User Manual
Digital Video Monitor
DVM-A1
DVM-A2

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.

Table of Contents

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 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.

The Digital Video Monitor is intended for patients requiring endoscopic diagnosis or treatment.

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.

- ***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-A1 & DVM-A2, including cables specified by 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.

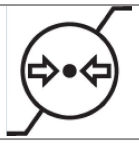
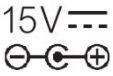
- Keep all electrical equipment away from any liquid.

- Wear suitable protective filtering spectacles when the laser is used. 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 product is not intended to be repaired. In case the product becomes defective, it should be discarded.

2. Symbols

Symbols	Expression	Symbols	Expression
CE	CE marking of conformity		Waste Bin symbol, indicating that waste must be collected according to local regulations and collection schemes for the disposal of electronic and electrical waste (WEEE)
	General warning sign		Manufacturer
	Refer to instruction manual		Country of manufacture: CN (China) Production date, 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		Batch code
	Authorized representative in the European Community/European Union		Keep dry
	Humidity limitation		Temperature limitation
	Atmospheric pressure limitation		Keep away from sunlight
	UL recognized component mark for Canada and the United States		Type BF applied part
	Application of endoscope ports		Input voltage: 15 VDC
	Universal Serial Bus ports	HDMI	High Definition Multimedia Interface port
	Only for indoor use		Wireless Local Area Networks port
	Fragile, handle with care		Tested to comply with FCC Standards – medical equipment
MD	Medical device	#	Model number
	Protective earth (ground)	UDI	Unique device identifier
	Direct current		

3. System

The product is designed as the system controller of an endoscopic image observation system to display, record and print 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 Instructions for Use.

3.1. Digital Video Monitor

No.	Model	Specification of endoscope port
1	DVM-A1	14-pin
2	DVM-A2	16-pin

3.2. Product Compatibility

Warning

◆ The product can only be connected to equipment that has been qualified as per IEC 60601-1. Otherwise patient and operator injury may occur.

◆ Digital video monitor is only designed for use with Vahin endoscopes. Do not use with other endoscopes, Otherwise patient and operator injury may occur.

3.2.1. Compatible Endoscopes

The Digital Video Monitor has been designed to be used in conjunction with Vathin endoscope.

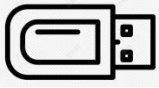
3.2.2. Compatible Monitor

Item	Recommended parameter
Screen brightness	≥ 300 cd/m²
Color gamut	BT.709 or SMPTE-C, 72 % NTSC
Resolution	720/50p, 1080/50i, 1080/50p, 1080/60p, 1080/30p, 1080/60i
Monitoring technology	Bright LED backlight technology
Input signal type	DVI-D or HDMI Video bandwidth < 165MHz TMDS: 600mV for each differential line Input impedance: 50 ohm
Contrast	≥ 1000/1

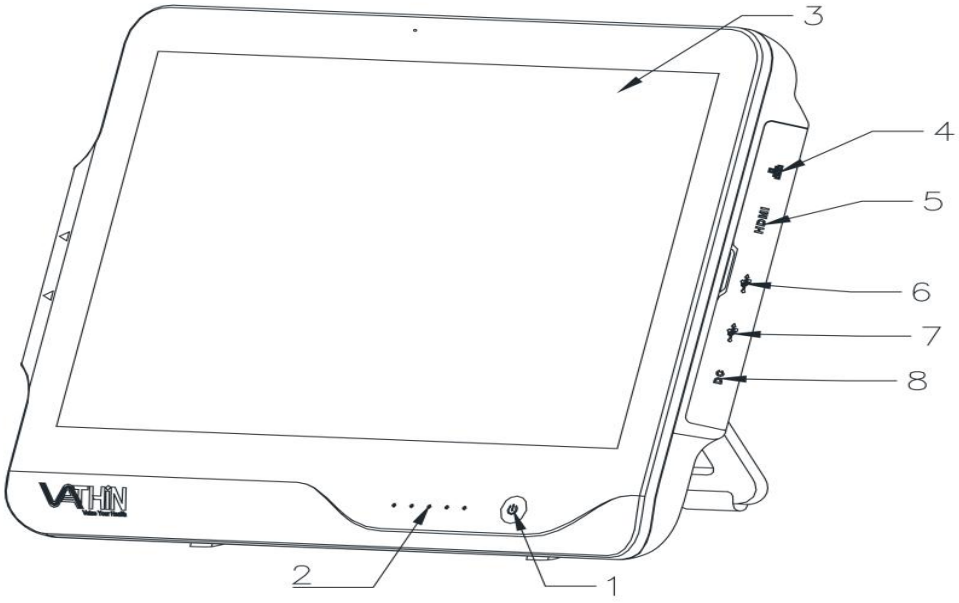
4. Checking the Package Contents

4.1. Package Contents

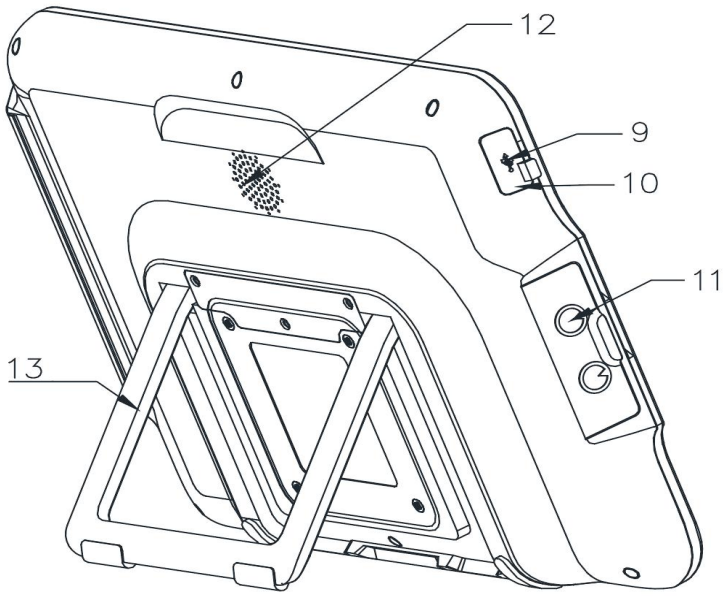
Open the product packaging to ensure that all components are included. Check all items in the package with the components shown below. Check each item for damage. Please contact Vathin Medical if any component is missing or damaged.

Item	Quantity	Image
DVM-A1 (or DVM-A2) 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	
USB cable	1 pc	
HDMI cable	1 pc	
User manual	1 pc	
Multilingual user manual (CD)	1 pc (optional)	
Reset pin	1 pc	
USB stick	1 pc (optional)	

4.2. Structure and Function



No.	Part	Menu Functions
1.	**Power button**	Press and hold to turn on the product, and press to turn off the product.
2.	**Power indicator**	Indicates the battery power status. Lights up blue when the device is on. Flashes when the device is being charged and when the battery is low.
3.	**Display**	Displays the image after the endoscope is connected; touch screen.
4.	**LAN interface**	Connect the Local Area Network via network cable here.
5.	**HDMI interface**	Connect an external high-definition monitor for display expansion here.
6.	**USB interface 3.0**	Connect external devices, such as USB stick here.
7.	**USB interface 3.0**	Connect external devices, such as USB stick here.
8.	**Power socket**	Receives 15 VDC input, and provides the power supply for the entire system.



No.	Part	Menu Functions
9.	**USB 2.0**	Can be connected to a PC for image display.
10.	**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.
11.	**Video endoscope cable connector socket**	Insert the video endoscope cable here to connect the video endoscope to the product.
12.	**Ventilation holes**	Cooling the hardware during use.
13.	**Stand**	Supports the product on a plane surface.

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 avoid 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 is 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 according to its instruction manual.

5.2. Installing the Digital Video Monitor

Warning

- To avoid the risk of electric shock, this equipment must only be connected to 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.

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.

1. Open the stand (no. 13 in Chapter 4.2 Structure and Function) of the product and place it on a solid surface. Do not place the Digital Video Monitor in a place where it is difficult to operate the disconnection device.
2. Connect the power cable to the power adapter, and connect the power adapter to mains power (no.8 in Chapter 4.2 Structure and Function) of the Digital Video Monitor.
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.
4. Connect the Digital Video Monitor to a medical display or PC as needed.
5. Connect the endoscope to the Digital Video Monitor by inserting the endoscope connector into the endoscope socket (no. 11 in Chapter 4.2 Structure and Function) properly as indicated by the arrow.

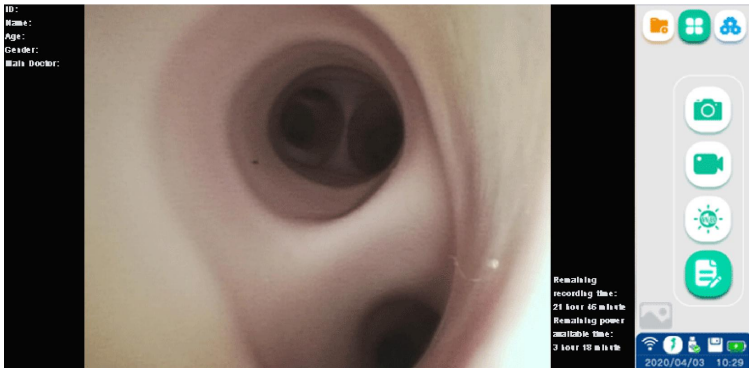
5.3. Switching On and Setup

Warning

- When the loss of built-in power supply under normal working condition would result in unacceptable risks, the medical electrical equipment must be connected to an appropriate external power supply.
- If a battery is used, check the battery capacity before use. Otherwise patient injury may occur.

1. Press and hold the power button to turn on the product. After the boot animation is over, the Basic Functions Menu (Chapter 6.1 Basic Function Menu) will appear by default.

2. The real-time image will be displayed. Icons on screen turn green and their functions are available.
3. If a battery is used, check the battery capacity of the equipment, and charge when the battery is low.
4. Set the parameters of the Digital Video Monitor according to Chapter 6.3 System Settings Menu.



Note

- The battery capacity icon in the lower left corner displays the remaining battery capacity, which changes depending on the remaining capacity and status of the battery.
- When the battery capacity is greater than 20 %, this icon is green; when the battery capacity is less than 20 %, it is orange; when the battery capacity is less than 10 %, it is red, and a prompt of insufficient. battery capacity is displayed. A lightning symbol appears in the icon during charging.

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 severe equipment damage.

1. Inspect photo capture and recording function of the equipment. Please refer to Chapter 6.1.3 Photo Capture and Chapter 6.1.4 Video Recording.
2. Inspect the endoscope function according to the instruction for use of the endoscope.
3. Before each use check to ensure the view observed through the display provides a live image and has the correct image orientation.

5.5. Operating the Digital Video Monitor

Warning

- When advancing or withdrawing a Vathin endoscope, always watch the real-time endoscopic image on the monitor.

1. Enter patient information: Enter patient information according to Chapter 6.1.1.
2. Adjust the white balance: Adjust the white balance according to Chapter 6.1.2.
3. Perform examination: Related function of the Digital Video Monitor, please refer to Chapter 6 Function.

5.6. After Use

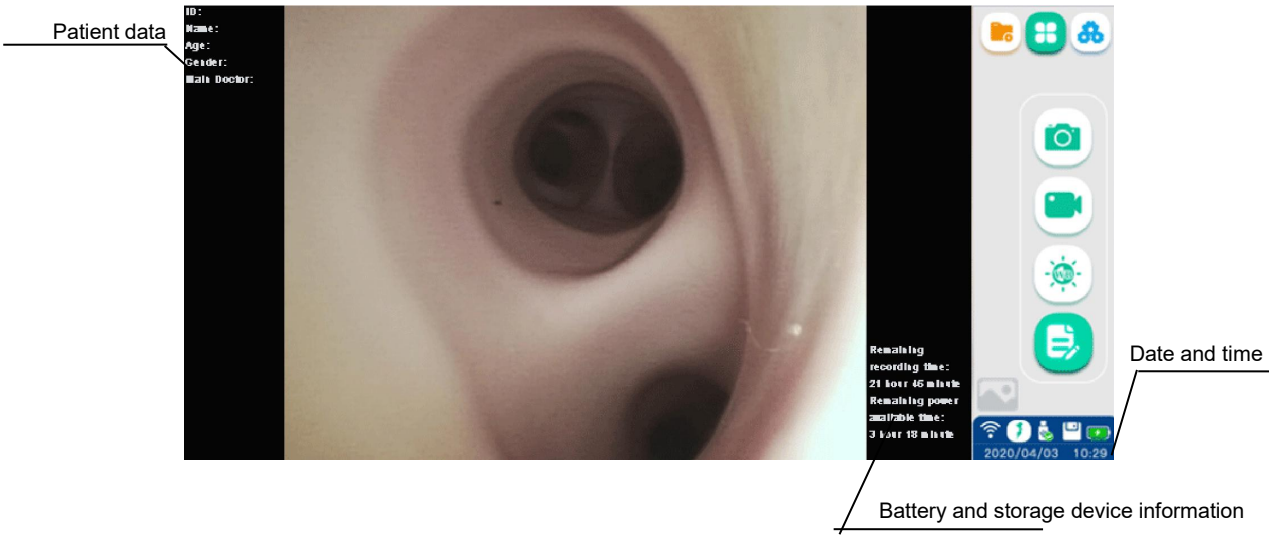
1. Disconnect the Vathin endoscope from the product. For information on how to dispose of the Vathin endoscope, refer to its user manual.
2. Press the power button to turn off the product, and disconnect the power cable. To disconnect the Digital Video Monitor from mains, remove the mains plug from the wall outlet.
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.
- For access to some key functions you need to enter the user password; the initial user password is 123456. Please reset the user password during first login.
- Exit the current menu by swiping from right to the left.

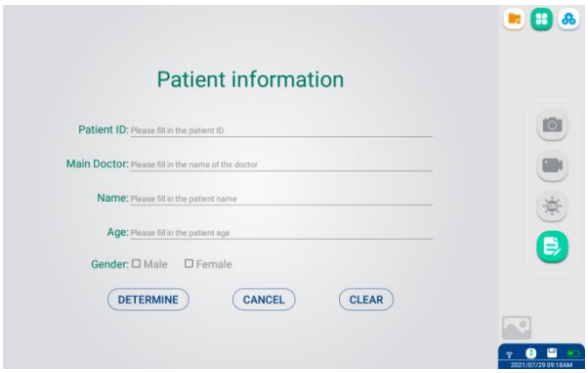
6.1. Basic Function Menu



Description of basic function icons			
Icon	**Name**	**Menu Functions**	**Reference section**
	Basic Functions	Icon for the Basic Functions menu.	6.1
	File Management	Icon for the File Management menu.	6.2
	System Settings	Icon for the System Settings menu.	6.3
	Photo apture	Tap this button or the Vathin endoscope camera button to capture the image and automatically save it in the patient file. The endoscope is connected. Functions of the icons are available.	6.1.3
	Video Recording	Tap this button to start recording a video. Tap it again to stop recording and save the recorded video in the patient file.	6.1.4
	White Balance	The white balance adjustment is required before surgery.	6.1.2
	Patient Data	Tap to enter the Patient Data menu.	6.1.1
	Patient Data	Tap to return to the Basic Functions menu.	/
	Photo Preview	Photo preview zone, will be updated after an image is taken. Tap to preview the latest images.	6.1
	WiFi	Indicates WiFi connection/disconnection.	/
	Endoscope Connection	Indicates endoscope connection/disconnection and endoscope insertion status.	/
	Memory	Indicates the available memory. A prompt will be displayed in case of insufficient memory.	/
	Memory	Storage space is insufficient.	/
	Battery Capacity	Indicates the remaining battery capacity.	/
	Battery Capacity	Low power capacity.	/

6.1.1. Entering Patient Data

1. Tap  to enter the Patient Data menu. Tap the input box on screen to enter patient data via the virtual keyboard. Icon  is used to enter the next input box.



2. After the operation, tap “CLEAR” to re-enter the patient data; tap “DETERMINE” to confirm the operation, or tap “CANCEL” to cancel the operation; the Basic Function menu will appear automatically with the patient data displayed in the upper left corner.

3. Tap  again to modify or clear the patient data being entered.

Caution

- Once the patient information is entered, the photos and videos taken will be appended with the patient data until the patient data is cleared.

Note

- The image shown in the image zone will be cleared after the patient ID is modified.

6.1.2. 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.

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 in 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  on the screen. Icon  will appear in the upper right corner of the image. When the icon disappears, the white balance adjustment is complete.

6.1.3. Photo Capture

1. There are two methods to take photos.
   * Press the photo button on the endoscope
   * Tap icon  on the screen.
2. When taking photos, icon  appears in the upper right corner of the screen. The photo has been taken when the icon  disappears, and “Photo saved successfully” is displayed.
3. After taking a photo, the image area in the lower right corner will be updated accordingly. Click the updated image to preview the image.

Note

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

6.1.4. Video Recording

Tap icon  to start recording, the icon will turn red  , 00:00:00  will appear in the upper right corner of the screen to indicate the recording time. Tap  again to end the video recording, and

00:00:00 will disappear. The video has been taken when “Video saved successfully” is displayed.

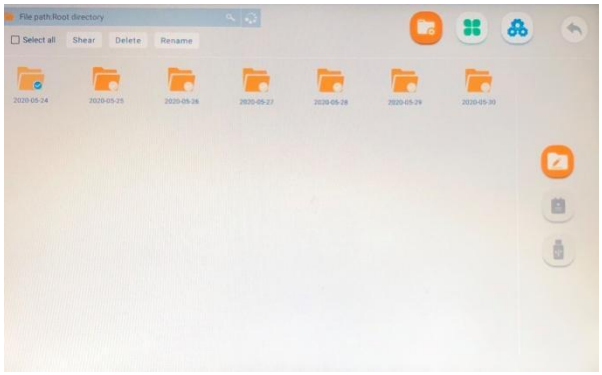
Note

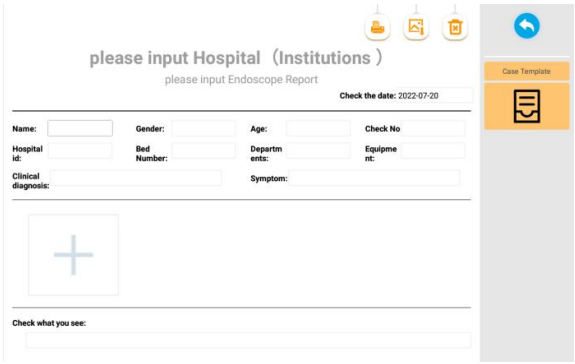
- The maximum allowable length of the video is 60 minutes (i.e. <1GB). Therefore, any video recording over 60 minutes will be automatically stored by splitting into two or more video clips.

6.2. File Management Menu

6.2.1. Entering the File Management Menu

Tap the file management button to enter the file management menu. This menu is used mainly for operations such as file viewing, folder editing & deleting, file moving, and medical record editing, as shown in the figure below.





Description of file management-related icons

Icon	Name	Menu Functions	Reference section
	File Management	Icon for the File Management menu.	6.2
	File editing	Tap the icon or press and hold a folder/file to enter selection mode to perform multiple selection, cutting, renaming, and deletion operation on the file or folder.	/
	USB storage device management	Indicates the connection of a USB storage device. When connecting a storage device, you can choose to copy/cut files to a USB storage device. If no USB storage device is connected, the icon is gray, which means this function cannot be used.	/
	Medical record	Edit medical records.	6.2.3

	Save medical record	Saves images of medical records.	6.2.3
	Print	Prints medical records, where Wi-Fi connection is required.	6.2.3
	Erase	Erases the current data.	6.2.3

6.2.2. Playback Photos/Videos

In the File Management menu, tap the icon to open the intended folder. Tap the corresponding image/video for playback.

Note

- The photos/videos taken are stored according to date and patient ID, and the file folder is named accordingly. For example, if the operation date is Sept. 17, 2020, patient ID is 12, the file path will be: >2020-09-17>12.
- If the patient ID is not set: A “pictures/media” folder will be generated in the date folder after photo capture/video recording, and the file path will be: >2020-09-17>picture/media.
- The images are stored in PNG format, videos are stored in MP4 format.

6.2.3. Medical Record Menu

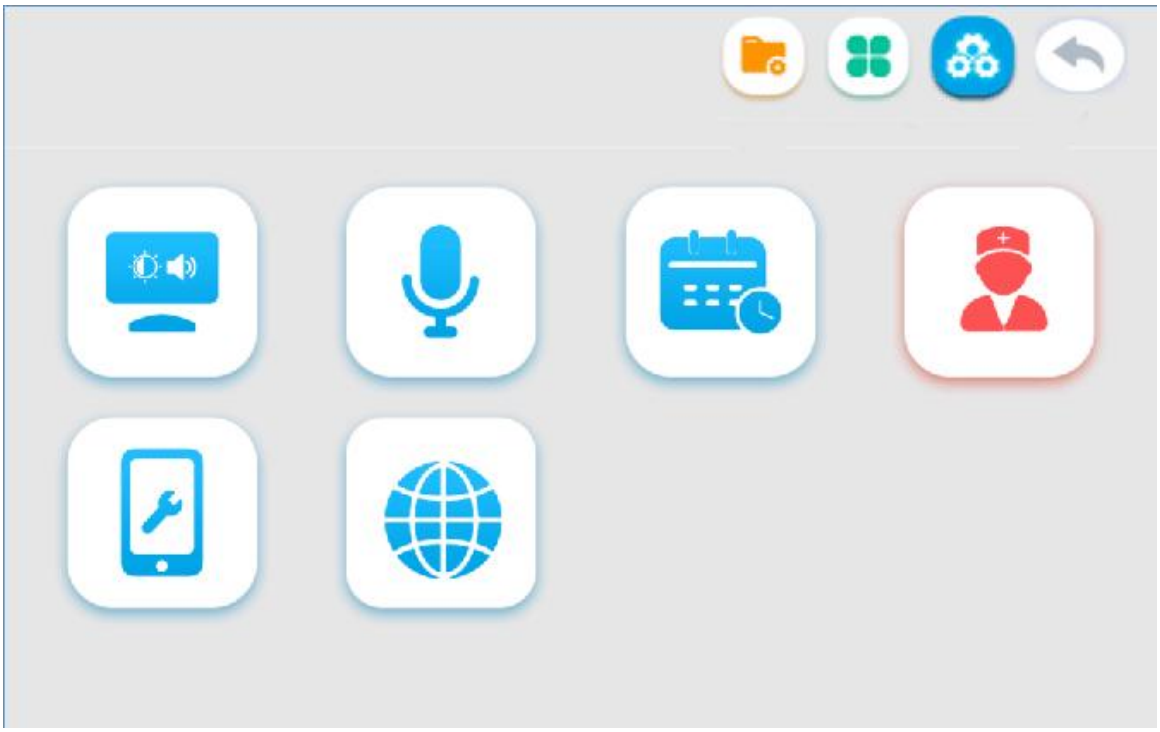
Click the medical record icon , then enter the patient ID to enter the record sheet menu. Select the case template; the report will be displayed. Select the date of the report, fill in the report ID and related information, select patient photos, fill in the diagnosis and treatment outcome, then tap to save the image of the record. Tap the print icon to select HP’s Wi-Fi printer for printing. Tap the erase icon to erase the current data.

Note:

- Please connect to HP Wi-Fi printer to print the files.

6.3. System Settings Menu

Tap to enter the System Settings menu. This interface is used mainly for setting brightness, time, user permissions, network and language, and viewing the equipment data.



Icon	Name	Function	Reference section
	Screen adjustment	Used to adjust screen brightness, volume parameters	/
	Microphone	Turn the microphone on or off	/
	Calendar	Used to set the date and time	/
	Equipment information	Used to view the equipment information	/
	User account	Used to set the user accounts	/
	Network setting	Used to set languages, Wifi and LAN	6.3.1

6.3.1. Wi-Fi Setting

Warning

- Please connect the Digital Video Monitor to a reliable network. An unreliable network may cause data loss or equipment failure.

- For related warnings and information about Wi-Fi please refer to Appendix 3. Information About Wi-Fi.

Turn on Wi-Fi, and enter a valid password to connect to the network.

After the network is connected, the network connection symbol  appears in the status bar.

6.3.2. LAN Setting

Warning

- 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.

Connect the network cable to the Ethernet interface  of the device. After the network is connected, the network settings menu displays the network IP address.

Note:

- The Digital Video Monitor uses Wi-Fi direct connection to connect to mopria-supported Wi-Fi printers. The expected communication data involves medical and health data.
- The Digital Video Monitor can be connected to the local Internet via the RJ45 interface to obtain the network synchronization time. The intended communication involves the interaction of network synchronized time data.

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 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.
5. Use a sterile soft brush dipped in enzyme solution to clean the buttons until all dirt is removed.
6. Wait 10 minutes (or the duration recommended by the detergent manufacturer) for the enzyme to be activated.
7. Use the sterile gauze dipped in RO/DI water to clean the product to ensure that all traces of detergent are removed.
8. Repeat Steps 1 to 7 until the Digital Video Monitor is clean.

7.2. Disinfection

1. Disinfection solution: Isopropanol (alcohol) concentration 70 - 80 %;
2. Preparation: Add 80 ml of 95 % isopropanol (alcohol) to 20 ml of purified water (PURW) (or use the EPA registered medical disinfectant wet wipes containing at least 70 % isopropanol; all 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. 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

After the product's service life expires, you should remove the monitor, and dispose of the battery and monitor separately according to local regulations.

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. Specifications

Item	Specifications
Menu Functions	
White Balance	Manual
Data record	Videos (MP4)/photos (PNG)
Memory	64G memory
Language setting	English/Français/ 日 本 語 / 中 文 简 体

	/Deutsch/Español/PORTUGUÊS/italiano
Time setting	Manual/Internet-based self-calibration
Monitor	12.1"; 1280 x 800; touch screen
Video output mode	HDMI
Screen brightness	Manual adjustment
Wi-Fi	IEEE 802.11ac/a/b/g/n
LAN connection	RJ45, 10/100/1000 Mbps
USB connection	A-type
Expected service life	5 years
Electrical power (Digital Video Monitor)	
Input power	15 VDC, 4.2A max.
Internal battery	10.8 VDC
Power adapter	
Power supply requirement	100 - 240 VAC; 47 - 63 Hz; 1.62 - 0.72 A
Output power	15 VDC, 4.2A max.
Protection against electric shock	Class I
Dimensions	
Length x width x thickness	310 mm x 231 mm x 39 mm
Weight	2140g
Storage and transportation	
Recommended storage temperature [°C, (°F)]	-10 °C to +40 °C (14 - 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 - 104 °F)
Relative humidity [%]	30 % to 80 %
Atmospheric pressure [kPa]	86 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.

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 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 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

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
DC power cable	1.3 m	Unshielded	1 set	DC power supply
USB cable	2.8 m	Shielded	1 set	Signaling
HMDI-DVI cable	2.8 m	Shielded	1 set	Signaling
HDMI cable	2.8 m	Shielded	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 manual shall apply when using it. The product complies with IEC 60601-1-2:2014 in terms of immunity and emission. However, the following special considerations shall be observed:

The equipment with above-mentioned ESSENTIAL PERFORMANCE is intended to be used in the 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 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

- 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	±8kV 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	±2kV 100kHz repetition frequency
Line-to-line surge	IEC 61000-4-5	±0.5kV, ±1kV
Line-to-ground surge	IEC 61000-4-5	±0.5kV, ±1kV, ±2kV
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 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°
		0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°
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 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

Appendix 2. Information About Wi-Fi

⚠Warnings

Please take note 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 license-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 chosen such 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 Chapters, 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 - 2.462 GHz 2: 5.15 - 5.25 GHz 3: 5.25 - 5.35 GHz

4: 5.47 - 5.72 5 GHz 5: 5.725 - 5.875 GHz

RED Certification:

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

4: 5.47 - 5.72 5 GHz 5: 5.725 - 5.875 GHz

CE

Hunan Vathin Medical Instrument Co., Ltd.
1/F, Building 12, Innovation and Entrepreneurship Service Center, No 9 Chuanqi west road, Jiuhua Economic Development Zone, 411100, Xiangtan, Hunan, China
Website: www.vathin.com
Email: service@vathin.com

EC REP

Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
peter@lotusnl.com
+31645171879, +31626669008

Version Number/Revision Number: A/1
Issue Date: 11.23.2022

Release Notes

Version No.	Modification Date	Modification Description	Prepared/ Modified By
A/0	2020.12.11	New Document	奉仰林
A/1	2022.11.23	Replace the content of the instruction for use with the contents of the file QP-DMR-DVM-004 A/4,revise company telephone and address and other errors and omissions,delete information of optional accessories pylons and trolley	石闯勋