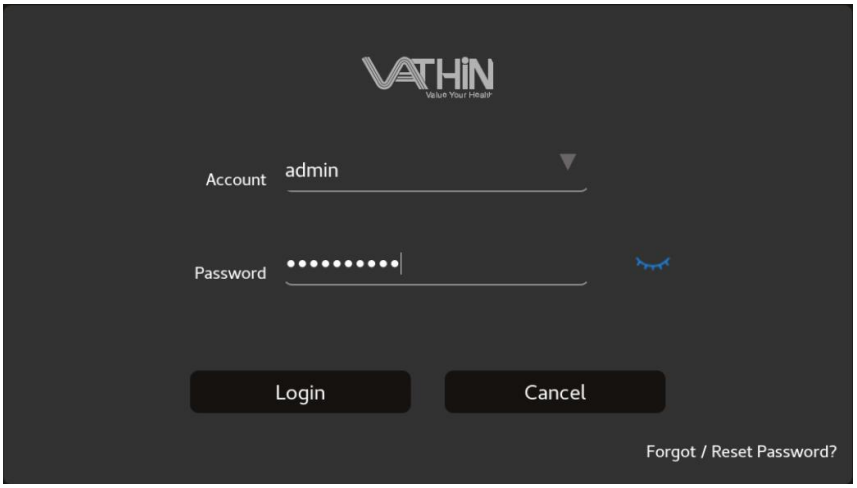
6.1.2 When using this device for the first time, click the button “create administrator” to enter the administrator creation interface, enter an administrator account and set a password, and click confirm to complete the creation.The password must contain special characters.



6.1.3 After creating an administrator account, the device automatically returns to the login interface and logs in using the created administrator account and password



6.1.4 When using this device not for the first time, there is no need to create an administrator button. Simply enter the administrator account password to access the administrator account.



6.1.5 User type specification

User / Privilege	Non-account user	Administrator	Common user	Maintenance personnel
Real-time image	Y	Y	Y	N
Photo/Video	Y	Y	Y	N
Storage file browsing	N	Y	Y	N
Image parameter adjustment	N	Y	Y	N
Storage file export	N	Y	Y	Y
Setting	N	Y	Y	N
A common user was created or deleted	N	Y	N	N
Change the	N	Y	Y	Y

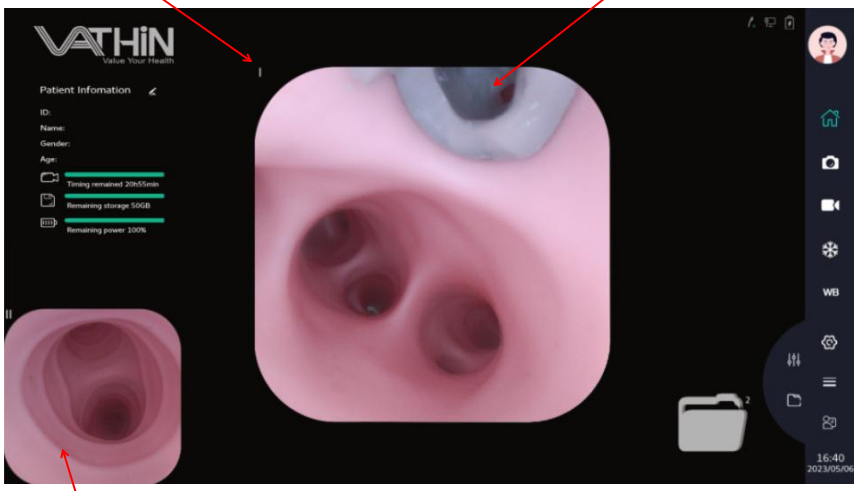
password of this account				
Clear data	N	Y	N	N
Upgrade	N	N	N	Y
factory reset	N	N	N	Y
*The administrator can restore the password of a common account *A common user can only operate files created by this account, and cannot operate files created by other users at the same level or by advanced users				

6.2. Basic Function Menu

This device supports dual endoscope image display. When multiple endoscopes are connected, the display displays images acquired by two endoscopes connected from top to bottom by default.

The number of the interface connecting the endoscope

The central image display area can be zoomed in or out with two fingers



Single endoscope connection: image/video preview area
Dual /multi endoscope connection: the area of image. single finger movement of this area to the center image area can achieve position exchange between the center image and the bottom left

Description of basic function icons

Icon	Name	Function	Reference section
	Basic functions	Icon for the Basic Functions menu.	/
	Photo capture	Tap this button or the Vathin endoscope camera button to capture the image.	6.2.1

	Video Recording	Tap this button to start recording a video. Tap it again to stop recording	6.2.2
	Freezing	Tap this button to freeze the center image.	6.2.3
	White Balance	Tap this button to perform a manual white balance operation on the center image.	6.2.4
	Quick preview icon	Tap to call up the quick preview interface to preview the currently taken image.	/
	Image sending icon	Tap to send the selected preview image to the Case Report .	
	Other interface menus	Tap to select the popup window, including the patient information icon, file management icon, image parameter adjustment icon, and system setting icon.	/
	Patient Data	Tap to enter the Patient Data menu.	6.3
	File Management	Icon for the File Management menu.	6.4
	Image parameter adjustment icon	Tap to enter the image parameter adjustment interface, and you can adjust the image parameters such as red / green / blue monochrome color bias, gamma curve, contrast and sharpness. Select department image modes, adjust parameters, and save modes.	6.5
	System Settings	Icon for the System Settings menu.	6.6
	U disk connection status indication icon	Indicates the U disk insertion status, and it appears when the U disk is inserted.	/
	Endoscope Connection	Indicates endoscope connection/disconnection and endoscope insertion status.	/
	WiFi	Indicates WiFi connection/disconnection.	/
	Eithernet connection status indication icon	Indicates the connection state of the wired network.	/
	Battery icon	Indicates the battery base status.	/
	Battery charging icon	After inserting the adapter for charging, the charging symbol appears on the battery power icon in the upper right corner of the display screen.	/
	The remaining recording time indicates the icon	This icon and status bar reflect the remaining time.	/

	Memory	Indicates the available memory. A prompt will be displayed in case of insufficient memory.	/
	Battery Capacity	Indicates the remaining battery capacity.	/

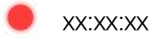
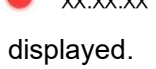
6.2.1. Photo Capturing

1. There are two methods to take photos.
   * Press the photo button on the endoscope
   * Tap icon on the screen.
2. When taking photos, the icon turn to . The photo has been taken when the icon will return to its original state.
3. After taking a photo, the quick preview icon displays the current number of photos after the photo is added.

Note

- Keep the Vathin endoscope as still as possible to prevent obscure images during photo capture.

6.2.2. Video Recording

1. Tap icon to start recording. The icon will turn to ,  will appear in the lower right corner of the screen to indicate the recording time. Tap icon again to end the video recording and  will disappear. The video has been taken when "Video saved successfully" is displayed.

When a single endoscope is attached, a thumbnail image of the captured video is displayed in the lower left corner of the monitor when the recording is complete. If multiple endoscopes are inserted at the same time, the center image and the bottom left corner image can be recorded simultaneously and there is no thumbnail image displayed in the bottom left corner of the display after recording..

6.2.3. Image freezing

Tap icon , the icon will trun to . The center image will be frozen, and zoomed out to the bottom left corner of the screen for real-time display. Tap icon again to end the freezing operation, the icon will return to its original state, and the center image will become a real display..

6.2.4. White Balance Adjustment

This adjustment procedure is used to display the correct image color on the monitor. Be sure to always adjust the white balance in the following cases:

* Before observation.

*After exchanging the endoscope

*When restarting the Digital Video Monitor

*When any abnormality can be seen in the color of the image even if white balance adjustment has been completed.

> ***Warning***
>
> - When adjusting the white balance of the endoscope, use a white object such as a piece of gauze without bringing it in contact with the endoscope. Contact of the endoscope with a non-sterilized object may result in cross-contamination.

> ***Caution***
>
> - When adjusting the white balance, make sure the light built in the distal end is on and take care not to expose the distal end of the endoscope to external light. Otherwise, it may cause an incorrect white balance adjustment.
> - When performing white balance, please ensure that the endoscopic image that requires white balance is the central image. This device can only perform white balance processing on the central image.

1) The adjustment procedure is used to display the correct image color on the monitor. Be sure to always adjust the white balance before observation or when any abnormality can be seen on the color of the image even if white balance adjustment has been completed.

2) Hold the endoscope stable to avoid wash-out of the monitor image, monitoring a white object such as a piece of gauze in such a way that it does not contact the endoscope; contact of the endoscope with a non-sterilized object may result in cross-contamination. Vathin Medical does not provide any accessories (e.g. white cap) for white balance.

3) Maintaining the stable condition in step 1, tap the icon WB on the screen. Icon WB will turn to WB. When the icon WB return to WB, the prompt "White balance successful" will be displayed in the bottom right corner of the screen.

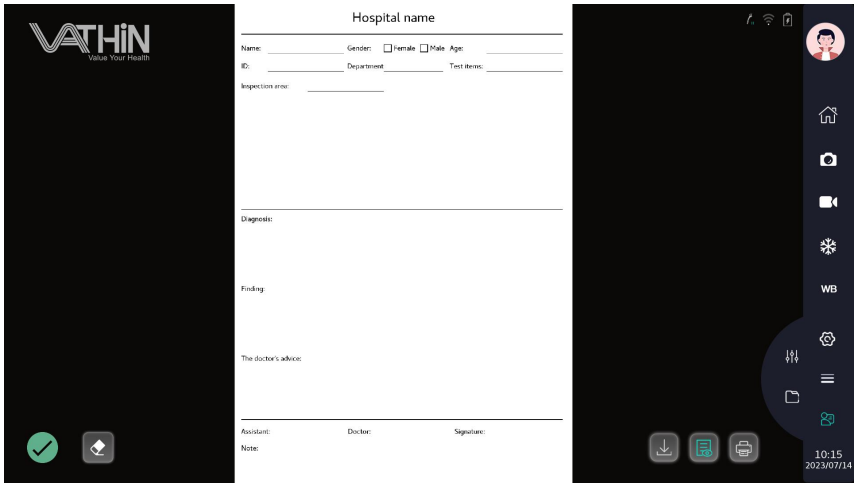
6.2.5. REMOTE function

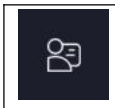
1) Connect D-SUB9 cable or REMOTE cable according to related digital video recorder and Digital Video Monitor.Preparation work can also refer to Chapter 5.2.4.

2) Press the button on the endoscope handle to complete the REMOTE function, control the recording of videos and images.

6.3. Patient Information Menu

Tap icon to enter the Patient Information Menu to edit patient information and management medical record report.

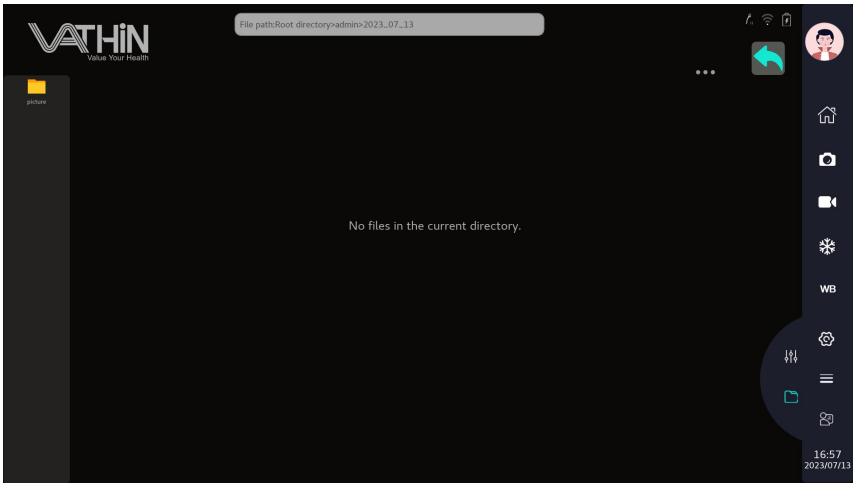


 **Description of Patient Information Menu**			
Icon	**Name**	**Function**	**Reference section**
	Clearing	Tap to clear the input content	/
	Confirmation	Tap to confirm input	/
	Downloading	Tap to save the Case Report to the Document Management System	/
	Previewing	Tap to preview the case report	/
	Printing	After connecting the PC printer, tap to print the case report	/

6.4. File Management Menu

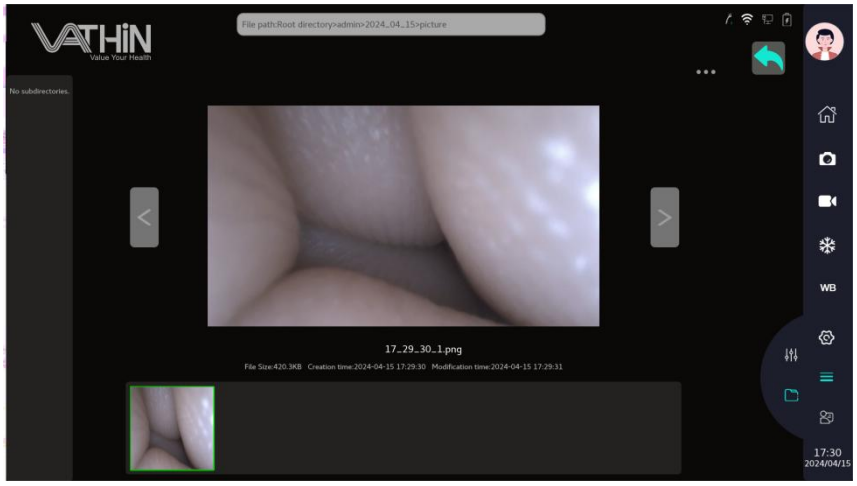
6.4.1. File Management Menu

Tap icon to enter the file management menu.



6.4.2. Playback Photos/Videos

In the File management menu, tap the icon to open the intended folder. Tap the corresponding image/video for playback. viewing patient report forms.

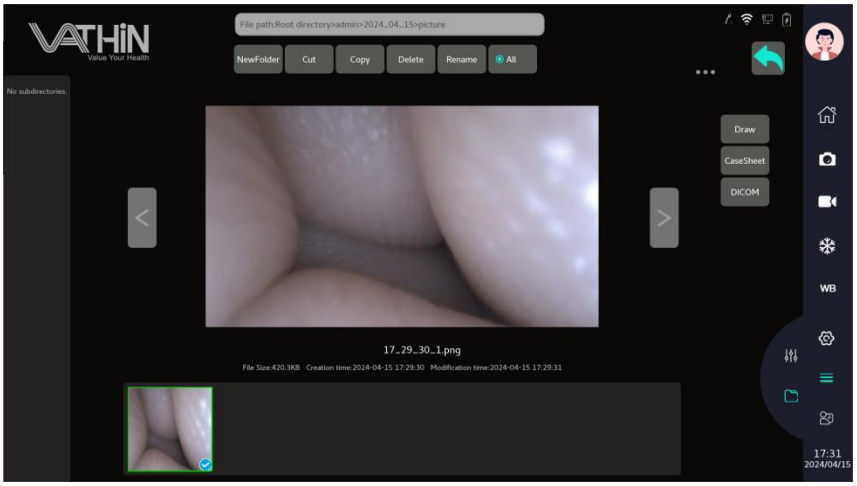


Note

- The captured images/videos are stored separately based on user name, capturing date, and patient ID.
- If a patient ID is set, the file storage path is: /username/patient ID/shooting time/picture (video). If the patient ID is not set, the file storage path is: /username/shooting time/picture (video).
- The captured images are stored in PNG format, and the videos are stored in MP4 format.

6.4.3. File edit

After selecting a file, tap the icon ••• to enter the file editing menu to copy, clip, rename, delete the file.

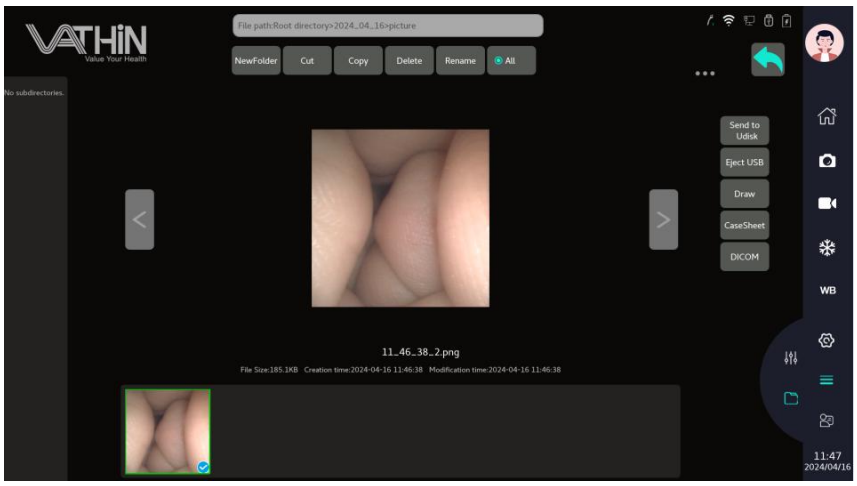


6.4.4. Exporting files

Before you export files, ensure that connection to the PACS server has been set up or USB flash drive connected to the Digital Video Monitor.

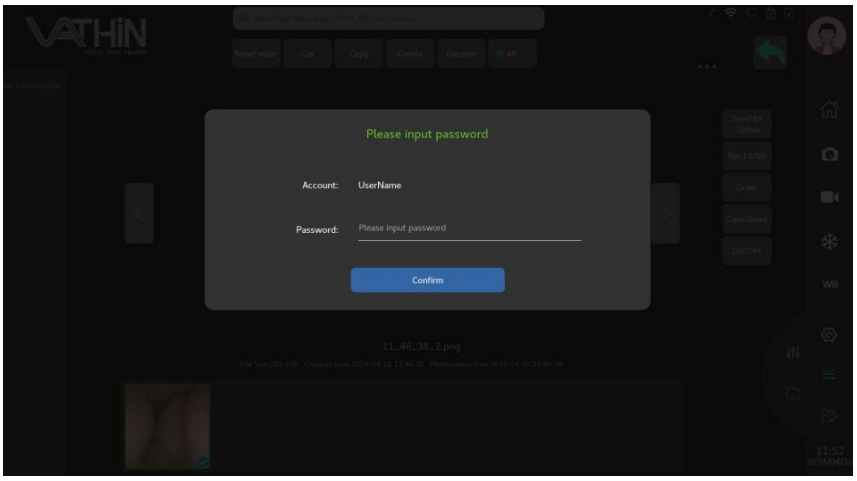
Select files for export:

- Press and hold a file or folder to enter selection mode
- Click on the desired files in turn or click Select all



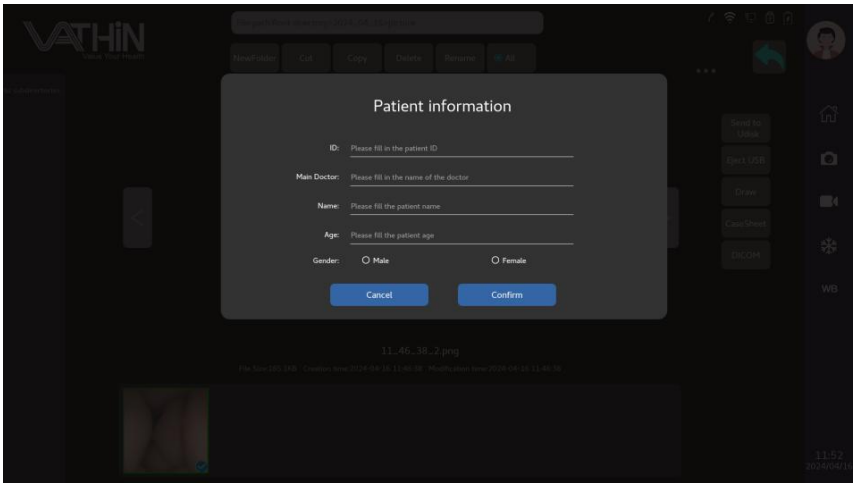
Export to USB flash drive:

After selecting the image or video, click the "Send to Udisk" button, enter your account password, and the transfer progress bar will be displayed until the transfer is completed.



Export to PACS:

After selecting a picture or video, click the "DICOM" button, input patient ID, name of attending physician, patient name, patient age, patient gender, and tap the confirmation button. Then wait for the file transfer to complete.



Warning

- Users are not recommended to use USB to import and export data.
- Before using the USB to import and export data, you need to check whether the USB is infected with viruses, and you need to keep the USB properly

Note:

- Please complete the DICOM setting first and test the network link successfully before transferring DICOM files.
- Only DICOM format can be used for export to PACS server. See table below for more information about file formats.
- Always check if the entered patient data is correct before exporting to PACS.
- Protected Health Information (PHI) will be saved on the local storage of the digital video monitor until the files are deleted, either manually or with auto delete function. Notice access to PHI requires logging in.
- Always use a secure network when exporting files from the digital video monitor.
- A stable network connection (Wi-Fi or LAN) is required when exporting photos and videos to a PACS server. If a network error occurs while exporting, the export will be cancelled.
- You can choose to export files to a USB flash drive instead or wait until the connection has reestablished before exporting to the PACS server.

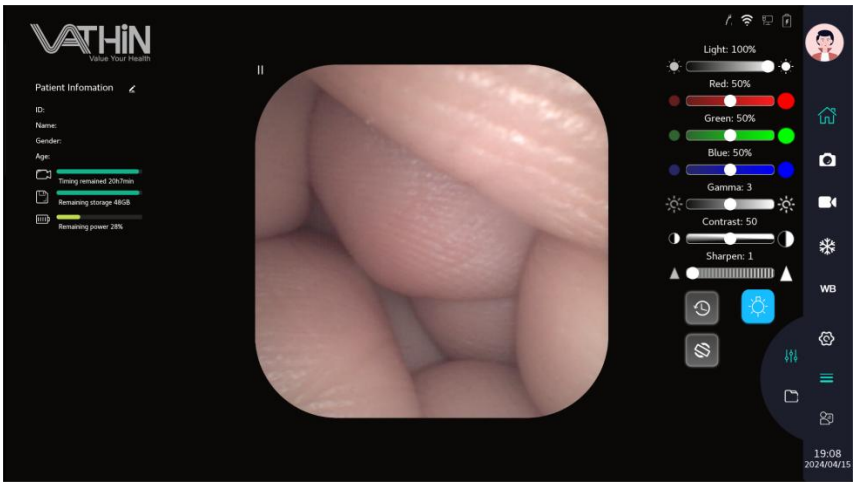
Note:

- It is recommended to perform regular backup of the digital video monitor by exporting files to a PACS server or USB flash drive. Protected Health Information (PHI) is stored with password protection in the digital video monitor's memory and is not deleted from the digital video monitor by exporting files. To delete PHI from the digital video monitor, the files must be deleted from the digital video monitor, either manually or using the auto-delete function.
- Transferring imagery requires that the digital video monitor is connected to the network via Wi-Fi or LAN/Ethernet cable.

6.5. Image Parameter Adjustment

6.5.1 Image parameter adjustment

Tap the icon to enter the image parameter adjustment menu to adjust image parameters such as red saturation, green saturation, blue saturation, gamma, contrast, brightness and sharpness.



6.5.2 Image parameter reset

In the parameter adjustment menu, tap the icon to reset the image parameters to their initial state.

6.5.3 Image rotation

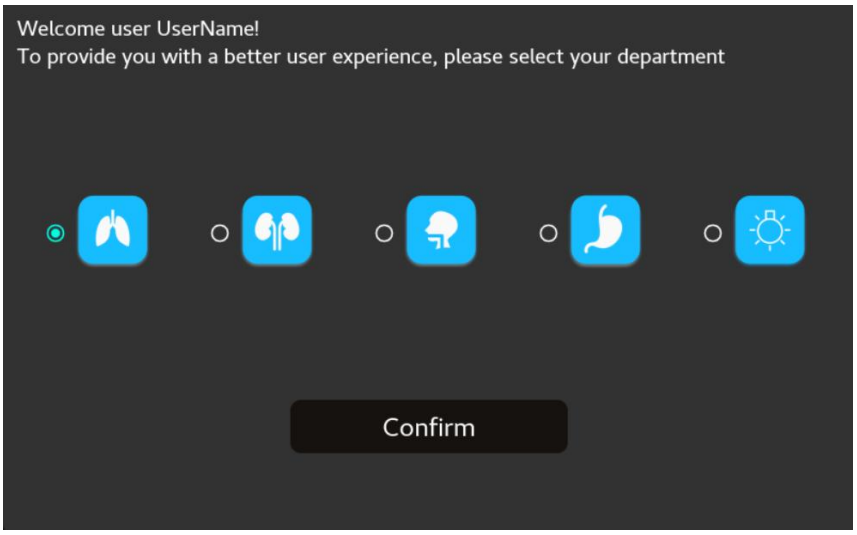
Tap the icon to rotate the image interface 180 °.

6.5.4 Image mode selection

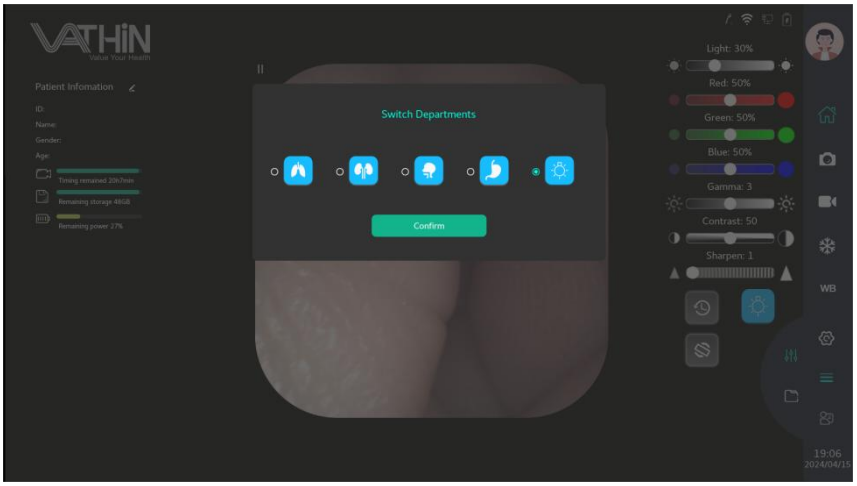
Image mode switching function, corresponding to respiratory, urology, nasopharyngeal, digestive, and a custom department.

Click the corresponding button to switch modes. You can adjust the image parameters such as red/green/blue monochromatic color deviation, gamma curve, contrast, and sharpness. Each department's image parameters will be recorded and saved separately, making it convenient for users to switch image modes.

The image mode parameter information is bound to the user. When setting the account for a regular account for the first time, a pop-up window for image mode selection will appear.

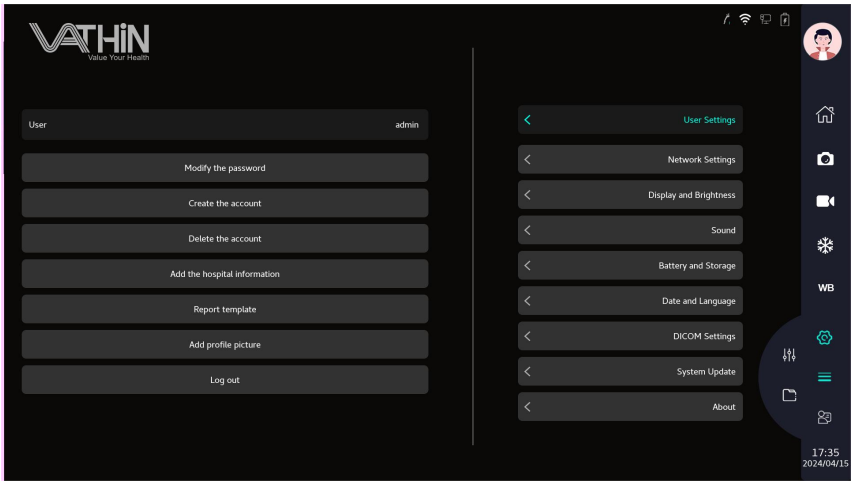


In the image mode parameter adjustment interface, image parameters can also be adjusted and saved.



6.6. System Settings Menu

Click the icon to enter the System Settings Menu for user settings, network settings, display and brightness settings, sound settings, time zone and language settings.



Description of System Settings Menu

Item	Name	Function	Reference section
1.	User settings	Tap to enter the user Settings interface for user management, including password modification, exit login and other permissions.	6.6.1
2.	Network Settings	Tap to enter the network settings interface for connecting wired networks and local area networks.	6.6.2
3.	Display and brightness	Tap to enter the display and brightness setting interface for screen brightness adjustment and image mask setting.	/
4.	Sound	Tap to enter the sound settings interface and set the speaker switch, speaker volume, microphone switch, and microphone gain for the host.	/
5.	Battery	Tap to enter the battery information viewing interface, where you can view battery information such as remaining power, temperature, and voltage.	/
6.	storage	Tap to enter the storage information viewing interface, where you can view the remaining memory of the host, all memory information, and the remaining storage information of the connected USB drive.	/
7.	Data and language	Tap to enter the time zone and language setting interface. You can choose to set the time automatically or manually, and set the language and time zone.	/
8.	DICOM Settings	Tap to configure the parameters of the DICOM server	6.6.3
9.	System update	Tap to enter the system update interface.	/
10.	About	Tap to enter the device information view and restore factory settings interface.	/

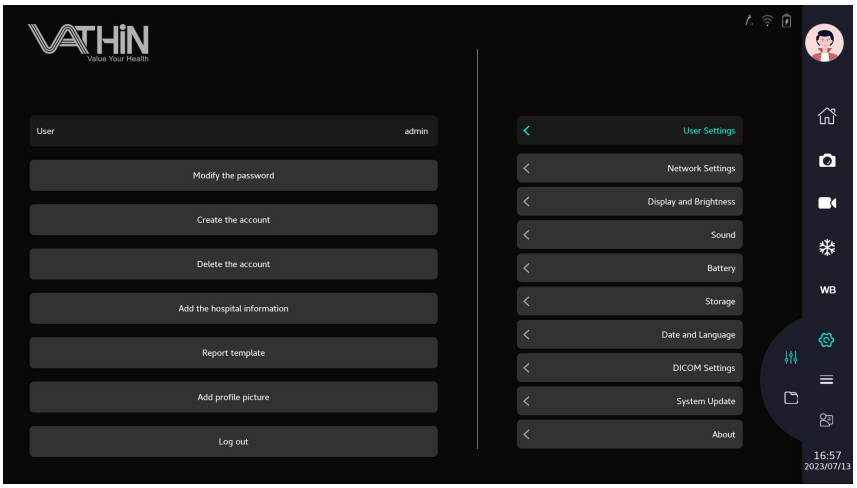
6.6.1. User Settings

Caution

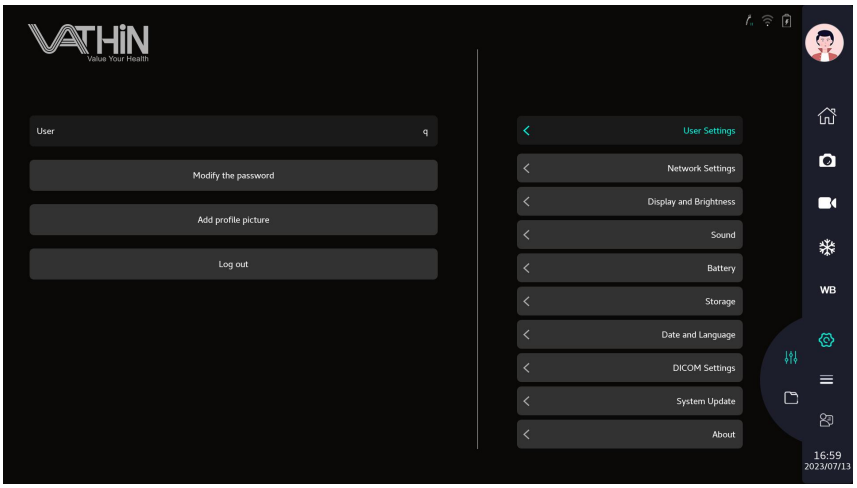
- Ordinary accounts do not have the authority to modify passwords,
- The password must contain numbers and uppercase and lowercase letters, and the length of the password must not be less than 8 digits.For related warnings and information about Wi-Fi please refer to Appendix 3. Information About Wi-Fi.
- Only the administrator account has the authority to create user accounts, delete user accounts and newly created user accounts are all regular accounts
- After deleting a user account, the account information cannot be restored
- Only the administrator account has the authority to add hospital information and modify report templates

The equipment has user settings function. Users can set relevant permission content as needed.

1) When the current user is an administrator, they have the authority to modify passwords, create users, delete users, add hospital information, modify report templates, add avatars, and log out.

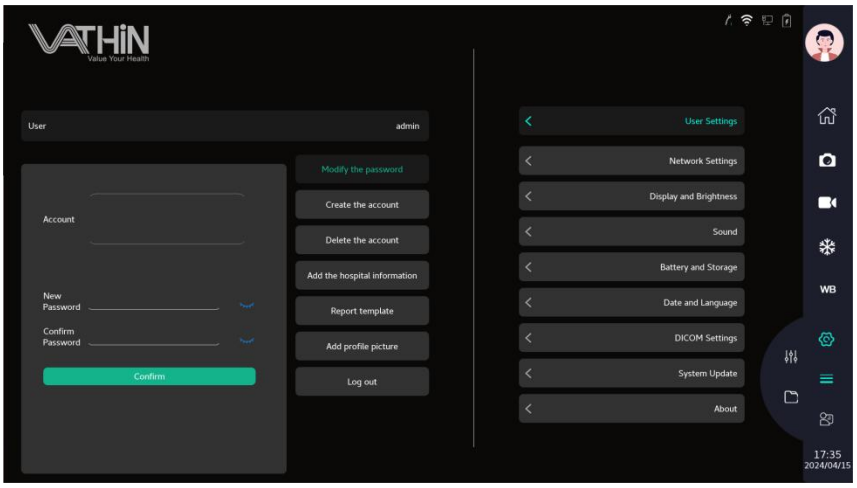


2) When the current login account is a regular user, it has the authority to modify password, add avatar, and log out.



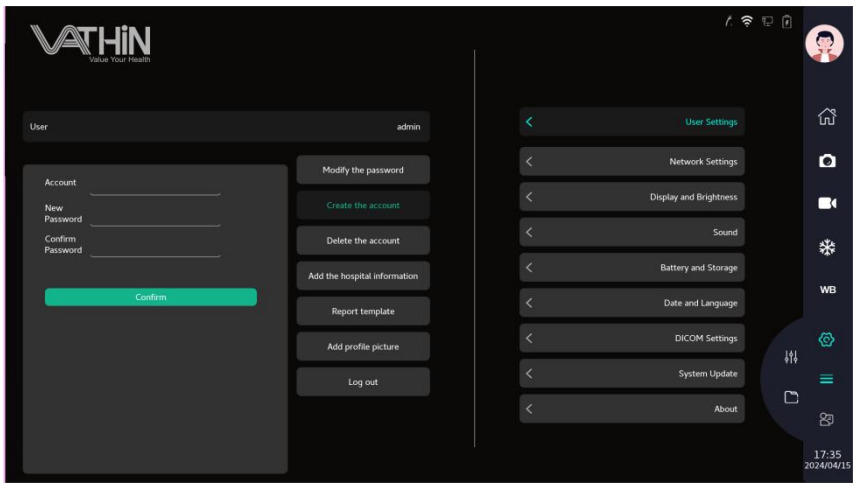
6.6.1.1 Modify password

In the administrator account, enter a new password, confirm the new password, click confirm to complete the password modification



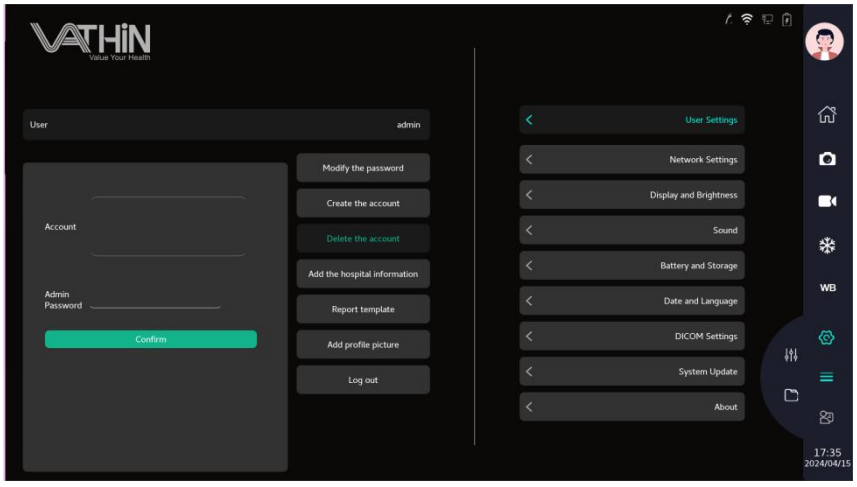
6.6.1.2 Create a user account

In the administrator account, select the account that needs to be modified, enter the new password, confirm the new password, and click confirm to complete the password modification.



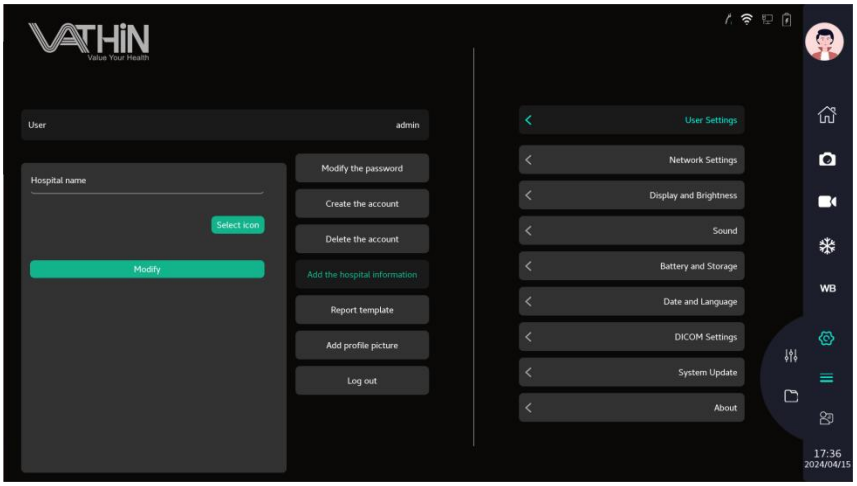
6.6.1.3 Delete a user account

In the administrator account, After selecting the account that needs to be deleted, enter the administrator password and click confirm to complete the deletion of the user account.



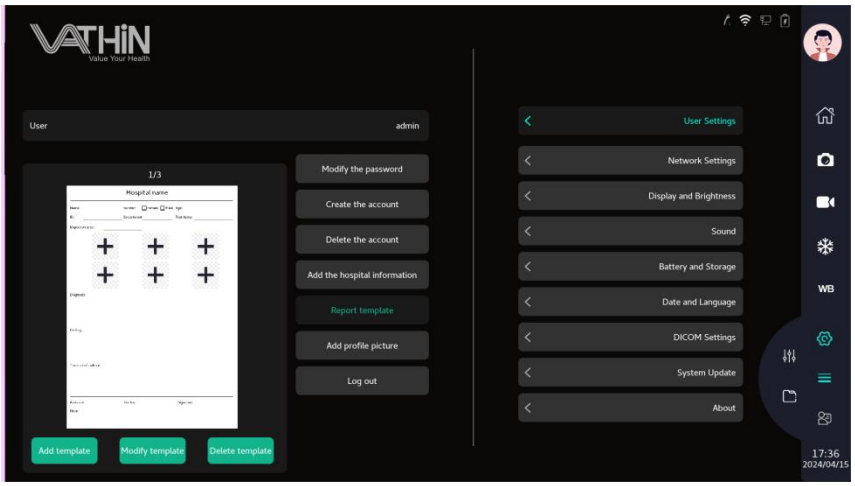
6.6.1.4 Add hospital information

In the user settings interface, modify the hospital name and icon, and click on modify to save the setting.



6.6.1.5 Report template

In the report template window, you can add, modify, and delete reports



6.6.1.6 Add avatar

Click the add avatar button to select the avatar icon and modify the current user's avatar

6.6.1.7 Log out

Click the logout button to exit the current account and return to the login interface

6.6.2. Network Settings

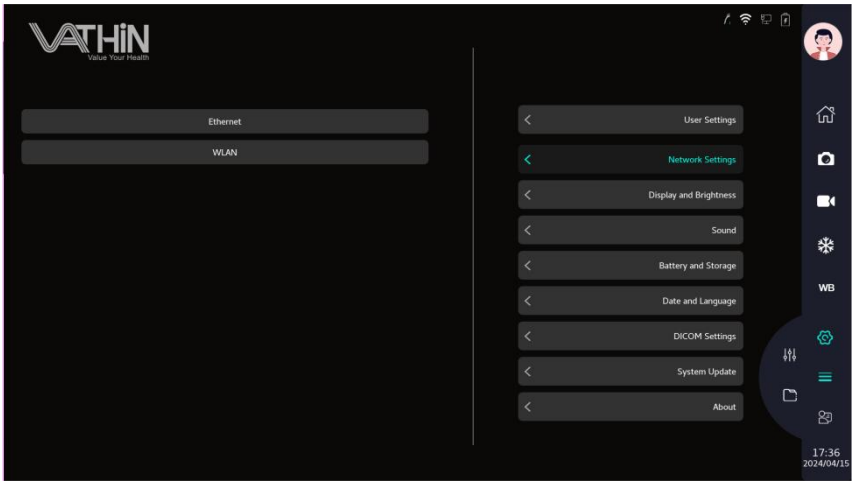
Warning

- It is prohibited to connect to unsafe WIFI access nodes, and it is prohibited to access public WIFI.

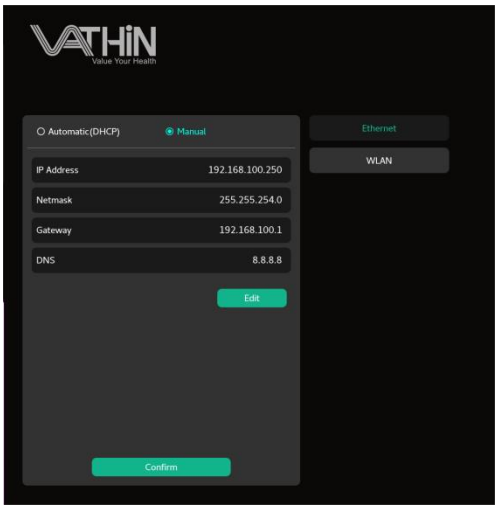
Caution

- Turn on the operating system firewall function of the workstation computer.
- When connecting to a network, make sure that the device is connected to a private Local Area Network and that the private network is secure. Reliability of the network needs to be confirmed when network settings are updated. An unreliable network will cause a certain risk of data loss or function failure of the device.
- For related warnings and information about Wi-Fi please refer to Appendix 3. Information About Wi-Fi.

Under the system settings interface, click the network settings option to enter the network settings interface, where you can connect to wired and wireless networks.



When connecting to a wired network, plug the network cable into the RJ45 interface, select IPv4 automatic acquisition, or manually set the IP to connect to the wired network.

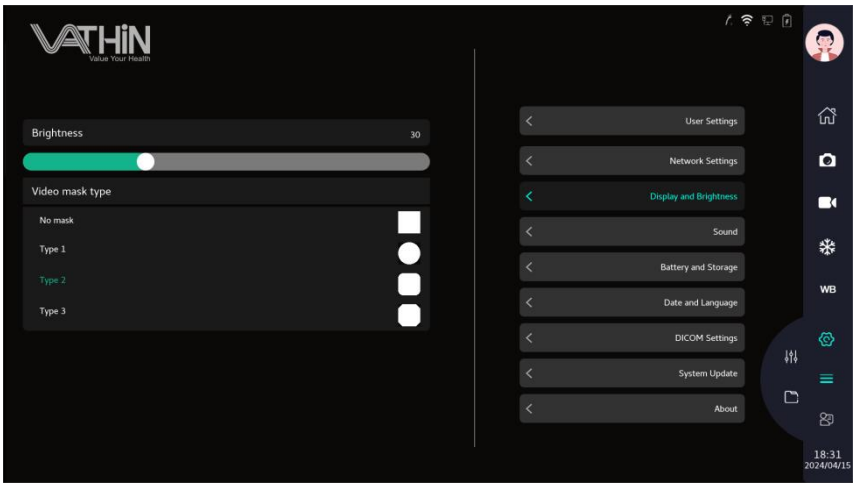


When connecting to a wireless network, start scanning the network, select the corresponding wireless network, and enter a password to connect to the network.

6.6.3. Display and brightness

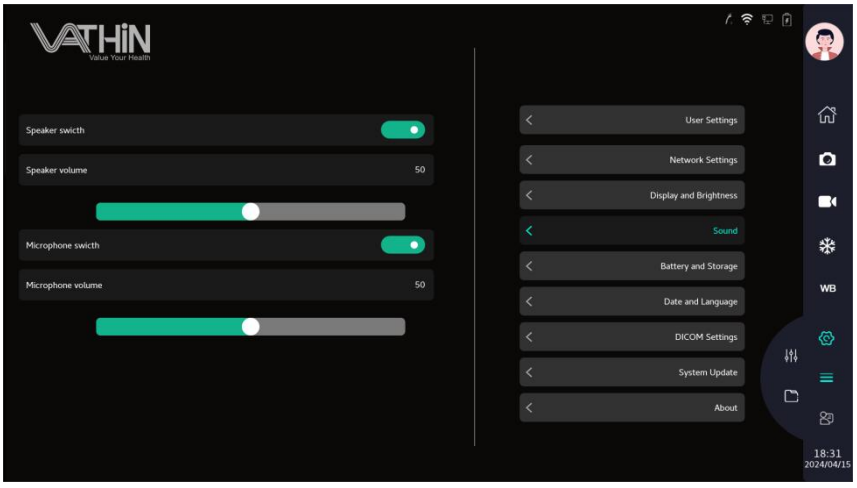
Under the system settings interface, click on the display and brightness options to enter the display and brightness settings interface.

Drag the slider to adjust the screen backlight brightness; Select a video mask type and adjust the image mask



6.6.4. Volume

Under the system settings interface, click on the sound settings option to enter the sound settings interface, where you can set the speaker and microphone



6.6.5. Battery and storage

Under the system settings interface, click on the battery and storage settings option to enter the battery and storage settings interface, where you can view the current device's battery and storage information

Battery: displays the percentage of battery charge;

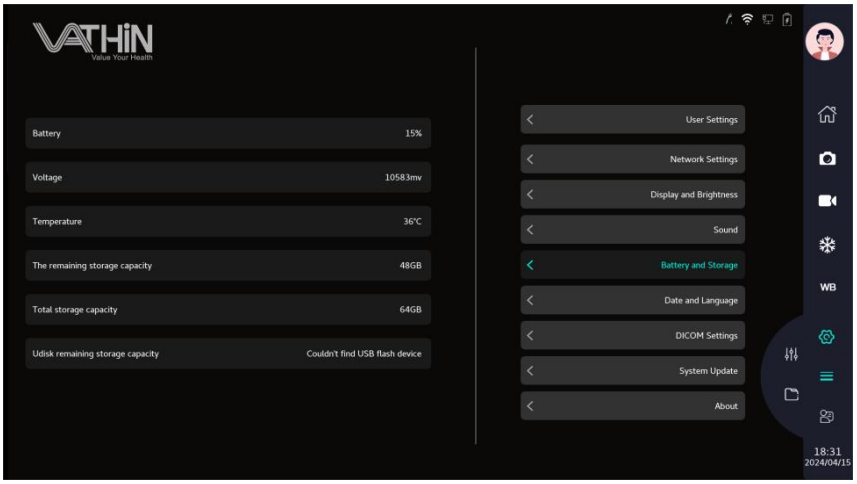
Voltage: Display the current voltage of the battery;

Temperature: Display the current battery temperature;

Remaining storage size: The remaining storage size of the device;

Total storage size: The total storage size of the device;

Remaining storage size of USB flash drive: The remaining storage size of USB flash drive. If no USB flash drive is inserted, it shows that no USB device has been found.



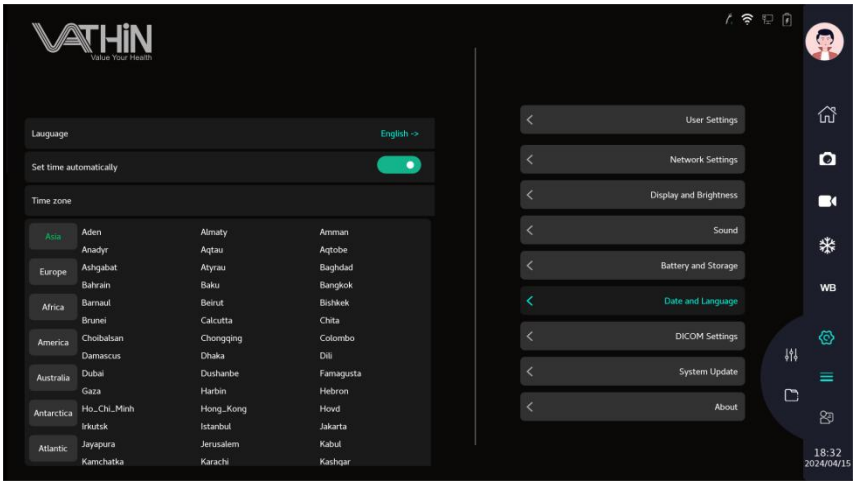
6.6.6. Time zone and language

Under the system settings interface, click on the Time Zone and Language Settings option to enter the Time Zone and Language Settings interface. You can select the current system language, system time, and time zone information

Language: After clicking, you can select the system language. After clicking on the corresponding language, the system switches to the corresponding language;

Automatic synchronization time: The automatic synchronization time function can be turned on/off. If the synchronization time function is activated, it will access the synchronization time service for time synchronization; If the synchronization time function is turned off, the current time can be manually entered for time setting;

Time zone: Select the time zone of the current region for time zone setting



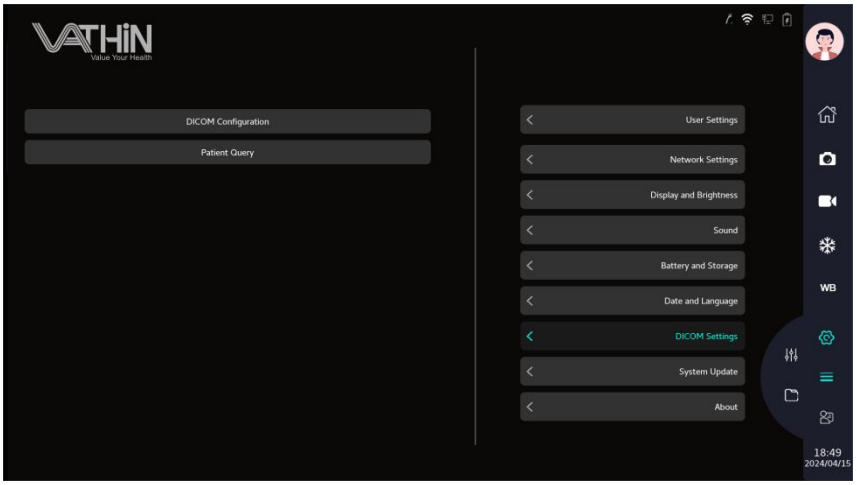
6.6.7. DICOM Settings

Warning:

- Please make sure that the network connection is normal before using the DICOM function.
- When connecting to a DICOM network, make sure that the device is connected to a private Local Area

Network and that the private network is secure. Otherwise, the files cannot be transferred.

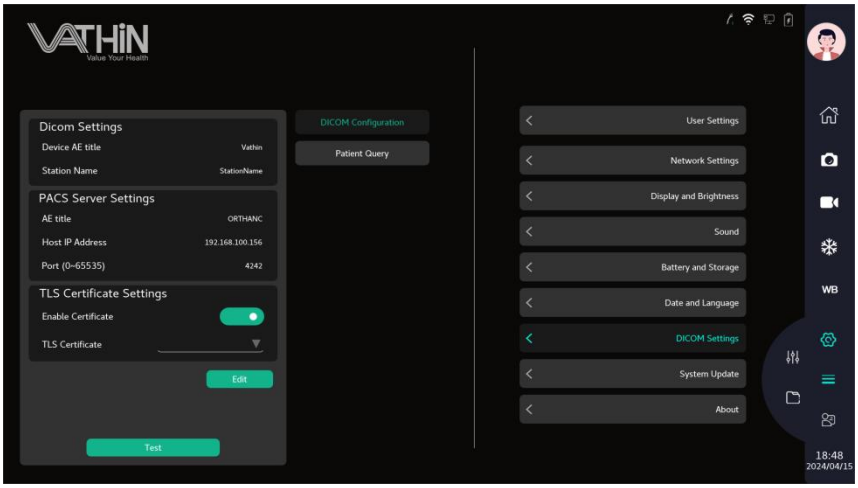
Under the system settings interface, click on the DICOM settings option to enter the DICOM settings interface, where you can configure DICOM services and query patient information



6.6.7.1 DICOM configuration

Configure DICOM sites and PACS servers to send images, recordings, and medical records from the host to the DICOM server through wired or wireless network connections, or query patient information from the PACS server.

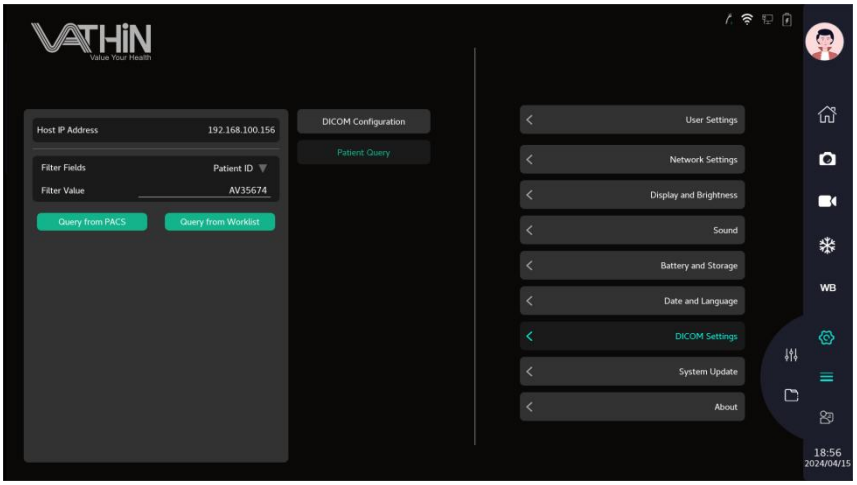
Information needed	**Explanation**
Dicom settings	configure the current device name and site name
PACS server settings	configure target PACS server information;
TLS certificate settings	Set TLS certificates, which can be obtained externally through a USB drive;
Edit	Modify current interface parameters
test	Attempting to connect to PACS server



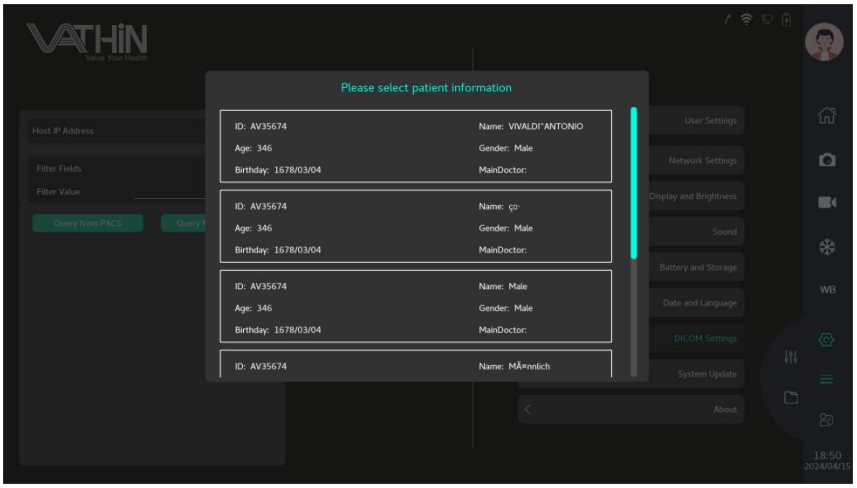
6.6.7.2 Patient inquiry

After connecting to the PACS server, patient information can be filtered and queried through keywords

Information needed	Explanation
Host address	Current PACS server address
Filter Fields	Set filter fields, providing three types of fields: patient number, patient name, and registration number;
Filter value	Set filter value

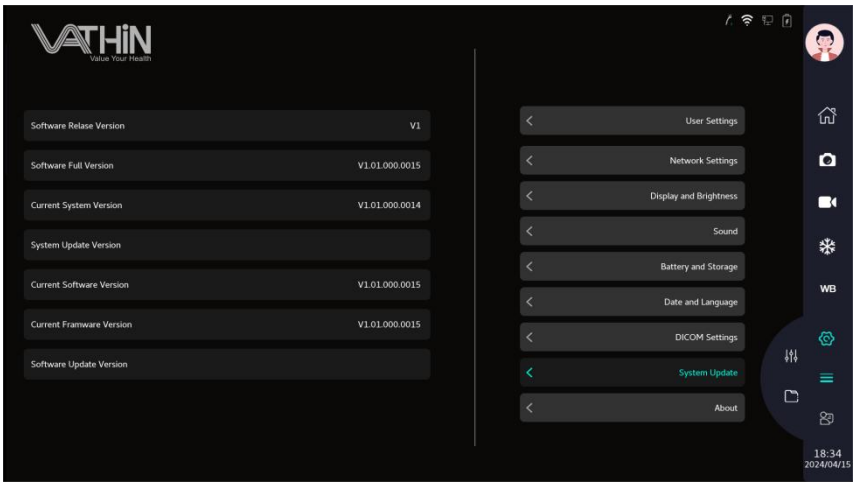


Click "Search from PACS" or "Search from Worklist" to search for patient information. After selecting patient information, double-click to update patient information to the main interface



6.7 System update

On the device information page, view information about the digital video monitor, such as software version, available disk space, etc.
Please contact your local sales agent or after sales for an upgrade



6.8. Reporting a problem

Please contact your local sales agent or after sales.

6.9 Clear data

If a digital video monitor is to be handled by a third party or needs to be disposed, it is advised to delete all sensitive data. Please follow your local guidelines for data protection. Only the Administrator can reset the data.
The data reset function will delete:

- All procedure folders with saved images and videos

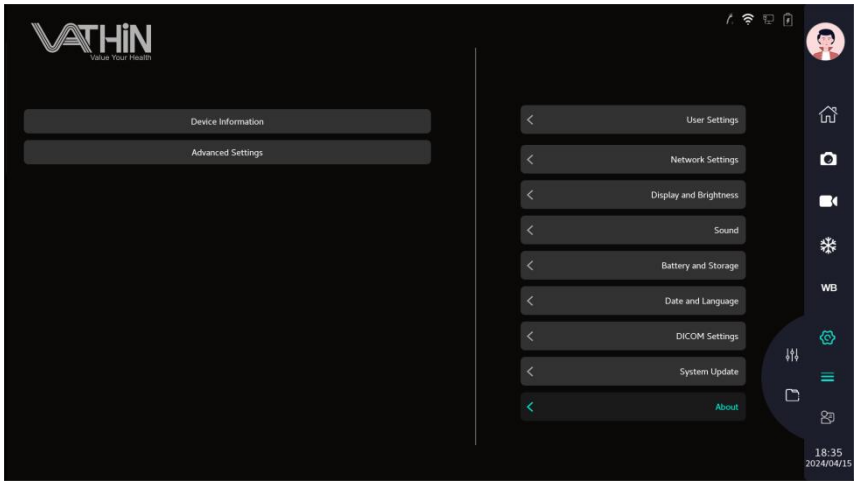
• **UserAdministrator** will be reset to default password.
• Wireless network settings
• DICOM, PACS server settings

Clear the data:

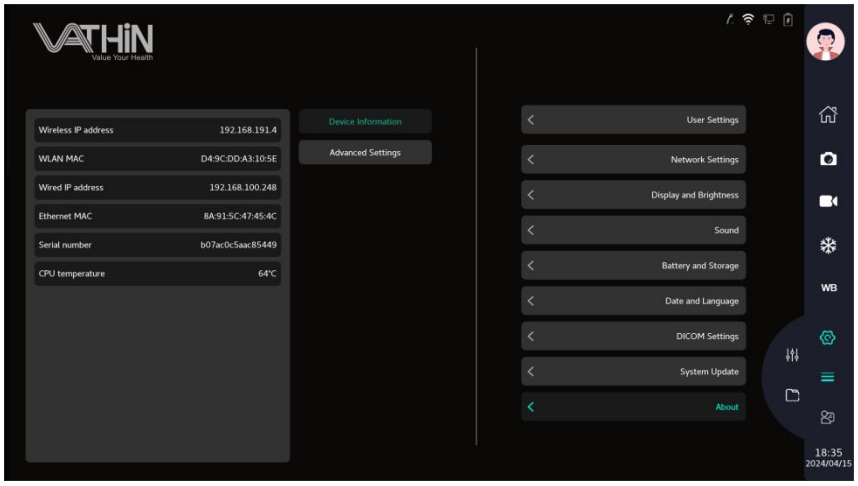
• Press the **Settings enter UserAdministrator password** and press **Continue**
• Press **Clear data** . A dialog box appears informing of the consequences and asking to confirm.
• Press **Confirm**,
• A dialog box appears informing that this operation may take a while, the operation can succeed or fail. If failed, please try again.

6.10 Device information

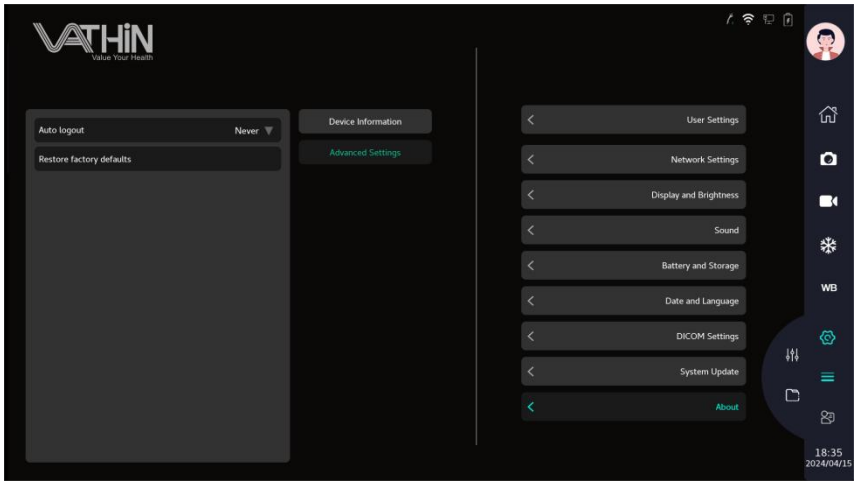
Under the system settings interface, click on the "About Local Settings" option to enter the system update settings interface, where you can view the current system version information



Device information: can view the current device's IP address, MAC address, serial number, and chip temperature information



Advanced settings: You can set the automatic logout time or perform appearance settings (regular accounts do not have advanced settings permissions)



7. Cleaning and Disinfection

The product should be cleaned and disinfected before and after each use. It is recommended to clean and disinfect the product according to the following instructions before and after use. Any deviations from the instructions shall be assessed properly to determine its effectiveness and potential adverse consequences to ensure that it continues to achieve its intended purpose.

> ***Warning***
>
> - Disconnect the Digital Video Monitor from any mains power supply, remove any accessories and make sure the Digital Video Monitor is completely turned off before cleaning and disinfection.

You should take the following steps to clean and disinfect the product according to good medical practices:

7.1. Cleaning

1. Recommended detergent: enzymatic, mild pH of 7–9, and low foam (Enzol or equivalent).
2. Prepare the cleaning solution by using the standard enzymatic detergent prepared according to the manufacturer's recommendations.
3. Dip the sterile gauze into the enzyme solution and ensure that the gauze is moist without dripping.
4. Use the wet gauze to thoroughly clean the buttons and housing of the product. Well protect the product from being wet to avoid damage to its internal electronic components.
4. Use a sterile soft brush dipped in enzyme solution to clean the buttons until all dirt is removed.
5. Wait 10 minutes (or the duration recommended by the detergent manufacturer) for the enzyme to be activated.

6. Use the sterile gauze dipped in RO/DI water to clean the product to ensure that all traces of detergent are removed.

7. Repeat Steps 1 to 7 until the Digital Video Monitor is clean.

7.2. Disinfection

1. Disinfection Solution: isopropanol (or alcohol) concentration 70–80%;

2. Preparation: add 80 cc of 95% isopropanol (or alcohol) to 20 cc of purified water (PURW) (or use the EPA registered medical disinfectant wet wipes containing at least 70% isopropanol; all the appropriate safety precautions and manufacturer's instructions must be followed).

3. Use a piece of sterile gauze dipped in the alcohol mixture described above to wipe the surface of the product for about 15 minutes (approximately once every 2 minutes). The isopropanol should be handled according to appropriate safety procedures. The gauze should be moist without dripping because any liquid may impair the electronics inside the product. Always pay close attention to the buttons, housing, slots and gaps on the product. Sterile cotton swabs should be used for the disinfection in these areas.

8. Maintenance and Disposal

8.1. Storage

After being cleaned and disinfected, the product must be subjected to the pre-inspection procedures described in Chapter 5. The product must be stored during the period between two operations according to local guidelines and the storage environment requirements in this manual.

8.2. Battery Maintenance

In order to extend the service life of the battery, it is recommended to fully charge the product at least once every three months. The battery can last over 6 hours. The temperature range during charging should be controlled within 10–35 °C.

If the battery needs to be replaced, never refit any accessory of the product at will, and instead, contact your local dealer or Vathin Medical.

8.3. Returning the Digital Video Monitor for Repair

Vathin Medical shall have the right to request the technical department or equivalent at the customer's site to repair the product under the proper guidance of Vathin Medical. Any defective Vathin Digital Video Monitor must be disposed of by the person authorized by Vathin Medical. Circuit diagrams, component part lists, descriptions, calibration instructions, or other information are available on request by authorized SERVICE PERSONNEL.

In order to prevent infection, it is strictly forbidden to transport contaminated medical equipment. The medical equipment must be disinfected on site before being shipped to Vathin medical. The cleaning

and disinfection procedures described in Chapter 7 must be followed. Vathin Medical reserves the right to return contaminated medical equipment to the sender.

8.4. Disposal

At the end of product life, clean and disinfect the Digital Video Monitor.

Before disposing of the Digital Video Monitor, it is advised to follow these steps to erase all data:

- Log in as Administrator.
- Delete all files stored in the digital video monitor from the Archive - Select all folders and press the bin .
- Delete Wi-Fi network and password though the Settings – Setup – Network setup menu.
- Delete DICOM network via the Settings – Setup – DICOM setup menu.
- Delete all Advanced Users from the Settings – User profiles menu.
- Then, dispose of the digital video monitor in accordance with local guidelines for electrical and electronic waste.

9. Technical Specification

9.1. Standard Applied

The Vathin® Digital Video Monitor meets the following standards:

- IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical Electrical Equipment Part 1-2 General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

9.2. Specification

Item	Specifications
Menu Functions	
White balance	Manual
Data record	Videos (MP4)/photos (png)
Memory	64G memory
Language setting	English/中文简体
Time setting	Manual/Internet-based self-calibration
Monitor	15.6"; 1920 ×1080; touchscreen
Video output mode	HDMI, SDI

Screen brightness	Manual adjustment
Wi-Fi	IEEE 802.11b/g/n/ac 2.4G,5G
LAN connection	IEEE 802.11 1000base-T
USB connection	USB3.0 A-type
Expected service life	5 years
Electrical power (Digital Video Monitor)	
Input Power	15V DC, 4.2A max
Internal battery	10.8V DC 9000mAh
Power adapter	
Power supply requirement	100–240 V AC; 47–63 Hz; 1.62–0.72 A
Output Power	15V DC, 4.2A max
Protection against electric shock	class I
Dimensions	
Length× width × thickness	382 mm × 238mm × 44.5mm
Weight	3000g
Storage and transportation	
Recommended storage temperature [°C, (°F)]	-20 °C to +40 °C (-4°F–104 °F)
Relative humidity [%]	10% to 80%
Atmospheric pressure [kPa]	50 kPa to 106 kPa
Operating environment	
Temperature [°C, (°F)]	+10 °C to +40 °C (50°F–104 °F)
Relative humidity [%]	30% to 80%
Atmospheric pressure [kPa]	80 kPa to 106 kPa

10. Troubleshooting

If there is a problem with the product, please refer to this chapter to determine the cause and solve it. If the problem still exists after troubleshooting, please contact your local dealer.

Many problems can be solved by restarting the digital video monitor through a Power OFF Cycle.

Power OFF Cycle
NOTE: Do not power off the digital video monitor during the software update/upgrade

download and installation process!

Restart the digital video monitor

1. Press and hold the power button until the shutdown dialog appears, then tap 'Confirm' in the dialog, and wait for the device to complete the shutdown. (**no light in power button**).

If the machine can not complete the normal shutdown.

1. Hold down the power for more than 6 seconds and wait for the display to turn off to force it to completely turn OFF.(no light in power button)
2. Press the power button again to turn the digital video monitor back ON.

Phenomenon	Possible cause	Recommended measures
The device cannot be turned on	The battery is low or the battery is protected	Connect the power adapter to charge the battery or wake up the protected battery, and then press the power button to start the Digital Video Monitor
No image	The device cannot recognize the medical endoscope	Replacement of disposable medical endoscope, if there is still no image, please contact the agent
HDMI/SDI cannot output normally	The monitor is not compatible, the monitor is not set correctly	Follow the steps below: Reconnect the device to the monitor and set up the monitor correctly Replace the monitor of another model If not, please contact your local dealer
Wi-Fi signal cannot be obtained.	Wi-Fi antenna cannot reach the Wi-Fi signal in the room.	Choose a new placement of the digital video monitor OR make sure that the external Wi-Fi antenna is connected and oriented optimally.

Appendix 1. Electromagnetic Compatibility

Essential Performance

The product is designed to provide images for observation, excluding short-term automatically recoverable reduction caused by electromagnetic interference.

The following cable information is given for EMC reference only.

Cable	Max. cable length Shielded/unshielded		Qty.	Category
AC power cable	1.8 m	Unshielded	1 set	AC power supply
Adapter cable	1.2 m	Unshielded	1 set	DC power supply
HMDI-DVI cable	2.8 m	Shielded	1 set	Signaling
SDI cable	2.8 m	Shielded	1 set	Signaling
Endoscope connection cable A	2m	Shielded	1 set	Signaling
Endoscope connection cable B	2m	Shielded	1 set	Signaling
HDMI cable	2.8 m	Shielded	1 set	Signaling
D-SUB9 cable	2m	Unshielded	1 set	Signaling
REMOTE cable	1.5m	Unshielded	1 set	Signaling

Important information on electromagnetic compatibility (EMC)

The product shall be subjected to special precautions regarding EMC, and the EMC information provided in its user's manual shall apply when using it. The product complies with IEC 60601-1-2:2020 in terms of immunity and emission. However, the following special considerations shall be observed:

The equipment with above-mentioned ESSENTIAL PERFORMANCE is intended used in Professional healthcare facility environment, except for any places that are near the RF shielding room of the ME system for magnetic resonance imaging (MRI) with high electromagnetic interference intensity.

Warning

- It is required to avoid using the product next to or stacked with other equipment; Otherwise, improper operation may be caused. If you have to do so, the product and other equipment should be observed carefully to verify that they can operate properly.
- The use of accessories, transducers or cables other than those specified or provided by the manufacturer of the product may increase electromagnetic radiation or reduce electromagnetic interference, and cause improper operation.
- When using any portable radio frequency communication equipment (including antenna cables, external antennas and other peripheral equipment), such equipment should be placed over 30 cm (12 inches) away from any part of the product, including the cables specified by the manufacturer; Otherwise, the performance of such equipment may be impaired.

Statement

- The product is designed compatible with the high-frequency surgical equipment, i.e. it is allowed to keep working or standby near the high-frequency surgical equipment.
- In case of interrupted AC input voltage, the product will shut down, and once the power supply is restored, it can be manually restored by the operator. The degradation in such case is acceptable because it will neither cause unacceptable risks nor impair basic safety or essential performance.
- The degradation due to electrostatic discharge or electrical fast transient/burst is acceptable because it will neither cause unacceptable risks nor impair basic safety or essential performance.
- The vertical-line flashing on the screen can automatically restore to the previous state.

EMI compliance

Table 1. Emission

Phenomenon	Compliance	Electromagnetic Environment
Radio frequency emission	CISPR 11 Group 1, Class A	Professional medical environment
Harmonic distortion	IEC 61000-3-2 Class A	Professional medical environment
Voltage fluctuation and flicker	IEC 61000-3-3 Compliance	Professional medical environment

Caution: The emission characteristics of the product make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If being used in the residential environment (CISPR 11 Class B required usually), the product may not provide adequate protection for radio frequency communication services. The user may be required to take mitigation measures, for example, relocating or redirecting the product.

EMS compliance

Table 2. Enclosure port

Phenomenon	Basic EMC standards	Immunity test level
		Professional medical environment
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated, radio-frequency, electromagnetic field	IEC 61000-4-3	3 V/m 80 MHz–2.7 GHz 80% AM at 1 kHz
Fields near the radio-frequency wireless communication devices	IEC 61000-4-3	Refer to Table 3
Rated power frequency magnetic field	IEC 61000-4-8	30 A/m 50 or 60 Hz

Table 3. Fields near the radio-frequency wireless communication devices

Test frequency (MHz)	**Band (MHz)**	Immunity test level
		Professional medical environment
385	380–390	Pulse modulation 18 Hz, 27 V/m
450	430–470	FM, ±5 kHz deviation, 1 kHz sine, 28 V/m
710	704–787	Pulse modulation 217 Hz, 9 V/m
745		
780		
810	800–960	Pulse modulation 18 Hz, 28 V/m
870		
930		
1720	1700–1990	Pulse modulation 217 Hz, 28 V/m
1845		
1970		
2450	2400–2570	Pulse modulation 217 Hz, 28 V/m
5240	5100–5800	Pulse modulation 217 Hz, 9 V/m
5500		
5785		

Table 4. Input AC power supply ports

Phenomenon	**Basic EMC standards**	Immunity test level
		Professional medical environment
Electrical fast transient/burst	IEC 61000-4-4	±2 kV 100kHz repetition frequency
Line-to-line surge	IEC 61000-4-5	±0.5 kV, ±1 kV
Line-to-ground surge	IEC 61000-4-5	±0.5 kV, ±1 kV, ±2 kV
Conducted disturbances induced by radio-frequency fields	IEC 61000-4-6	3 V, 0.15–80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Voltage dips	IEC 61000-4-11	0% U_T; 0.5 cycle At 0º, 45º, 90º, 135º, 180º, 225º, 270º, and 315º
		0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0º
Voltage interruptions	IEC 61000-4-11	0% U_T; 250/300 cycles

Table 5. Signal input/output ports

Phenomenon	**Basic EMC standards**	Immunity test level
		Professional medical environment
Conducted	IEC 61000-4-6	3 V, 0.15–80 MHz

disturbances induced by radio-frequency fields		6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz

Table 6. Proximity magnetic fields

Test frequency	Modulation	Immunity test levels
		Professional healthcare facility environment
134,2 kHz	Pulse modulation 2,1 kHz	65 A/m
13,56 MHz	Pulse modulation 50 kHz	7,5 A/m

Appendix 2. Information About Wi-Fi

⚠Warnings

Please take attention that changes or modification not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) This device must accept any interference received, including interference that may cause undesired operation.

This equipment complies with FCC/IC RSS-102 radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator & your body.

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions:

(1) this device may not cause interference, and

(2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radioexempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

(1) l'appareil ne doit pas produire de brouillage, et

(2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

(For licence-exempt equipment with detachable antennas, the user manual shall also contain the following notice in a conspicuous location)

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

Conformément à la réglementation d'Industrie Canada, le présent émetteur radio peut

fonctionner avec une antenne d'un type et d'un gain maximal (ou inférieur) approuvé pour l'émetteur par Industrie Canada. Dans le but de réduire les risques de brouillage radioélectrique à l'intention des autres utilisateurs, il faut choisir le type d'antenne et son gain de sorte que la puissance isotrope rayonnée équivalente (p.i.r.e.) ne dépasse pas l'intensité nécessaire à l'établissement d'une communication satisfaisante.

If the distance from the product to the human body is greater than 20cm, the following warning is required (this requirement is not required for micro-power SRD devices.

This equipment complies with FCC/IC RSS-102 radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the

radiator & your body.

ce matériel est conforme aux limites de dose d'exposition aux rayonnements, FCC / CNR-102 énoncée dans un autre environnement.cette eqipment devrait être installé et exploité avec distance minimale de 20 entre le radiateur et votre corps.

The user manual for local area network devices shall contain instructions related to the restrictions mentioned in the above sections, namely that:

(i) the device for operation in the band 5150-5250 MHz is only for indoor use to reduce the potential for harmful interference to co-channel mobile satellite systems;

(ii) the maximum antenna gain permitted for devices in the bands 5250-5350 MHz and 5470-5725 MHz shall comply with the e.i.r.p. limit; and

(iii) the maximum antenna gain permitted for devices in the band 5725-5825 MHz shall comply with the e.i.r.p. limits specified for point-to-point and non point-to-point operation as appropriate.

(iv) the device does not be capable of transmitting in the band 5600–5650 MHz.

(i) Les dispositifs fonctionnant dans la bande 5150-5250 MHz sont réservés uniquement pour une utilisation à l'intérieur afin de réduire les risques de brouillage préjudiciable aux systèmes de satellites mobiles utilisant les mêmes canaux.

(ii) le gain d'antenne maximal autorisé pour les appareils dans les bandes 5250-5350 MHz et 5470-5725 MHz doivent respecter le pire limiter; et

(iii) le gain d'antenne maximal autorisé pour les appareils dans la bande 5725-5825 MHz doivent respecter le pire limites spécifiées pour le point-à-point et l'exploitation non point à point, le cas échéant.

(iv) le appareil n'est pas capable de transmettre dans la bande 5600-5650MHz.

Users should also be advised that high-power radars are allocated as primary users (i.e. priority users) of the bands 5250-5350 MHz and 5650-5850 MHz and that these radars could cause interference and/or damage to LE-LAN devices.

Les utilisateurs de radars de haute puissance sont désignés utilisateurs principaux (c.-à-d., qu'ils ont la priorité) pour les bandes 5250-5350 MHz et 5650-5850 MHz et que ces radars pourraient causer du brouillage et/ou des dommages aux dispositifs LAN-EL.

.

Frequency Band

FCC/IC Certification:

1: 2.412-2.462GHz 2: 5.15-5.25GHz 3: 5.25-5.35GHz

4: 5.47-5.725GHz 5: 5.725-5.875GHz

RED Certification:

1: 2.412-2.472GHz 2: 5.15-5.25GHz 3: 5.25-5.35GHz

4: 5.47-5.725GHz 5: 5.725-5.875GHz

Appendix 3. Cybersecurity

This appendix is intended for the IT network responsible at the organization where the Digital Video Monitor is used. It contains technical information regarding the setup of the IT network and the devices connected to the Digital Video Monitor. It also contains information regarding the types of data contained in and transmitted from the Digital Video Monitor.

Digital Video Monitor can work normally in a non-network environment. At present, the network functions are DICOM data transmission, LAN printing, and network timing. The DVM-D has Wi-Fi wireless transmission capability, which can be accessed to the hospital network after obtaining access permission, and wireless data communication with other equipment in the hospital. Whether the DICOM data transmission or Wi-Fi data transmission, it will not be connected to the external Internet during the actual clinical application, but will only be connected to the designated equipment inside the hospital, and work in the controlled network environment inside the hospital.

The Digital Video Monitor does not allow any input from external devices (except from Vathin endoscopic devices and secured software updates).

The endoscope, Digital Video Monitor and power adapter can form the minimum system unit. The real-time image display and adjustment of the endoscope can be realized through the touch screen of Digital Video Monitor. Essential functionality is secured in case of network problems.

Note:

- The Digital Video Monitor does not allow any non-Vathin-licensed programs to be upgraded or otherwise installed via a USB interface. If the installation package name, RAS authentication, installation package hash value, or any parameter is inconsistent with the Vathin rule, the installation will be rejected. Even if this installation package works properly on other Android systems, it will be judged as illegal software by the Digital Video Monitor. The installation of non-authorized third-party applications will be prohibited. If the installation is performed, the system will pop up a window indicating that the application is not installed. If this pop-up window appears when your device is in normal use, it indicates that your device may be under attack. In this case, remove the network cable and disable the Wi-Fi function on the Settings screen to ensure that the device is disconnected from the network. When the attack affects the function of the device, you can contact the local representative of Vathin to help you restore the basic function of the product. Do not connect to the network until the network is secure. Please Feedback this abnormal event to our after-sales mailbox by email.
- After we receive the incident feedback, we will reply to the email address of the feedback incident, including but not limited to the confirmation of the receipt of the incident, the information required for the investigation of the incident, the results of the incident processing, etc.

Appendix 3.1. Network Setup

When preparing the network for connection to the digital video monitor, the following should be considered:

Overview of the existing ports and their communication protocols		
Item	**Standards used**	**Comments**

Wireless communication	Wireless communication	The device uses a WPA_Supplicant to support WPA2 Wireless communication as TKIP and CCMP. The authentication and integrity of the communication is provided by the underlying FIPS 140-2 compliant chipset wireless driver. Wi-Fi option supports WPA2 Enterprise for mschapv2.
LAN communication	IEEE 802.3 IEEE 802.3ab IEEE 802.3az PICMG3.1	The device uses a standard Gigabit Ethernet controller supporting a 1000base-T interface.
Network adaptor configuration	DHCP Static IP	Static IP address (IPv4) is configurable in the GUI.
Static IP address (IPv4) is configurable in the GUI.		The device does not support re-routing traffic from Wi-Fi to LAN or vice versa, therefore the device cannot act as a NAT (Network Address Translation) gateway.
PACS servers	DICOM	To support a broad range of network infrastructures and PACS servers.Supports TLS encrypted transmission
Ports		There are no open ports,

Note: By default, there is no open port, only the corresponding set port is opened for communication in dicom transmission, network printing, or NTP timing function, and the port is closed after the function is used.

Appendix 3.2 Data at rest and in transit

The digital video monitor uses system memory to store information about scope, process, and network configuration. The memory file system cannot be accessed directly from the GUI, and the file system is divided by permissions, and the GUI can only access a fixed storage path, and the images and videos in the storage path can be exported to the PACS server and/or USB storage devices.log file can exported to USB storage devices.

The following exportable data are stored:

Item	Format
Images	JPG
Video	MP4
Log file	TXT

Images and videos can be transferred to a PACS server. The following formats and protocols are used during the transfer from the displaying unit to the PACS server:

When the image or video is transmitted to PACS, the system automatically converts the stored image file into dcm format for transmission, and automatically deletes the dcm file after the transmission is completed

Item Format Protocols Comments:

Item	Format	Protocols	Comments

Images	Images DICOM object / JPG	DICOM over TCP/IP or DICOM over TLS	Can use either Wi-Fi or LAN communication.
Video	Video DICOM object / MP4	DICOM over TCP/IP or DICOM over TLS	Can use either Wi-Fi or LAN communication.

Appendix 3.3. Software Bill Of Materials (SBOM)

The following main off-the-shelf software components are used in the digital video monitor.

Main known vulnerabilities of each component including explanations of why they are acceptable for this application are continuously updated by Vathin. Contact your local Vathin representative for an up to date list with this information. Vulnerabilities with a low CVSS score are omitted as a consequence of the medium security risk rating of the digital video monitor.

Component name	Supplier name	verison	Author	Hash（sha1）	UID	Relation ship
endoscope-release	Vathin	V1.02.002.0083	Shi chuangxun	369c94cb91fa0d14ae4d7a562a8e860d64dd5960	53f011ad-d585-b9d7-8dcd-f85741018eb5	Include in
Android system	Google	7.1.2	Google	aaf8f605d6f6556c16dae9b975d60cb9df493972	dc88a754-b5bf-035f-c9b3-942e5c9a9d77	self
Mopria print service	Mopria Alliance	2.14.9	Mopria	2717F924A712484CE8DADF52250703DD16D78DB4	d714e252-ca7b-33d5-6e1e-9f3eff7706c0	Include in
FPGA image process	Vathin	1.00.000.0021	wayne	b71cccacc005f47cb6091aaaae9ed97e623e3f5f	cada3629-e17c-4a23-10d4-4aeb1be3a4c3	self
MCU power management system	Vathin	1.00.000.0017	seny	6f15c87d7966b715437dcbf30ff9188bf6d46e42	0a8e348e-2ca4-82fa-f991-20adfd08e32c	self
Aosp	Google	7.1.2	Google	aaf8f605d6f6556c16dae9b975d60cb9df493972	cdb52673-83b6-4a55-9c1e-b91ef399bdba	Include in
Chaquopy	Chaquopy	9.0.0	Chaquopy	247b4ee11dd914800dc8a444d5f4773b9ae2f7a5	63f07819-755d-44d1-bc52-e13ce6c74383	Include in
DCM4CHEE	DCM4CHEE	5.26.1	DCM4CHEE	c3c59426bfdfd180de5a6930be7cd614c476e88e	e00bd1f8-66a3-4c3e-9e63-91e3f72dd245	Include in

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Release Notes

Version No.	Modification Date	Modification Description	Prepared/ Modified By
A/0	2023.03.15	New Document	Yanglin Feng
A/1	2024.04.15	Add new model DVM-D2 Add worklist operation process and add network security information	Yanglin Feng