PROFESSIONAL MEDICAL PRODUCTS

RILEVATORE DI VENE PROFESSIONALE QV-500

QV-500 PROFESSIONAL VEIN FINDER

MANUALE D'USO – USER MANUAL

• È necessario segnalare qualsiasi incidente grave verificatosi in relazione al dispositivo medico da noi fornito al fabbricante e all'autorità competente dello Stato membro in cui si ha sede.

• All serious accidents concerning the medical device supplied by us must be reported to the manufacturer and competent authority of the member state where your registered office is located

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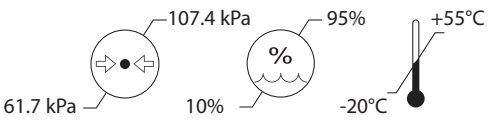
REF **QV-500**



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1 - Overview

1.1 Intended Use

Vein finder can help medical professionals to locate certain superficial veins. This equipment is intended to be used as a supplement to appropriate medical training and experience. It should not be used as the sole method for locating veins. And should be used only by a qualified medical professional, who should do so either prior to palpation to help identify the location of a vein, or afterwards to confirm or refute the perceived location of a vein. When using the device, medical practitioners should always follow the appropriate medical protocols and practices as required by their medical facility, as well as exercise sound medical judgment.

When used properly, it enables users to locate certain superficial veins in connection with medical procedures, such as venipuncture.

This vein finder can be used whenever the determination of vein location is appropriate such as hospitals and clinics.

1.2 Product Description

Using the Vein FInder allows you to significantly speed up the puncture and cannulation procedure.

Vein finder operates by using infrared light to detect only veins beneath the skin, then projecting the position of the veins on the skin surface directly above the veins. Qualified medical personnel can observe the vasculature as displayed to assist them in finding a vein of the right size and position for venipuncture and other medical procedures requiring the location of superficial veins. No training is required to operate this device.

The device only shows superficial vasculature. The maximum depth that veins are displayed varies by patient. In addition, some patients' veins or a portion of their veins might not be displayed well or at all. Causes for less than optimal or lack of vein display include, but are not limited to, vein depth, skin conditions (e.g., eczema, blemishes, scars, tattoos), hair, scarring or other highly contoured skin surface, and adipose (fatty) tissue.

Remember not to point the light source directly into the eyes of the patient or professional

When held directly overhead, the device accurately locates the center of a vein. Increasing the displacement from directly overhead results in an offset in the displayed vein position. Width of displayed vein may differ from the actual width depending on patient to patient differences and vein width. The center line of the vein is accurate when the device is being used correctly and should always be used as the target when performing venipuncture or other medical procedures.

Vein finder is portable machine. And the optional is table stand and mobile stand.

1.3 Use and Operation

Hold the device from 25 to 35 cm over the surface of the skin. Scan the area of interest to view. Once a vein is selected, make sure the vein display light is centered directly above the vein's center line. Tilting the device to either side of the vein will offset the projected vein from its true location beneath the skin. You can often enhance display quality by slightly adjusting the height and angle to the skin. In particular, moving the device closer or further from the skin can help bring additional veins into view, depending on the patient's vasculature, room lighting, and depth of the veins.

While the vein display light is on, shine the device over the patient's skin. You can do this before palpation, use sport mode scanning quickly over the skin to help narrow down possible locations. After confirming suitable vein location, you can change to enhance mode to find the deep veins.

After assessing the patient's vasculature, confirm the site for your procedure by verifying the location and suitability of the vein using normal medical techniques and good medical judgment, such as vein visualization, palpation, and other medical techniques.

2 - Safety

WARNING:

- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and / or patient is established
- All devices, medical and non-medical, operating on the basis of high frequency can cause interference in the operation of the device. Use Finder away from such devices
- If the available electric network is not equipped with an earthing system, use only the battery power supply.
- Do not allow the patient's body to come into contact with the device
- This Finder does not show the location of the arteries. It only visualizes the veins.
- A medical device is not intended for diagnosis or treatment
- The product is not waterproof, if you suspect that a liquid has entered the device, stop using it.
- Before each use, check all components and accessories of the device, including the power cord, power adapter. In the event of any damage, please discontinue use of the product and contact QUALMEDI after-sales service or your local supplier.
- Only use the dedicated accessories supplied by QUALMEDI.
- The battery of this device is replaceable. If you do not plan to use the device for an extended period of time, charge the battery to 100% and remove it from the device.
- The device and accesorry should be operated, stored and transported in accordance with the provisions of the operating manual.
- The device must not be used in a flammable or explosive environment or in the vicinity of flammable or explosive materials

- Dispose of the device, accessories and battery according to local regulations.
- Do not:
  upgrade software;
  open shell of device;
  replace battery with different model
  try to repair the device.

The manufacturer, authorized representative, importer and distributor are not liable for damages caused both during and after this process.

- If the device could suffer mechanical damage (as a result of impact, fall, flooding, etc.), please contact the local supplier and arrange for an inspection to exclude any damage inside the device.

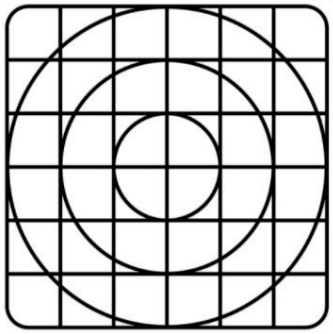
CAUTION:

- The device or change its settings.
- The device cannot be used only on the mains power supply (without the battery installed)
- If you have any comments regarding the device, please inform your local dealer or QUALMEDI after-sales support.

3 - Product Specifications

Name	Vein Finder
Model	QV-500
Dimensions	200 (L) x 55 (W) x 60(H) mm
Weight	About 0.3kg
Power Adapter	Input: 100-240Vac 50/60Hz 0,4A Output: 5V, 2A
Battery	Built-in lithium battery: 3.6V, 3000mAh Battery model: 18650-319 Continuous operation duration of the lithium battery: not shorter than 2.5 hours Time required for fully charging an exhausted lithium battery: not longer than 3 hours (the device is powered off during the charge) Charge mode of the lithium battery: The battery can be charged using a power adapter when AC input is available.
Display Mode	Projection mode
Light Source Type	Near-infrared light
Infrared Wavelength	850nm dual light sources
Optimal Focus Position	250mm±50mm
Depth of Field of Imaging	7-9mm
Infrared Radiation Energy	≤0.6mW/m
Operating Conditions	Temperature: 5°C~40°C Humidity: 20%~90% RH, non-condensing Pressure altitude: 70~106.0kPa
Storage and Shipping Conditions	Temperature: -20°C~+55°C Humidity: 10%~95% RH, non-condensing Pressure altitude: 61.7~107.4kPa
Service Life	5 years
Classification	1. Class I/Internally powered equipment; 2. IPX0; 3. Not sterilized; 4. Not category AP/APG equipment; 5. Mode of operation: continuous
Date of Manufacture	See the product label.
Main Safety Standards	IEC 60601-1:2012 Medical Electrical Equipment, Part 1: General Requirements for basic safety and essential performance IEC 60601-1-2:2014 Medical Electrical Equipment - Part1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility-Requirements and tests

4 - Installation Description



Calibration Card

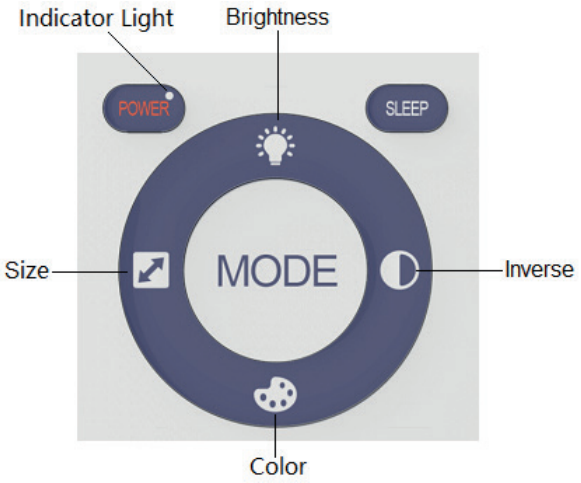
If the project image have deviation comparing card line. Please contact the supplier or manufacturer.

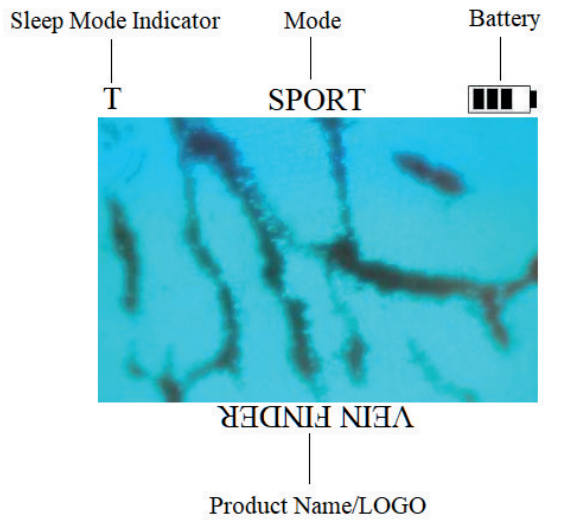
The machine needs to be checked weekly to see if it needs to be recalibrated

5 - Operating Instructions

In the sport mode, a picture is collected and projected in every frame. In the enhance mode, many pictures are collected and intermittent veins in the picture are connected into a complete vein through image processing, so the display frame rate will decrease

Operating Instructions – Functionality of Buttons





Power	POWER	Press the button to power or off the device
Sleep	SLEEP	As for default setting, machine enter sleep mode automatically when there is no operation for 10 mins. As for manual setting, Short press make machine enter low energy consumption mode immediately. Long press for 3 seconds makes machine enter never sleep mode, which be shown no 'T' projected in top left corner.

Mode	MODE	Enhanced mode to improve vessel clarity. Sport mode for the quick response. Mode indicate on the top of projection image.
Brightness		7 Levels of brightness. Adjust projection image to the most comfortable level.
Size		5 Sizes Available. Suitable for adults, children and newborns.
Inverse		Inverts the dark and light projection areas such that veins can be depicted by either light or dark. Changing the inverse setting may improve vein visibility.
Color		10 Colors Available. Suitable for different skin colors or operating environments.
Indicator Light		Blue: Working; Green: Fully charged; Red: Charging Red Blinking: Insufficient battery power. (Less than 10% battery capacity)

6 - Common Faults

The device is connected to the power supply, but it is not turn on

Possible cause:

a. The connection to the power supply is defective or the power supply is damaged and there is no voltage in it

b. As a result of using a non-dedicated power supply, the motherboard was damaged

Check method:

a. Check the correctness of the connection between the device and the power supply by verifying that the information diode is permanently illuminated

b. Try to start the device with the power supply disconnected from the device (Battery takes over all power)

The image from the projector is out of focus or there are artifacts in the image

The optical lens is grubby.

Clean optics as mentioned in chapter 7.2

The wire finder does not work when power is supplied only from the battery

Storing the battery in humid conditions may damage it or the battery is discharged

Connect the vein finder to the power supply to charge the device battery. The diode turns off when the battery is fully charged. If the device still cannot be turned on, please contact the QUALIMED technical department.

The battery discharges faster than expected in continuous operation.

The battery charge is too low or far from full. Battery life also diminishes over time due to physical constraints.

Check the battery by connecting it to charging. The flashing diode informs about the ongoing charging process, and when it goes out completely, the process is finished. As the charge and discharge cycles increase, the continuous operating life of the battery naturally slowly decreases. When this time is no longer acceptable, please contact the QUALIMED technical department. (How to replcae the battery: Open the back cover of the battery, take out the original battery, and put the new battery into the battery compartment.)

The device does not respond to user commands or freezes

The temperature of the device has risen to higher values through a long time of continuous operation

Turn off the device and wait a long time until the internal temperature returns to normal

7 - Cleaning and Disinfection

7.1 Preparations

1. To clean and disinfect, turn off the vein finder and disconnect it from the power supply.
2. For the sake of your own health, all operations should be performed with rubber gloves and a face mask.
3. Only the external surfaces of the device should be cleaned and disinfected. It is forbidden to disassemble the device on your own. If necessary, please contact the service.
4. Follow the instructions!

7.2 Cleaning

Do not put the device in detergents.

Do not allow the detergents to come into contact with the electronics of the device.

Do not use any harsh detergents such as, for example: acetone, glass detergent, halogenated or petroleum based solvents.

Only manual cleaning is advisable, it is forbidden to use automatic cleaning mode.

1. Wipe the outer parts of the device with squeezed gauze, previously dipped in a detergent solution with a neutral or slightly alkaline pH.
2. Wipe the device until it is completely clean.
3. To clean the optics, use a piece of optical lens cleaning paper with a few drops of ethyl alcohol. Do it only one way.
4. Do not forget to clean the end parts of the device.
5. After cleaning, use dry gauze to wipe off any remaining cleaning solution.

7.3 Disinfection

- Do not put the device in disinfectants.
- Do not allow the disinfectant to come into contact with the electronics of the device.
- Do not autoclave the device.
- The only permissible disinfection method for the device is manual disinfection.

1. Before starting the disinfection process, clean the device in accordance with section 7.2.
2. The device should be wiped with medical gauze, then dipped in a disinfectant. Agents with high or medium disinfection efficiency are allowed.
3. It is recommended to wipe the entire exterior of the device. The instructions for use of the disinfectant, in particular - the contact time of the disinfectant with the device, must be followed.
4. To clean the optics, use a piece of optical lens cleaning paper with a few drops of disinfectant. This should be done gently.
5. Do not forget to disinfect the end parts of the device.
6. Finally, wipe the device with a soft medical gauze, dipped and then squeezed out of clean water.

Do not use a dryer or items similar to drying the vein finder.

The device may only be connected to the power supply after it is completely dry.

When cleaning and disinfection is complete, place the vein detector in a cool, ventilated place out of direct sunlight to dry it.

If the device is not to be used immediately after it is dry, it should be stored in its original packaging.

8 - Maintenance

Regular maintenance and inspection of the device is essential to maximize its lifetime and ensure safety during use.

8.1 Appearance Check

Check the external condition of the device for cracks or other damage.

Check whether the buttons are functioning properly and whether it is comfortable to click them.

The appearance and keys of the machine should be checked once a week to see if there is any damage

8.2 Power Adapter and Power Cable Check

Visually assess the external technical condition of the cable and the power supply. Please contact your distributor for repair if any damage to the surface or contact problems of the plug and socket are found.

Contact the distributor for repair if it is not possible to start the device or if the indicator does not show the correct operation of the AC / DC adapter.

Power adapters and data cables should be checked monthly

8.3 Electrical Safety Test

The safety check complies with IEC60601-1. Dielectric strength test, ground impedance test and leakage current test should be performed.

It is forbidden to store the device in excessively hot or humid places.

Do not store the device near dust and gases that can cause corrosion. Avoid vibrations.

Avoid places with high sun exposure and ultraviolet light to prevent the possibility of color fading.

The device can be transported in a common vehicle, but protection against excessive vibrations and mechanical damage should be ensured. It must be protected against rain, snow and other weather conditions. The contractual transport requirements must be adhered to.

Consult your distributor for recycling your decommissioned device. Alternatively, disposal of the device and batteries should be carried out in accordance with national regulations.

Packing List

No	Name	Quantity
1	Main Machine	1
2	Charging cable	1
3	Charging adapter	1
4	Aluminum Carrying Case	1
5	User's manual	1
6	Calibration card	1
7	Product certification	1
8	Warranty card	1

Guidance and manufacturer's declaration - electromagnetic emissions		
The QV-500 mu is intended for use in the electromagnetic environment specified below. The customer or the user of the QV-500 should ensure that it is used in such an environment.		
Emissions test	*Compliance*	*Electromagnetic environment -guidance*
RF emissionsCISPR 11	*Group 1*	This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likelyto cause any interference to nearby electronic equipment.
RF emissions CISPR 11	*Class A*	

Harmonic emissions IEC 61000-3-2	*Class A*	This device is suitable for use inprofessional healthcare facility environment.
Voltage fluctuations /flicker emissions IEC 61000-3-3	*Complies*	

Guidance and manufacturer's declaration - electromagnetic immunity			
The QV-500 mu is intended for use in the electromagnetic environment specified below. The customer or the user of the QV-500 mu should ensure that it is used in such an environment.			
Immunity test	*IEC 60601 test level*	*Compliance level*	*Electromagnetic environment - guidance*
Electrostatic discharge (ESD) IEC 61000-4-2	+/– 8 kV contact +/– 15 kV air	+/– 8 kV contact +/– 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
	At 8 kV and 15 kV air discharge a temporaly degradation of performance can occur resulting in a loss of function . Within several minutes performance is restored. Basic safety is guaranteed. The user is advised to contact Diagnoptics technical support.		
Electrical fast transient/ burst IEC 61000-4-4	+/– 2 kV for power supply lines	+/– 2 kV for power supply lines	Mains power quality should be that of a typical hospital en- vironment.
	Temporarly degradation of performance can occur resulting in a loss of function. Basic safety is guaranteed. The user is advised to contact Diagnoptics technical support.		
Surge IEC 61000-4-5	+/–1 kV line(s) to line(s)	+/–1 kV line(s) to line(s)	Mains power quality should be that of a typical hospital environ- ment.
Voltage dips, short interruptions and voltage variations to power supply input lines IEC 61000-4-11	0% U_T for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T for 1 cycle 70% U_T for 25/30 cycles 0% U_T for 250/300 cycles	0% U_T for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T for 1 cycle 70% U_T for 25/30 cycles 0% U_T for 250/300 cycles	Mains power quality should be that of a typical hospital en- vironment. If the user of the vein Finder requires continued operation during mains power interruptions, it is recommended that the vein finder is powered from an uninterruptible power supply or a battery. U_T is the AC. mains voltage prior to application of the test level.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital environment.
Conducted RF IEC 61000-4-6	3 V 0,15MHz to 80 MHz 6 V in ISM bands between 0,15 MHz & 80 MHz 80 % AM at 1 kHz	3 V 0,15MHz to 80 MHz 6 V in ISM bands between 0,15 MHz & 80 MHz 80 % AM at 1 kHz	Portable and mobile RF com- munications equipment should be used no closer than the re- commended separa- tion distance calculated from the equation applicable to the frequency of the transmitter to any part of the vein finder, including cables,.

Immunity to RF wireless communication equipment						
The QV-500 mu is intended for use in the electromagnetic environment specified below. *The customer or the user of the QV-500 mu should ensure that it is used in such an environment.*						
Test frequency (MHz)	*Band (MHz)*	*Service*	*Modulation*	*Maximum power (W)*	*Distance(m)*	*Immunitytest level (V/m)*
385	380 - 390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27
450	430 - 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0,3	28
	At this frequency degradation of performance can occur resulting in a loss of function and a measu-rement setup error. Basic safety is guaranteed. The user is advised to contact Diagnoptics technical support.					
710 745 780	430 - 470	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9

810 870 930	704 - 787	GSM 800/900,TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0,3	28
1720 1845 1970	800 - 960	GSM 1800; CDMA 1900; GSM 1900;DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0,3	28
2450	2400 - 2570	Bluetooth,WLAN, 802.11 b/g/n,RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0,3	28
5240 5500 5785	5100 - 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9
The frequencies and services listed are representative examples that are based on RF communications equipment in use at the time of publication of IEC 61000-4-3. The test specification does not attempt to cover every frequency and service used in every country.						

Symbols

	Follow instructions for use		Imported by
CE	Medical Device compliant with Regulation (EU) 2017/745		Caution: read instructions (warnings) carefully
SN	Serial number		Type B applied part
REF	Product code		Date of manufacture
EC REP	Authorized representative in the European community	MD	Medical Device
	Manufacturer	LOT	Lot number
	WEEE disposal		Keep away from sunlight
	Keep in a cool, dry place	%	Humidity limit
	Temperature limit		Atmospheric pressure limit

GIMA WARRANTY TERMS
The Gima 12-month standard B2B warranty applies.

Disposal: *The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment*