Hunan Vathin Medical Instrument Co., Ltd.
User's Manual

Name	User's Manual of Digital Video Monitor	Page	0/31	No.	QP-DMR-DVM-004

Prepared By		Date		Release Date		Controlled Status	
Reviewed By		Date		Effective Date			
Approved By		Date		Competent Department	R&D Department	Version No.: A Revision No.: 0	
Distributed To							

Release Notes

Version No.	Modification Date	Modification Description	Prepared/ Modified By
A/0	2020.12.11	New Document	

CE 0344

User's Manual
Digital Video Monitor for
Medical Endoscopes
DVM-A1
DVM-A2

◆ For use by trained clinicians/physicians only.

◆ The product is designed to be used in hospitals.

◆ Suitable for Vathin endoscope.

◆ Always read this manual carefully before using the product.

◆ Please keep this manual and related documents in a safe and accessible place.

◆ Please contact Hunan Vathin Medical Instrument Co., Ltd. if you have any questions or comments about this manual.

Hunan Vathin Medical Instrument Co., Ltd.

Table of Contents

Important Information - Read Before Use

Please read this manual carefully before using the Digital Video Monitor for Medical Endoscopes, especially the safety-related instructions therein. This manual is subject to change without notice. You can request a copy of the current version of this manual. Please note that no clinical procedure is explained or discussed in this manual. This manual only provides the basic operations and preventive measures for the Digital Video Monitor for Medical Endoscopes.

In this manual, the monitor whenever mentioned refers to the Vathin Digital Video Monitor for Medical Endoscopes, and this manual only applies to the Vathin Digital Video Monitor for Medical Endoscopes. See relevant manuals for other products from Vathin Medical. For more information, visit www.vathin.com.

The Vathin Digital Video Monitor for Medical Endoscopes is refereed to as the product in this manual.

Expected Purpose

The product 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.
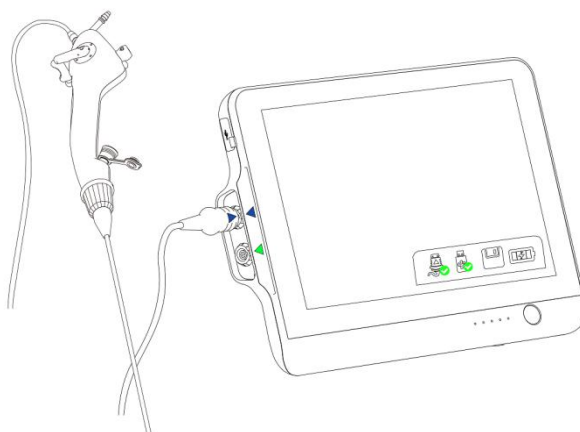
Basic Performance

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

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.

Keywords

The following keywords are used throughout this manual:

Danger

Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

Warning

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

Caution

Indicates a potentially hazardous situation which, if not avoided, could 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.

Dangers, Warnings and Cautions

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

Danger

◆ 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 touch the power socket, the docking connector or the bracket of the product when using it for patients.

◆ To minimize the risk of contamination, always clean and disinfect the product as specified in Chapter IV after using it.

◆ To avoid the risk of electric shock, only the appropriately approved medical electrical equipment are allowed to be connected with the product.

◆ In order to avoid the risk of power supply, the switching power supply with medical certification specified in the manual should be selected.

◆ When using the product, always protect it from being placed adjacent to or stacked with other equipment to avoid improper operation. If you have to do so, observe the product and other equipment first to confirm that they can operate normally.

◆ Always observe the following precautions; or else, 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. In case of any splash onto the product, stop it immediately and contact Vathin Medical.

△ Do not prepare, inspect or use the product with wet hands.

◆ Do not use the product in case of any damage to it or any unacceptable item in the functional inspection described in Chapter III.

◆ When the lithium battery is replaced, it needs to be returned to the manufacturer and replaced by professional personnel, otherwise it will cause certain risks

Caution

◆ When advancing or retreating a Vathin endoscope, always watch the real-time endoscopic image on the monitor connected to the product. You should carefully check whether the image on the screen is a real-time image or a video record, and check that the direction of image meets the expectations.

◆ The use of accessories other than the accessories, sensors or cables specified or provided by the manufacturer of the product may increase the electromagnetic radiation or reduce the electromagnetic immunity of the product, and cause improper operation.

◆ When using any portable radio frequency communication equipment (including antenna cables, external antennas and other peripheral equipment), such equipment should not be placed over 30 cm (12 inches) away from any part of the product, including the cables specified by the manufacturer; or else, the performance of such equipment may be impaired.

◆ Do not connect or disconnect the endoscope connector when the product is started; or else, the endoscope may be damaged.

◆ Do not use any sharp object to operate the screen of the product; or else, the screen may be damaged.

◆ Never apply excessive force to the connector; or else, the product may be damaged.

◆ Always prepare an applicable and immediately available standby system to ensure that treatment procedure can be continued in the event of equipment failure.

◆ Always keep the product dry when preparing, using and storing it.

◆ Always use the spare parts provided by Vathin Medical. Never refit any spare part.

◆ Always place the power cable in the place where it is unlikely to be stepped on. Do not place any objects on the power cable.

◆ 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 repairable. In case that the product becomes defective, it should be discarded.

In case of any serious accident arising out of the use of the product, please report it to both the manufacturer and the competent authority of your country.

Applicable Standards
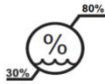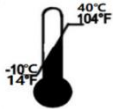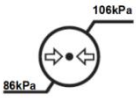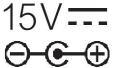
The Vathin® Digital Video Monitor meets the following standards:

- REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices

- 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

Labels and Symbols

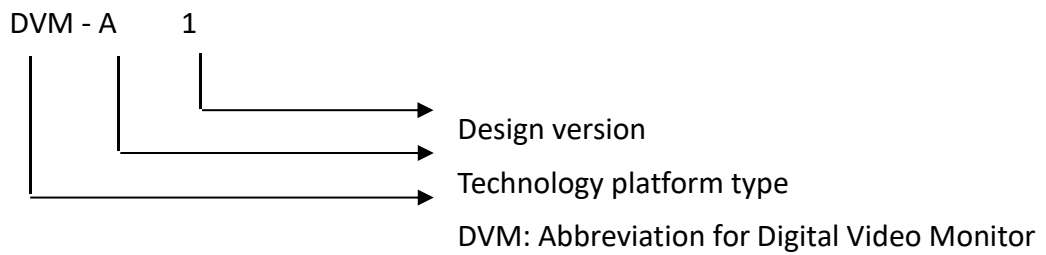| Symbols	Expression	Symbols	Expression
CE_{0344}	CE mark, which indicates the product complies with the Council Directive 93/42/EEC concerning medical devices.	(waste bin symbol)	Waste bin symbol, which indicates that the waste of electrical and electronic equipment (WEEE) must be disposed of according applicable local regulations and collection programs.
(warning triangle)	Warning	(factory symbol)	Manufacturer.
(read manual symbol)	Read the user's manual.	(factory symbol)	Production date, followed by YYYY-MM-DD.
℞ 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	LOT	Batch number
EC REP	Authorized representative of the European Community	(umbrella symbol)	Keep dry
(humidity symbol 30%–80%)	Operating environment humidity limit: 30% to 80%.	(thermometer symbol 40°C/104°F, -10°C/14°F)	Operating environment temperature limit: −10 °C (14 ℉) to 40 °C (104 ℉)
(pressure symbol 106kPa/86kPa)	Operating environment atmospheric pressure limit: 86 kPa to 106 kPa	(sun symbol)	Keep away from sun
REF	Product number. Indicates the manufacturer's catalog number for the identification of medical device.	(type BF symbol)	Electrical Safety Type BF Applied Part.Part of the application is on the main device
c(UL)us	UL Recognized Component Mark for Canada and the United States.	15V ⎓ ⊖–C–⊕	Input voltage: 15V DC;
(endoscope port symbol)	Application of endoscope Ports	HDMI	High definition multimedia interface Port
(USB symbol)	Universal serial bus Ports	(network symbol)	wireless local area networks Port

	Indoor use only mark		Federal Communications Commission mark

Product Specifications and Recommended Accessories

Model List

NO.	Model	Applicable data line interface
1	DVM－A1	14PIN
2	DVM－A2	16PIN

DVM - A   1

→ Design version

→ Technology platform type

DVM: Abbreviation for Digital Video Monitor

Endoscopes: BCV series bronchoscopes produced by Vathin Medical Instrument Co., Ltd..

Operating Environment

Ambient temperature: +10 °C to +40 °C (50–104 °F)

Relative humidity: 30% to 80%

Atmospheric pressure: 86 kPa to 106 kPa

Storage and Transportation Environment

Temperature: -10 °C to +40 °C (14–104 °F)

Relative humidity: 10% to 80%

Atmospheric pressure: 50 kPa to 106 kPa

Specifications

The product is designed as the system controller of 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 more details, see the user's manuals of the product and other connected instruments.

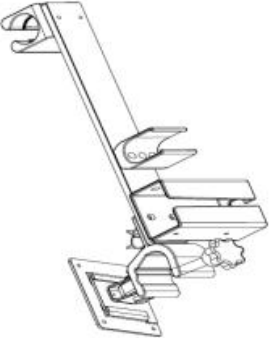| *Item*	*Specifications*	
Function	White balance	Manual
	Data record	Videos (MP4)/photos (png)
	Memory	64G memory
	Language setting	English/ /Français/日本語/中文简体
	Time setting	Manual/Internet-based self-calibration
	Monitor	12.1"; 1280 × 800; touchscreen
	Video output mode	HDMI
	Resolution	400x400
	Screen brightness	Manual adjustement
	Microphone	Used for sound recording; closable
	Loudspeaker	Used for sound playing
	Wifi	IEEE 802.11 a/b/g/n/ac 2.4G, 5G
	LAN connection	IEEE 802.11 1000base-T
	USB connection	A-type
Electrical power	Power supply requirement	100–240 VAC; 47–63 Hz; 1.62–0.72 A
	Input Power	15VDC,4.2A max
	Protection against electric shock	Type BF, class I
	Internal battery	10.8VDC 9000mAh, over 6 h endurance
Dimensions	Length× width × thickness	310 mm × 231 mm × 39 mm
	Weight	2140g

CHAPTER I PACKING LIST CHECK

Warning:

Check all the 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.

1.1. Packing List

Items	Quantities	Pictures
DVM-A1 (or DVM-A2)Digital Video Monitor	1 pcs	
Monitor cable (HDMI-DVI)	1 pcs	
Power cable	1 pcs	
Power adapter	1 pcs	
USB cable	1 pcs	
HDMI cable	1 pcs	
User's manual	1 pcs	

1.2. Optional Accessories

Items	Quantities	Pictures
U Disk	1 pcs	

pylons	1pcs	
Trolley	1pcs	

CHAPTER II DENOMINATION AND FUNCTION
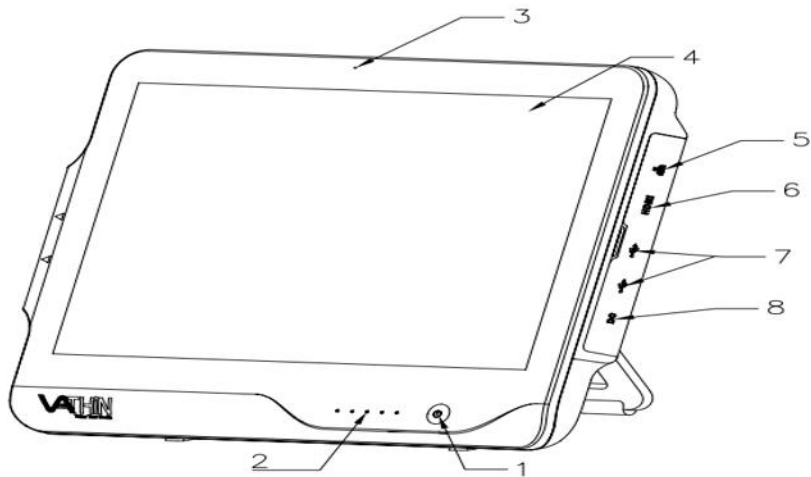
1. Power button

Before use, short press the power button to turn on the product, and long press it for 3 seconds to turn off the product.

2. Power indicator

It is normally ON when the power supply is not connected, while it flashes when the product is being charged.

3. Microphone

It indicates the position where the sound is received, and this function can be enabled/disabled in the setting.

4. Display screen

It is used to display the image after the endoscope is connected, and is touchable.

5. WLAM interface

It is used to receive the network cable for connecting to the wide area network.
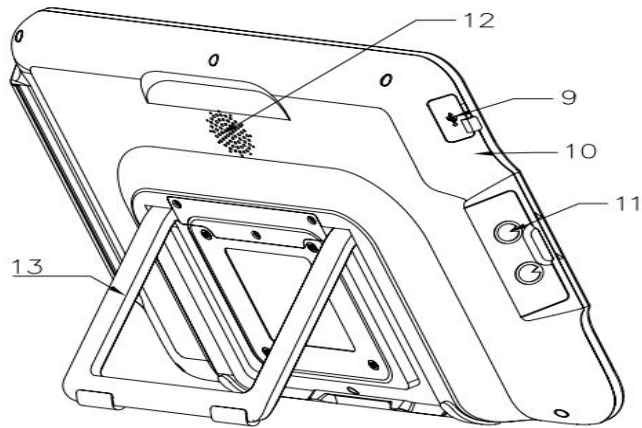
6. HDMI interface

It is used to connect an external high-definition monitor for display expansion.

7.USB interface 3.0

It is used to connect external devices, such as U disk, scanner, keyboard and mouse.

8. Power jack

It receives 15V DC input, and provides the power supply for the entire system.

9. USB 2.0

It can be connected to a PC for image display.

10. Reset button

You can insert a pin into the hole and press the reset button in the hole to restore the factory

settings.*It is recommended to use a φ 1 mm and 10 mm long pin.

11. Video endoscope cable connector socket

The video endoscope cable can be inserted to this socket to connect the video endoscope and

the product.

12. Amplification sound hole

Indicates the position of sound amplification.

13. Bracket

It is used to support the product on a plane surface.

CHAPTER III HOW TO USE THE PRODUCT

3.1 Preparation, Connection and Inspection

Danger:

◆ Connect the power plug of the power cable directly to a grounded wall outlet. Electric shock and/or fire

may be caused if the product is not properly grounded.

Warning:

◆ Do not get the power cable wet; or else, electric shock may be caused.

◆ Do not bend, pull or twist the power cable; or else, electric shock, equipment damage or fire may be

cause.

◆ The user must provide a stable power supply for the product. In case of severe fluctuations in the power supply, a power regulator or UPS power supply should be used for adjustment purpose.

Warning:

◆ All the system components shall be powered off before connecting them. Only appropriate cables can be used for the product; or else, the product may be damaged or malfunction.

◆ The product can only be connected to a medical display screen that has been qualified as per IEC 60601-1.

◆ The product can be operated only under the conditions that meets the requirements given in "Product Specifications and Recommended Accessories", "Operating Environment", "Storage and Transportation Environment" sections; or else, malfunction, impaired safety and/or equipment damage may be caused.

◆ Do not bend, pull, twist or squeeze the cables sharply.

◆ Do not place any equipment on top of the product; or else, 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); or else, the product may malfunction.

◆ Make sure the product completely dry before connecting the endoscope connector to it; or else, electric shock or equipment damage may be caused.

When using the product for the first time, please refer to this User's Manual and install the product according to the following steps. See Chapter II for the positions corresponding to the numbers referenced below:

3.1.1 Open the product packaging to ensure that all the components are provided. See Chapter I for the attached components.

3.1.2 Carefully check the product and all the components for damage (and without wear). Never the product in case of any damage.

3.1.3 Open the bracket (12) of the product and place it on a solid surface.

3.1.4 Connect the power supply to the power adapter and the power jack (8).

3.1.5 Insert the endoscope connector into the endoscope socket (11) properly.

3.1.6 Connect the power cable to the AC power socket.

3.1.7 Short press the power button (1) to turn on the product.

3.1.8 Set the product with reference to Section 3.3.4.

Note: Some key functions need to enter the user password when using,The initial user password of this product is 123456, you can reset the user password according to the instructions in the manual.

3.2 Installation, Preparation and Operation of Vathin Electronic Endoscopes

See the "User's Manual of Vathin Electronic Endoscopes".

3.3 Operating DVM-A1 Digital Video Monitor

The product can by 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 precautions related to the product.
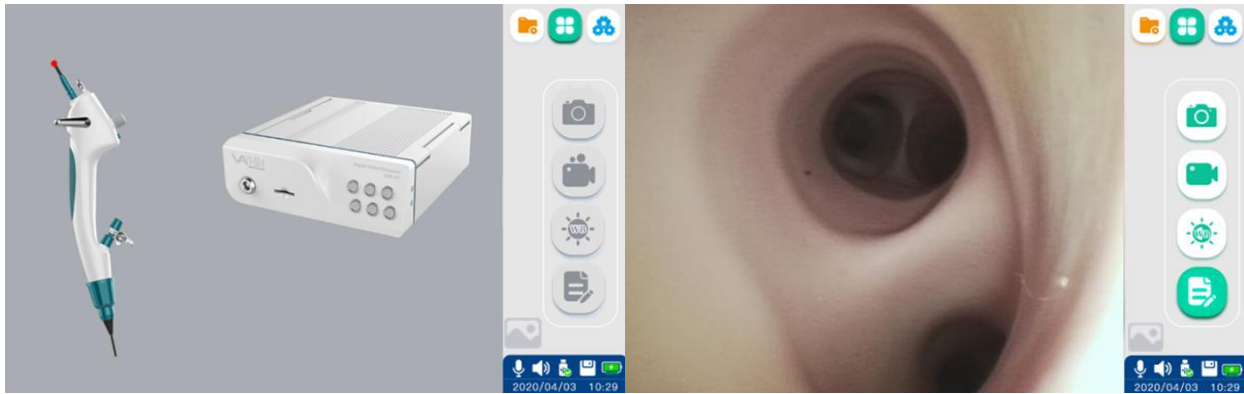
Warning:

◆ If you suspect the product malfunctions in any time, stop and inspect it immediately. Always follow the steps given below. Using a defective digital video monitor may cause injury.

◇ If the endoscope image disappears or the image freezes and cannot be restored, turn off the product and wait for about 10 seconds, and then turn it on again.

◇ If any other abnormality occurs or is suspected, stop using the product immediately, and slowly pull out the endoscope from the patient according to the user's manual of the endoscope. Then take the remedial measures as described in Chapter V. If the problem still exists, contact Vathin Medical.

◆ The white balance adjustment is required to restore the original color tone. Every time you replace the endoscope, be sure to adjust the white balance for accurate color reproduction.

◆ When the loss of built-in power supply under normal working condition will cause the machine to fail to work normally, the medical electrical equipment must be connected to the appropriate external power supply.

3.3.1. Power-on: Short press the power button to turn on the product. After the boot animation is over, the Basic Function interface will appear by default.

3.3.2. Basic function interface: This interface is used mainly for photo-shooting, video recording, white balance adjustment, patient information editing and other operations.

If no endoscope is connected, the connection prompt animation will appear on the screen, and the function icons below are grayed out, indicating that all are available.

Once the endoscope is connected, the real-time image will be displayed on the screen, and the icon on the upper right corner is checked, as shown in the figure below.

Description of basic function icons			
Icon	**Name**	**Function**	**Reference section**
	Basic function	Icon for the basic function interface	3.2.2
	File management	Icon for the file management interface.	3.3.3
	System setting	Icon for the system setting interface	3.3.4
	Photo-shooting	Tap this button or the Vathin endoscope camera button to take the image and automatically save it in the patient file.	3.2.2.3
	Video recording	Tap this button to start recording video. Tap it again to stop recording and save the recorded video in the patient file.	3.2.2.4
	White balance	The white balance adjustment is required before surgery.	3.2.2.2
	Patient information	Tap it to enter the patient information mode.	3.2.2.1
	Photo preview	Tap it to preview the latest images.	3.3.2.3
	Microphone	Tap this button, and the microphone function will be disabled; tap it again, and the microphone function will be enabled again.	/
	Audio volume	Tap this button, and the audio function will be disabled; tap it again, and the audio function will be enabled again.	/
	U-disk	Used to indicate the connection status of U-disk. It will not appear if no U-disk is connected.	/

	Memory	Used to indicate the available memory. A prompt will be given in case of insufficient memory.	3.3.2.5
	Battery capacity	Used to indicate the remaining battery capacity.	3.3.2.6

3.3.2.1. Patient information: Tap to enter the Patient Information interface; tap in the input box, and the keyboard will appear for you to edit the patient information.
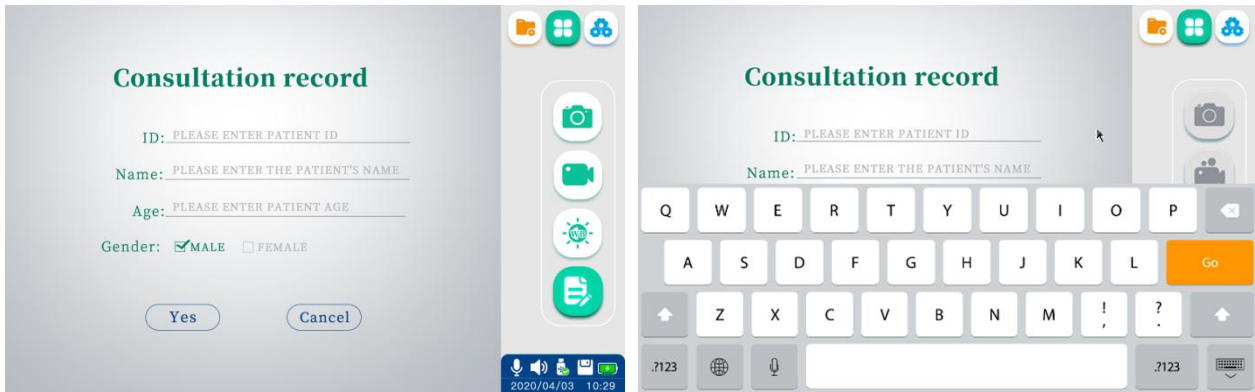
In addition to using the touch screen, you can connect an external device through the USB 3.0 interface:

1) You can connect a keyboard and a mouse to operate the product.

2) You can connect a scan head to scan the patient information QRcode/barcode for information entry.

After setting up the patient information, tap "Yes", and the the Basic Function interface will appear

automatically with the patient information displayed on the upper left corner.

3.3.2.2. White balance: If you need to use the product indoors in a hospital, turn on the lighting (with an intensity not less than 200 lx), and aim the endoscope insertion end at the white gauze. Keep the end of the endoscope insertion end about 10 mm away from the white gauze. Select the white balance

icon on the screen, and the screen will change accordingly.

Vathin Medical does not provide any accessories (e.g. white cap) for white balance. The physician may use the white gauze for white balance operations.

3.3.2.3. Photoshooting: Keep the Vathin endoscope as still as possible to prevent obscure images during the

photoshooting. Tap or press the button on the handle of the endoscope for photoshooting,

and the icon will turn red and the screen will flash with a prompt "The photo has been saved successfully". The image has been updated, and you can tap the preview icon to view it.

3.3.2.4. Video recording: Tap the video recording icon to start recording, and the icon will turn red

 and a red signal point and the duration prompt will appear on the upper right corner of the

screen; tap again to end the video recording, and the signal point and duration prompt will disappear from the screen with a text prompt "The video has been saved successfully.

3.3.2.5. Storage path: After photoshooting or video recording, a unique date folder named after the operation date will be automatically generated.

3.3.2.5.1. If the patient ID is set: A folder named by the patient ID will be automatically generated in the date folder after photoshooting or video recording. For example, if the operation date is Sept. 17, 2020, and the patient ID is 12, the file path will be: >2020-09-17>12.

3.3.2.5.2. If the patient ID is not set: A "pictures" folder will be generated in the date folder after photoshooting, and the file path will be: >2020-09-17>pictures, where all image files are stored in PNG format. A "medias" folder will be generated in the date folder after video recording, and the file path will be: >2020-09-17>medias, where all video files are stored in MP4 format.

The photo & video files are named after consecutive numbers in the order of year, month, day, hour, minute and second.

The maximum allowable length of the video is 90 minutes (i.e. 4GB). Therefore, any video recording over 90 minutes will be automatically stored by splitting into two or more videos. When the available memory is less than 4GB, a text prompt indicating insufficient memory will appear on the screen.

3.3.2.5. Battery capacity: The battery capacity icon in the lower left corner can display 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 text prompt of insufficient battery capacity appears on the screen.and a lightning symbol appears in the icon when charging.

3.3.3. File Management interface: Tap the File Management button to enter the File Management interface. This interface 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	Function	Reference section
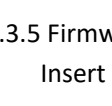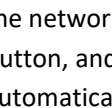
Icon	Name	Function	Reference section
	File management	Icon for the file management interface.	3.2.3
	File editing	You can tap the icon or long press a folder/file to enter the selection mode, and then perform multiple selection, editing, renaming, and deletion operations on the file or folder.	/
	Medical record	Used to edit the medical records	/
	Save	Used to save the current data	/
	Print	Used to print the medical records, where Wifi connection is required	/
	Erase	Used to erase the current data	/
	U-disk	You can select and move a file(s) or folder(s) to the U-disk. This button stays gray if no U-disk is connected, indicating this function is unavailable.	/

3.3.4. System setting interface: tap to enter the System Setting interface. This interface is used mainly for setting brightness, audio volume, time, user permissions, network and language, and viewing the equipment information.

	Description of file management-related icons		
Icon	**Name**	**Function**	**Reference section**

	System setting	Icon for the system setting interface.	3.2.3
	Screen adjustment	Used to adjust the brightness and audio volume	/
	Microphone	Used to enable or disable the microphone	/
	Calendar	Used to set the date and time	/
	System setting	Used to erase data, restore the factory settings, and set the user accounts	/
	Erase data	Used to erase internal files and user data	/
	Factory settings	Used to restore the factory settings	/
	User account	Used to set the user accounts	/
	Firmware update	Firmware update for system and APP	3.3.5
	Equipment information	Used to view the equipment information	/
	Network setting	Used to set languages, Wifi and mobile data	3.3.6.

3.3.5 Firmware update

Insert the U disk with the new system firmware or app into the USB port.in the system setting mode,click

the network setting button ,The system will automatically jump out of the dialog box, select the OK button, and enter the correct password in the new operation password dialog box. The system or app will automatically update the new system of the U disk. Until it's done.
Turn on the device again after shutdown, and the device will work according to the new firmware.
3.3.6 Network setup

In the system setting mode, click the network setting button ,you can setup connection with WIFI and local area network (LAN)
3.3.6.1 WiFi setting:
On the area of wifi setting,enabling the ON/OFF slider to the "on" position , the WiFi function is turned on, and Enter a valid IP address to connect to the network.

After the network is connected normally, the network connection symbol appears in the status bar of the screen

To turn off the WiFi function, you need to move the switch slider to the "off "position. After turning off the WiFi function, the device cannot transmit data through the network.

3.3.6.2 LAN setting

Plug the head end of the network cable into the Ethernet interface of the device, On the area of LAN setting, Enter a valid IP address to connect to the network.

After the network is connected normally, the network connection symbol appears in the status bar of the screen

To turn off the LAN function, you need to move the switch slider to the "off "position. After turning off the LAN function, the device cannot transmit data through the network.

Note: The network of the device is only connected to the private LAN. When connecting to the network, you need to know the security of the private network in advance. The update of the network settings needs to confirm the reliability. The unreliable network will cause a certain risk of data loss or function failure of the device,

3.4 After Use

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

3.4.2. Press and hold the power button for 3 seconds to turn off the product, and disconnect the power cable.

3.4.3. Clean and disinfect the product.

CHAPTER IV CLEANING, DISINFECTION, STORAGE AND DISPOSAL

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. Vathin Medical has validated these instructions according to AAMI TIR 12 and 30. 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.

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

4.1 Cleaning

1. Prepare the cleaning solution by using the standard enzymatic detergent prepared according to the manufacturer's recommendations. Recommended detergent: enzymatic, mild pH of 7–9, and low foam (Enzol or equivalent).

2. Dip the sterile gauze into the enzyme solution and ensure that the gauze is moist without dripping.

3. 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 6.

4.2 Disinfection

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

Solution: isopropanol (alcohol) 95%; concentration: 70–80%; preparation: add 80 cc of 95% isopropanol 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).

4.3 Storage

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

4.3.1. 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 up to 8 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.

4.4 Disposal

After the product's service life expires, you should remove the monitor, and dispose of the battery and the monitor separately according to local regulations by using the disposal equipment that meets appropriate national and local regulations.

CHAPTER V 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 machine
No image	The device cannot recognize the medical endoscope	Replacement of disposable medical endoscope,If there is still no image, please contact the agent for treatment
HDMI cannot output normally	The monitor is not compatible, the monitor is not set correctly	Follow the steps below: Re connect 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

The following cable information is given for reference only.

Cable	Max. cable length Shielded/unshielded		Qty.	Category
AC power cable	1.8 m	Unshielded	1 set	AC power supply
USB cable	2.8 m	Shielded	1 set	Signaling
DVI to HDMI 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's 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 product with the following basic performance is suitable for the professional medical environment, except for any places that is near the RF shielding room of the ME system for magnetic resonance imaging (MRI) with high electromagnetic interference intensity.

Basic performance

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

Warning: It is required to avoid using the product next to or stacked with other equipment; or else, 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.

Warning: When using any portable radio frequency communication equipment (including antenna cables, external antennas and other peripheral equipment), such equipment should not be placed over 30 cm (12 inches) away from any part of the product, including the cables specified by the manufacturer; or else, the performance of such equipment may be impaired.

Statements: 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 basic 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 basic performance.

The vertical-line flashing on the screen can automatically restore to the previous state.

EMI compliance (Table 1)

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 (Tables 2–5)

Table 2. Chassis ports

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		
870	800–960	Pulse modulation 18 Hz, 28 V/m
930		
1720		
1845	1700–1990	Pulse modulation 217 Hz, 28 V/m
1970		
2450	2400–2570	Pulse modulation 217 Hz, 28 V/m
5240		
5500	5100–5800	Pulse modulation 217 Hz, 9 V/m
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 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. Warranty and Replacement Policies

The warranty period of the product is one year after its delivery to the customer. If any proof of material or process error can be provided, Vathin Medical agrees to replace the product free of charge. To this end, Vathin Medical shall not bear any transportation cost or risk. If this option is feasible, Vathin Medical may repair the product due to material or process errors. Vathin Medical reserves the right to choose between repair and replacement options in each specific case.

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. In order to prevent infection, it is strictly forbidden to transport contaminated medical equipment. The medical equipment (the product or endoscopes) must be disinfected on site before being shipped to Vathin medical. The cleaning and disinfection procedures described in Chapter IV must be followed. Vathin Medical reserves the right to return contaminated medical equipment to the sender.

Appendix 3. Recommended combinations of equipment

Information on Monitor

Item	Recommended parameter
Screen brightness	≥ 300 cd/m²
Color gamut	BT.709 or SMPTE-C, 72% NTSC
Resolution	480/60 p,480/60 i, 576/50 p, 576/50 i, 720/60 p, 720/50 p, 1080/50 i, 1080/50 p, 1080/60 p, 1080/30 p, 1080/60 i
Monitoring technology	Bright LED backlight technology
Input signal type	DVI-D or HDMI Video bandwidth < 165 MHz TMDS: 600 mV for each differential line Input impedance: 50 ohm
Monitor size	8.5", 10", 15",19", 21", 24", and 26"
Contrast	≥ 1000/1

Appendix 4. <u>Information about wifi</u>

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.

(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.

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.

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frequency band
FCC/IC Certification:
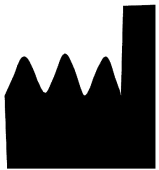
1：2.412-2.462GHz　2：5.15-5.25GHz　　3：5.25-5.35GHz

4：5.47-5.725GHz　　5：5.725-5.875GHz

CE 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

$C\epsilon_{0344}$

[Manufacturer Name, Registrant Name, and After-sales Service Provider]:
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[Production License Number and Product Technology Requirements Number]