PROFESSIONAL MEDICAL PRODUCTS

RILEVATORE DI VENE PROFESSIONALE QV-600

QV-600 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

REF **QV-600 (GIMA 23454)**

Qualmedi Technology Co.
Ltd. A302 Room, No. 23, HangBu Road,
Feixi County Economic Development Zone, Hefei
City, Anhui Province, China.
Made in China

EC REP Kingsmead Service
B.V. Zonnehof 36, 2632 BE, Noot-
dorp, Netherland

Gima S.p.A.
Via Marconi, 1 - 20060 Gessate (MI) Italy
gima@gimaitaly.com - export@gimaitaly.com
www.gimaitaly.com

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QV-600 VEIN FINDER - V3.1

PLEASE READ THIS OPERATION MANUAL CAREFULLY

BEFORE OPERATING THE VEIN FINDER

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.

Product Description

Vein finder operates by using infrared light to detect 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, tattoos), hair, scarring or other highly contoured skin surface, and adipose (fatty) tissue.

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.

Use and Operation

Hold the device from 15 to 25 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.

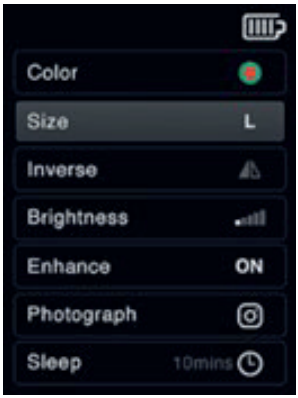
You can do this before palpation, use sport mode scanning quickly over the skin to help narrow down possible locations.

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

Operating Instructions

LCD User Interface



Key

Power, Sleep, OK, and Four Arrow Key

Key Power		Short press the button to startup or shutdown. Automatic power off when machine idle for 35 minutes. Light indicator: Blue: Working; Green: Fully charged; Red: Charging
Key Sleep		Machine enter sleep mode automatically when idle for 10mins(default) or set idle time by LCD interface. Short press make machine enter low energy consumption mode immediately.
LCD Color	Using the up and down arrow keys, select row “Color” in LCD and press the “OK” key or the left and right arrow keys to choose appropriate color.	
LCD Size	Using the up and down arrow keys, select row “Size” in LCD and press the “OK” key or the left and right arrow keys to choose appropriate size.	
LCD Inverse	Using the up and down arrow keys, select row “Inverse” in LCD and press the “OK” key or the left and right arrow keys to turn on/off inverse mode.	
LCD Brightness	Using the up and down arrow keys, select row “Brightness” in LCD and press the “OK” key or the left and right arrow keys to choose appropriate brightness.	

LCD Enhance	Using the up and down arrow keys, select row "Inverse" in LCD and press the "OK" key or the left and right arrow keys to turn on/off enhance mode.
LCD Photograph	Using the up and down arrow keys, select row "Photograph" in LCD and press the "OK" key or the left and right arrow keys to save real-time vein images. Captured veins can be accessed by computer through Type-C cable.
LCD Sleep	Using the up and down arrow keys, select row "Sleep" in LCD and press the "OK" key or the left and right arrow keys to set sleep idle time.
How to change language	Press "Sleep button" and "direction Down button" at the same time, for 3 seconds. Enter in the "developer mode", then select language (10 languages available) pushing "OK"

Technical parameters

Infrared light detection without harm to human body

Infrared Wave: 760-940nm

Infrared detection depth: 0-10mm

Best detection distance: 15-25cm

Accuracy of blood vessel position: ±0.3mm

Accuracy of blood vessel resolution: ±0.3mm

Low working noise: ≤40DB

The battery capacity can be displayed.

Low Battery capacity prompt.

Samsung 5000mAh rechargeable lithium battery, 3 hours duration.

TI DLP projection technology.

Power supply of charging: 5V 4,5A, 100V-240V 50Hz-60Hz

Size: 23(L)*6.4(W)*5.7(H)cm

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

Maintenance

- Maintain and clean the device once a month.

- Please unplug power cable and make sure device is off before cleaning.

- Please use the dust-free cloth to dip concentration of 70% alcohol to wipe the device.

- Should be returned to factory for servicing if the vein light window is scratched.

- If you do not use the device for more than 3 months, please remove the battery from Device.

- This device is with Independent battery compartment. It is easy to take out the battery.

- Please do not open the device to clean the inner of the machine.

- After using, please put the device to aluminum carrying case.

- Please store in a dry and cool place

Warning and Cautions

This vein finder should be used as a supplement for qualified professionals to determine the location of the veins.

This vein finder is dependent on a variety of patient factors and may not display veins on patients with deep veins, skin conditions, hair, scarring or other highly contoured skin surface, and adipose (fatty) tissue.

This vein finder displays only superficial veins and does so only to limited depths dependent on a variety of patient factors. The device does not indicate vein depth.

This vein finder should not be used to locate veins in the eyes.

Do not shine vein display light to the eyes for a long time.

The device projection may not display veins if operated under bright light such as bright sunlight.

This vein finder is not intended to be used as a diagnostic device or for treatment of any kind.

Keep the instrument dry and clean to prevent any fluid from entering the machine.

This vein finder must be repaired by authorized and qualified staff.

Do not attempt to open, disassemble, or service the battery.

Do not attempt to sterilize the device with heat or pressure sterilization.

Electromagnetic Interference can affect the performance of the device.

The Machine is fragile, do not falling.

Using unofficial accessories can reduce safety, so use only official accessories.

Do not throw this vein finder and battery to fire

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

Guidance and Manufacturer's Declaration

Electromagnetic Immunity

IEC 60601-1-2

The Vein Finder is suitable for use in the specified electromagnetic environment. The customer and/or the user of the Vein Finder should assure that it is used in an electromagnetic environment as described below:

Emissions Test	*Compliance*	*Electromagnetic Environment Guidance*
RF emissions CISPR 11	Group 1	The Vein Finder uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

RF emissions CISPR 11	Class B	The Vein Finder is suitable for use in all establishments, including domestic establishments and those directly connected to the public low- voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

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Immunity Test	*IEC 60601-1-2 Test Level*	*Compliance Level*	*Electromagnetic Environment Guidance*
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial and/ or hospital environment
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial and/ or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% UT (> 95 % dip UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 sec	< 5 % UT (> 95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial and/ or hospital environment. If the user of the Vein Finder requires continued operation during power mains interruptions, it is recommended that the Vein Finder be powered from an uninterruptible power supply or a battery.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	0.3 A/m	If image distortion occurs, it may be necessary to position the Vein Finder further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

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Immunity Test	*IEC 60601-1-2 Test Level*	*Compliance Level*	*Electromagnetic Environment Guidance*
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Vein Finder, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	Recommended Separation Distance $d=1{,}2\ \sqrt{P}$ $d=1{,}2\ \sqrt{P}$ 80 MHz to 800 MHz $d=2{,}3\ \sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

Recommended Separation Distances

between Portable and Mobile RF Communications Equipment and the Vein Finder

IEC 60601-1-2

Frequency of Transmitter Equation Rated Maximum OutputPower of Transmitter watts	150 kHz to 80MHz $d=1,2\sqrt{P}$ Separation Distance metres	150 kHz to 800MHz $d=1,2\sqrt{P}$ Separation Distance metres	800 MHz to 2,5 GHz $d=2,3\sqrt{P}$ Separation Distance metres
0.01	0,12	0,12	0,23
0.1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the separation distance can be estimated using the equation in the corresponding column, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and People.

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	UDI	Unique Device identifier

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*