**Vein Showing System** 

# Manual

Shenzhen YuanHua Medical Equipment Technology Co., Ltd.

The Vein Showing System Manual is written and compiled in accordance with the IEC 60601-1 (Medical electrical equipment Part1: General requirements for safety), and MDD 93/42/EEC.It complies with both international and enterprise standards and is also approved by State Technological Supervision Bureau.

The Manual, in accordance with the product features and needs, described the main structure, performance, specification and correct installation, usage, operation, repair, maintenance, hoisting, storage, etc. as well as the safety measures for protection of operator and the product. For details, please refer to the relevant sections.

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Software Name/Version No.: SZYH.MED.2017.V1.0 Icons in the Manual:

● Warning: Message used to prevent patient and operator from possible harms

 $\ensuremath{\textcircled{}^{\ensuremath{\oplus}}}$  Caution: Message used to prevent the Vein Showing System from damage

**Note:** Important tip for the relevant operation and use

# **Important Information**

Thank you for using our Vein Showing System. Pleased noted that the Manual shall be read carefully before using the Vein Showing System, and the requirements and operations in the Manual must be strictly followed. The Company shall bear no liability for any issues arising from any safety, reliability and performance problem as well as personal injury or device damage due to failure to comply with the requirements in the Manual of the Vein Showing System during the using, maintenance and storage! The Company shall provide no free repair for such problem either!

#### Warning:

- Never expose the instrument to any combustible and explosive gas.
- To ensure patient safety, please check whether the various mechanical fixing devices of the instrument are normal before use, to prevent the System from dropping onto the patient.
- Before use, always carry out safety check for the System, and ensure that it can be used safely and work normally.
- Before use, ensure that the System is correctly and reliably grounded.
- The device is not suitable for use in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide.
- The Vein Showing System is a device to be used separately, and clinically it is not intended to be interconnected or used with any other medical device.
- When carrying out magnetic resonance imaging (MRI) scan, please turn off the System.
- ◆<sup>™</sup> There is no patient circuit in this device. The output of the equipment is not allowed to be accessible to patient.
- The operator shall not touch the device and patient

simultaneously.

- Please carefully use the machine for patients who are allergic in IR light source at 650-950 nm or have a history of light allergy. Before using the instrument, clinicians or nurses should confirm whether the patient is allergic to light or has related history. Closely monitor the condition of patient during the procedure.
- The accessories of the System should not be replaced without authorization. To replace any accessory, use OEM product of the same model with same standard as the original. Otherwise the emission of the electromagnetic wave of the device or system may be increased, which reduces the immunity of the device for electromagnetic disturbance, resulting in negative consequences such as safety.
- Never open the device casing without authorization. It can only be opened by authorized service personnel only. When the casing is opened, the System parts might be damaged.
- If the System drops down accidentally or has any functional problem, please dispose without continue use. The user is recommended to send the System to the Company for complete safety and performance inspection, and it can be used again only when confirmed as conforming.
- For maintenance, disconnect the power supply first.
- Do not use the device near portable and mobile RF communication devices and instruments. Otherwise the normal operation of the device may be influenced.
- Keep the device away from any other electronic device to reduce electromagnetic disturbance to the device during operation.
- Do not use the instrument close to or stacked with any other device. If it must to do so, confirm that the instrument can operate normally first.

- Do not use the device in a room presented with any life support device, device having severe influence on the life or therapeutic effect of patients, low current measuring device or treatment device.
- As a professional medical instrument, the System can be used only by trained and qualified medical professionals. During the use, medical personnel shall not use the instrument as the only way to identify veins, and the instrument shall not be used to completely replace sound medical judgment and visual and tactile vein position judgment either.
- Do not dispose of electrical appliances as unsorted municipal waste, use separate collection facilities. Contact you local government for information regarding the collection systems available. If electrical appliances are disposed of in landfills or dumps, hazardous substances can leak into the groundwater and get into the food chain, damaging your health and well-being.

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# **Chapter 1. Overview**

#### **1.1 Product features**

The Vein Showing System series is a professional portable medical device for vein imaging. It is simple and convenient. Besides, it has the following features:

 $\diamond$  Clearly show surface veins on the basis of near IR light properties, so as to clearly identify veins, with a high resolution.

- ♦ Easy to operate, and one-key on/off.
- ♦ Light, simple and portable design.
- ♦ Low power consumption for the hardware
- $\diamond$  Invisible near IR light is used, having no harm to human body, and having no visible light pollution to the environment.
- ♦ Low battery warning.

#### 1.2 Name and Model

Name: Vein Showing System

Model: V-SHOW5, V-SHOW6, V-SHOW7, V-SHOW8, V-SHOW9, and V-SHOW10 The model differences are shown in the following table.

Difference	V-SHOW5	V-SHOW6	V-SHOW7	V-SHOW8	V-SHOW9	V-SHOW10
Appearance	Desktop	Desktop	Desktop	Handheld	Handheld	Handheld
Color	Sky blue	Rose red	Gray	Rose red	Sky blue	Gray
Structure	Including bracket	Including bracket	Including bracket	Not including bracket	Not including bracket	Not including bracket
Display	1.3"	1.3"	1.3"	1.3"	1.3"	1.3"
Battery low prompt	٧	v	٧	v	٧	V
Projection color options	v	v	v	v	v	v
Projection size options	٧	v	٧	v	v	v
Projection brightness options	v	v	v	v	v	v
Hair removal function	V	V	V	v	V	v
Overlap accuracy	٧	v	٧	v	٧	V
Resolution	V	V	V	V	V	V
Best imaging range	v	v	v	v	v	v

### 1.3 Scope of use

Observe and search subcutaneous superficial veins and help puncture in medical units.

#### 1.4 Using environment

- Working temperature: 5°C 40°C; Relative humidity: 30% - 83% (Non-condensation) Atmospheric pressure: 70kPa - 106kPa; Power supply: External power supply: AC100-240V, 50/60Hz Internal Li-ion battery: 7.4 V DC
- 2. The Vein Showing System should be placed in an area from direct sunlight, to prevent increase of temperature in the enclosure.
- 3. Store and use the instrument in the specified temperature, humidity and atmospheric pressure range. Anywhere out of the range will damage the System or the observation result is not accurate.
- If the System is moistened accidentally, it should not be directly turned on to prevent damage to the instrument. The instrument should be used after it is air dried up.
- 5. The System shall not be expose to toxic or combustible gas.
- 6. The System shall be fixed on a bench to prevent vibration.
- 7. The instrument is not suitable for using with any device other than those specified in the Manual.
- 8. Devices interconnected with the Vein Showing System should form an equipotential body (effective equipotential grounding connection).
- 9. One device for one patient only.

### 1.5 Impact on environment and energy

Low

### 1.6 Safety

- Comply with IEC60601-1 Medical electrical equipment -Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems;
- Comply with IEC60601-1-2 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests;

# Chapter 2. Structure Mechanism

# 2.1 Performance structure and composition of the product

The product mainly consists of the central processor, OLED display, camera module, projection module, Li-ion battery and near IR LED light source module.

# 2.2 Block diagram of the general structure



2.1: The block diagram of the general structure is shown in Figure

Figure 2.1 Block diagram of the general structural

The Vein Showing System series are modular products, consisting of integrated central processor, key operation module, control module, OLED display module, projection module, camera module and light module.

- 1. The key operation module turns on/off the machine.
- The control module sends out command to turn on the light module.
- 3、 The camera module acquires data, and feeds back information to the central processor.
- 4. The central processor processes data feedback, identifies veins and peripheral tissues before transferring the results to the projection module.
- 5、 The projection module projects the processed vein image to the skin surface of patient.

# Chapter 3. Installation and connection

# **3.1 Appearance**

# 3.1.1 Whole unit



Figure 3.1 Front view of the Vein Showing System

### (1) Main unit:

Main unit of the Vein Showing System: For details, refer to Section 3.1.2.

- (2) Base tightening knob
- (3) Knob fixing the main unit

- (4) Bracket
- (5) Cable fastener
- (6) Desktop base

Note: Item (2),(3),(4),(5) and (6) above are not applicable to Model V-SHOW8, V-SHOW9, and V-SHOW10.

# 3.1.2 Main unit



#### Figure 3.4 Front view of the main unit

#### (1) Power key:

Press the power key for 1 second to turn on the System. The OLED display will go on to start it.After about 5-8 seconds, it will enters into the home interface. Press the key again to turn off the Vein Showing System, and the power indicator goes off.

### (2) Battery indicator:

When battery is used for power supply, the battery indicator goes on.

- (3) **Display screen:**
- (4) Hair removal function/projection brightness selection key:

The hair removal mode is default. Press the key to reduce the picture noise points. Press and hold the key for over 1 second to switch to the brightness adjustment mode. Press the key to cycle in the projection picture brightness, and the brightness levels are Level 1, 2, 3, and 4 are shown on the display with icon.

# (5) **Projection size selection key**

Press the key to switch the projection size, and the default resolution is 640\*480.

### (6) Color selection key

Press the key to switch the background color of the projection picture among blue, pink, white, and reverse color. The default color is blue.

### (7) **Power indicator**

When the main unit is connected to AC power, the indicator remains on.

# (8) Indicator color and flash indication instructions

- $\diamond$  Indicator color: Blue
- $\diamond$  Power indicator on: The instrument is connected to AC power.
- ☆ Battery indicator on: The instrument is not connected to AC power and only battery is used for power supply.

### Note:

# $\hfill\square$ Do not hang anything on the instrument to avoid any impact on the device.

# 3.1.3 Left and right side of the main unit



Figure 3.6 Left view of the Vein Showing System



Figure 3.7 Right view of the Vein Showing System

(1) Ventilation hole of the main unit:

### Note:

 $\buildrel \ensuremath{\underline{\circ}}$  Do not block the ventilation hole for any influence on ventilation.

# 3.1.4 Back and terminal of the main unit



Figure 3.8 Back view of the main unit

- (1) Locker slot of the main unit
- (2) Nameplate on the unit
- (3) **Battery cover:** The standard delivery of the machine include a 7.4 V DC 2600 mAh rechargeable Li-ion build-in battery.

#### Note:

- Users are not encouraged to replace the battery currently. For any battery replacement, send the main unit to the instrument manufacturer or contact the instrument manufacturer or the region dealer for replacement by after-sales personnel on site. Never remove the battery without authorization, to prevent safety risks.
- For safety, please ensure the battery is away from moisture and fire. Do not knock or impact the battery with sharp object or external force.
- (4) Ventilation hole of the main unit
- (5) Near IR LED: Emit near IR light to the surface skin of patients.

- (6) **Projection window:** Project the screen picture processed by the instrument to the surface skin of patients.
- (7) Near IR LED: Emit near IR light to the surface skin of patients.

Note:

For the safety and operation of the device, do not touch the "Projection window", "Camera window" and "Near IR LED" of the instrument with any sharp object. Keep the lamp and window clean.



Figure 3.9 Terminal view of the Vein Showing System

(1) **Power socket on terminal of the main unit:** The power socket can be connected with the adaptor supplied as a standard to recharge the built-in battery.

# 3.1.5 Others

- (1) Power adapter:
- G For the safety and operation of the device, do not damage the adapter with any sharp object, and never

step on it. In case of any problem, please contact the manufacturer or region dealer.

- (2) Fuse: 0466002.NR 1206 2A
- (3) SYMBOL DESCRIPTIONS:

The following symbols may appear in this manual, on the device, or on it's accessories. Some of the symbols represent standards and compliances associated with the Vein Showing System and its use.

- < ▲▲▲

Manufacturer

Indicate "Caution". Please refer to the supplied documents.



Refer to instruction manual / booklet



Indicate AC power

∻

Specifies serial number

DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary

#### Installation 3.2

#### Unpacking and check 3.2.1

1. Open the packing box, carefully take out the main unit and accessories. Place or install the Vein Showing System in a safe, stable and easy-to-observe position.

2. Open the supplied documents and check the accessories against the packing list:

- Check the main unit for any mechanical damage.
- Check all spare parts for scratch or missing, including the plug and wire.
- Before use, check the instrument, accessory, etc. for hazards or abnormal conditions. In case of any abnormality (for example, broken cable, cracked enclosure, etc.), do not measure with it.

In case of any problem, contact the dealer or the Company.We will provide satisfactory services for you.

# **3.2.2** Connecting to the power

1. Procedures to connect the AC power cord:

- Confirm that the AC power meets the following specifications: 100-240 V AC, 50/60Hz.
- Use the power cord supplied with the Vein Showing System. Plug the power cord in the grounded single-phase power outlet.
- To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth

2. Power supply with rechargeable Li-ion battery

When the external AC power is shut off, the instrument is powered by the internal battery for the device to operate normally, until battery low voltage displays, i.e., after the battery indicator flashes for 10 minute, the remaining battery power is not enough for the instrument to operate normally, the instrument will be turned off automatically.

- After long-distance transportation or long-term storage, the battery may be fully discharged due to static power consumption. Therefore, If the instrument cannot be turned on with the battery, the battery must be recharged, normally for 2-3 hours.
- The user must check that the equipment functions safely and see that it is in proper working condition before being used.

# 3.2.3 Power on

Press the power key. The system will be available after the successful self detection.

- If battery is equipped, it must be recharged after use every time to ensure enough battery power.
- If any sign of functional problem of the Vein Showing System is found, or any error message is prompted, never use the Vein Showing System. Please directly contact the dealer or the Company.

# Chapter 4. Use and operation

# 4.1 Home interface

When the power key is pressed, the instrument carries out self test and is powered on to enter into the welcome interface as shown in Figure 4.1. After 5-8 seconds, the instrument enters into the home interface, as shown in Figure 4.2.



interrace

 $\diamond$ 

# 4.1.1 Description of the powering on interface

- ☆ "YuanHua Medical Welcome": Welcome to use instrument from Shenzhen YuanHua Medical Equipment Technology Co., Ltd.
- ♦ "SZYH.MED 2017.V1.0": Software Version.

# 4.1.2 Description of the home interface

♦ "SZYH.MED": The manufacturer.

Battery level display, which is shown when the power is supplied by the battery.

Projection brightness display,
 Projectively.

- "COLOR": Projection color indicator, with the default color to be 'blue'. The projection color can be selected with the 'Color' key, and the optional colors are blue, pink, white, and reverse color.
- 640\*480: Projection resolution indicator, default resolution as 640\*480. The'Size' key can be used to select, and the optional sizes are 640\*480, 120\*320, and 480\*640.
- ♦ "Hair removal": Hair removal function prompt.

# 4.2 Operation Introduction

 By default, the instrument enters into the blue mode, as shown in Figure 4.3. The "Color" key can be used to select the projection color, as shown in Figure 4.4, Figure 4.5 and Figure 4.6 below. The optional colors are pink, white, and reverse color.



Figure 4.3 Blue mode



Figure 4.5 White mode



Figure 4.4 Pink mode



Figure 4.6 Reverse color mode

♦ Press the "Projection size" key, and the user can switch to the small size mode, as shown in Figure 4.7. Press the key again to restore the basic mode.





Figure 4.8 Projection size illustration 120\*320

Figure 4.9 Projection size illustration 480\*640

The hair removal mode is default. Press the key to reduce the picture noise points. Press and hold the key for over 1 second to switch to the brightness adjustment mode. Press the key to cycle in the projection picture brightness, and the brightness levels are Level 1, 2, 3, and 4, which are shown on the display with icon.



Do not position the equipment so that it is difficult to operate the disconnection device.

# **Chapter 5. Technical Features**

1、 Power supply:

External power supply: 100-240V AC, 50/60Hz Built-in Li-ion battery: 7.4 V DC

2、Input power: 35VA

3、Display mode: OLED LCD, and DLP projection

4 > Overlap accuracy: Vertical offset  $\leq$  0.3mm and horizontal offset  $\leq$  0.3mm for 20-26cm.

5、 Minimum resolution: Test line at an interval of 0.6mm identifiable for 20-26cm.

6、Best imaging range: 20-26cm.

7、Classification

Safety standard: IEC 60601-1

The type of protection against electric shock:ClassI equipment.

Electro-Magnetic Compatibility: Group I, Class A

The degree of protection against harmful ingress of water: Ordinary equipment without protection against ingress of water.

The safety degree of flammable gas: Not suitable to use in the environment where flammable gas exits.

# Chapter 6. Dimensions and Weight

# 6.1 Pack and weight

The packing box is high quality corrugated carton box with foams inside to prevent any product damage. Gross weight: Refer to the outer packing box. Packing dimensions: 440mm (L) × 310mm (W) × 145mm (H)

# 6.2 Accessories

(1) Power cord	1 pc
(2) Adaptor	1 pc
(3) Cleaning cloth	1 pc
(4) Desiccant	2 bags
(5) Certificate of Conformity	1 pc
(6) Manual	1 pc

Note: The above accessories depend on the functions and configurations of the instrument. For details, refer to the packing list for the instrument.

# Chapter 7. Working Principle of the Vein Showing System

# 7.1 Working principle

On the basis of the fact that oxygenated hemoglobin in peripheral tissues and veins has different adsorption of near IR light at different wavelengths, optical / electrical conversion is carried out for the information, and images are processed, and the veins are finally shown on the screen for observing and searching subcutaneous superficial veins and helping puncture.

# 7.1.1 Human hemoglobin absorption spectra in near IR

The near IR spectrum features of oxyhemoglobin and deoxyhemoglobin are shown in Figure 7.1: The principle to select the incident light wavelength is: Minimize the absorption rate of substances except hemoglobin, and maximize the absorption rate of hemoglobin, so as improve the signal to noise ratio. As shown in Table 7.1, the measurement wavelength between 760 nm - 900 nm should be selected, but 760 nm and 850 nm are located near the absorption peak of deoxyhemoglobin and oxyhemoglobin respectively, which are very ideal wavelength of choice.



Figure 7.1 Hemoglobin and oxyhemoglobin to oxygen

葡萄糖	水	脂肪	蛋白质
714nm	749nm		
		770nm	
939nm		920nm	910nm
	980nm		
1126nm	1211nm	1040nm	1020nm

absorption peak

Table 7.1 Absorption peak of main human ingredients in near IR region

# 7.1.2 Image acquisition and processing

Near IR lens has to generate image at a wavelength of 700-1000nm, so as to gather the reflected near IR lights and generate images; as shown in Figure 7.1, the spectral response curve of CMOS photo detector is responsible for converting the collected electrical signals into charge signals and temporarily storing them in the memory, and then the signals can be read out with clock pulse by sequence. When the electrical signals are amplified by automatic gain control and then converted with adc to digital signals, digital processing can be carried out. It is when the digital signals can be stored in memory. On the other hand, when digital processing is carried out for images, they are sent to the display system, and the LCD display can display the surface distribution images of veins.



Figure 7.2 CMOS response spectrum Curve



Figure 7.3 CMOS camera acquisition flows

# **Chapter 8. Common Troubleshooting**

### 8.1 The unit cannot be turned on normally.

When the external power supply is not connected, the unit is turned on and it shows "Low battery", it indicates that the battery is used up. Please recharge the battery in time. When the unit cannot be turned on in any other situations, please directly contact the local dealer or the Company. Users are not allowed to open the enclosure without authorization.

# 8.2 The unit can be normally turned on, but the image quality is poor.

The near IR light source does not work normally or is out of the service life. Please directly contact the local dealer or the Company. Users are not allowed to open the enclosure without authorization.

# **8.3** The power indicator indicates that the unit is turned on, but the LCD display has no display.

Check the LCD display for damage during transportation or by accident. If it is normal in the above check, please directly contact the local dealer or the Company.

Note: If the device has any problem during use and the problem is not solved after carrying out check as above, please directly contact the local dealer or the Company. Users are not allowed to open the enclosure without authorization.

# Chapter 9. Maintenance and Repair

To ensure normal operation of the Vein Showing System and extend its service life, pay attention to maintenance and service of the Vein Showing System. For the warranty period for the main unit and parts of the System, refer to the sales contract for details. For the date of manufacturing of the Vein Showing System, refer to the product nameplate for details.

# 9.1 Maintenance check

# 9.1.1 Daily check

Before using the System, carry out the following check:

- Check the main unit for any mechanical damage;
- Check all parts for scratch or missing, including plugs and wires;
- Check all functions available for patients, ensure the instrument is in good working conditions;
- Note the fluctuation of the local power supply. If the fluctuation is out of the allowable range, it is recommended to add one voltage stabilizing device.

If any sign of damage to the Vein Showing System is found, please contact the dealer, or contact the Company, and we will provide you with satisfactory services in time.

# 9.1.2 Regular check

The design service life of the Vein Showing System is 5 years. For the date of manufacturing of the product, refer to the nameplate. During the long-term service, it is recommended to ensured the accuracy by calibrating the System once per year (or in accordance with the calibration schedule in the hospital). We will also provide calibration by request.

After repair every year or every time, a complete check must be carried by qualified personnel for the Vein Showing System, including the functions and safety.

- If a sound repair schedules can not be in place, the functions of the Vein Showing System may fail.
- If any cable has any sign of damage or aging, do not use or replaced by a new one.
- A Various adjustable components in the unit cannot be adjusted without authorization, to prevent avoidable problems and influence on normal use.
- A No modification of this equipment is allowed.

# 9.1.3 Battery maintenance

- ●<sup>™</sup> Do not replace the battery. Please contact the manufacturer or regional dealer for the service.
- ●<sup>™</sup> Do not insert any battery not specified by the manufacturer into the slot;
- ●<sup>™</sup> Do not recharge the battery with any other power device;
- ♦<sup>™</sup> When the battery is aged, do not throw it into a fire which might result in exploration;
- Do not power any other electric device with the battery;
- ●<sup>™</sup> Do not power the instrument with the battery at an ambient temperature below 0°C or above 45°C;
- Recycle or dispose of the lithium battery in accordance with all federal, state and local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.
- △ Please correctly use and maintain it for extended life.

When the instrument is not used for a long time, the battery must be regularly recharged. Normally the battery must be recharged once 1-2 months, and it takes 2-3 hours to fully recharge every time. When recharging, whether the instrument is turned on or not, the recharging speed is substantially the same. If the instrument is not used for a long time, please fully recharged before storing.

General Antipology Antip

# 9.2 Cleaning, sterilizing and disinfecting the Vein Showing System

- 1. The Vein Showing System should be kept from dirt.
- 2、Keep it clean. It is recommended to clean the enclosure surface and the display screen. Clean the enclosure with non-corrosive detergent, such as water.
- 3、 Camera lens surface and acrylic working surface can be wiped with medical alcohol and air dried up or cleaned with clean and dry cloth. Never wipe off the camera lens with hard object or any other corrosive liquid.
  - Before cleaning the Vein Showing System, always turn off the instrument and disconnect the AC power.
  - Be careful not to drop any cleaning liquid into the connecting socket.
  - When cleaning the System, only wipe the surrounding of the connector, but never wipe its inside.
  - A Most detergents must be diluted before use.

  - A Be careful not to drop any liquid into the

enclosure, and never dip any part of the device into any liquid.

- A Never leave any detergent and pesticide on the machine surface.

# 9.3 Cleaning, sterilizing and disinfecting parts of the Vein Showing System

When the spare parts of the product are used, a dry and clean piece of gauze can be soaked with medical alcohol at a concentration of 75% or isopropanol solution at a concentration of 70%, and then the surface of all the parts can be cleaned with the gauze.

- **●**<sup>™</sup> Do not continuously use any damaged part of the System.
- Do not soak any part of the System completely in water, solution or detergent.
- ●\* Do not sterilize any part of the product with X-ray and steam.

# 9.4 Storing the Vein Showing System

If the System will not be used for a long time, it should be cleaned and stored in the packing box and stored in a dry, dust free, non-corrosive and well ventilated room.

Storage environment:

Environmental	Main unit: -20℃-55℃
temperature range:	Battery: $-20^{\circ}C-60^{\circ}C$ , for less than one month $-20^{\circ}C-30^{\circ}C$ , for more than six months
Relative humidity range:	Main unit: 10% - 93% (Non-condensing); Li-ion battery: < 75%

Atmospheric 53kPa-106kPa pressure range:

# 9.5 Transportation

Road, railway, and air transportation can be used, depending on the provisions in the contract. Be careful to handle during transportation.

Transportation environment:

Environmental	Main unit: -20℃-55℃; Li-ion battery:
temperature range:	-20℃-60℃
Relative humidity	Main unit: 10% - 93%
range:	(non-condensing); Li-ion battery: <75%
Atmospheric pressure range:	53kPa-106kPa

# A Table of name and content of toxic and harmful substances or elements

	Toxic and harmful substances or elements						
				Hexaval	Polybro	Polybro	
Name of part	Lead	Mercu	Cadmi	ent	minated	minated	
	(Pb)	ry (Hg)	um (Cd)	chromium	biphenyl	diphenyl	
				(Cr6+)	(PBB)	ether (PBDE)	
Enclosure part	0	0	0	0	0	0	
Printed circuit assembly	×	0	0	0	0	0	
(PCA)*							
Cable and connector	0	0	0	0	0	0	
Display technology/lamp	0	0	0	0	0	0	
tube							
Power supply device	0	0	0	0	0	0	
Power cord	0	0	0	0	0	0	
Mechanical part - Bracket	0	0	0	0	0	0	
Mechanical part - Fan	0	0	0	0	0	0	
Mechanical part - Other	0	0	0	0	0	0	
Spare parts	0	0	0	0	0	0	

\*: Printed circuit assembly includes all printed circuit boards (PCB) and their own single assemblies, ICs, connectors, etc.

O: The content of toxic and harmful substances in the homogeneous materials of the part i below the limit defined in SJ/T11363-2006 standard.

×: Indicate that the content of the toxic and harmful substance in at least some homogeneou material of the part exceeds the limit specified in SJ/T11363-2006 standard; and parts marked with "x" in the above table cannot be replaced currently due to current technical reasons, and late improvements will be made gradually.

Attachment Table 1

# **B** EMC

**EMC** Declaration

1)The Vein Showing System is suitable for hospitals except for near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.

- 2)The Vein Showing System needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.
- Performance of the Vein Showing System such as Contraposition Accuracy, Resolution, and Optimal Imaging Range would be lost or degraded due to EM DISTURBANCES.

4) Caution: the Vein Showing System should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Vein Showing System should be observed to verify normal operation in the configuration in which it will be used.

5) Caution: don't use of accessories, transducers and cables other than those specified or provide by the manufacturer of this equipment, that could result in increased electromagnetic emissions or decreased electromagnetic immunity of the Vein Showing System and result in improper operation. 6) Caution: 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 Vein Showing System , including cables specified by the manufacturer.
Otherwise, degradation of the performance of this equipment could result.

7)Caution: The EMISSIIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals(CISPR 11 class A).If it is used in a residential environment (for which CISPR 11 class B is normally required)this equipment might not offer adequate protection to radio-frequency communication services.The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

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