

Specificație completată

Dispozitiv pentru vizualizarea venelor Modelul: VD80, Producătorul: AHT Inc, Țara: China

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină solicitată de către oferant
<p>Dispozitiv pentru vizualizarea venelor Descriere. Dispozitiv pentru vizualizarea venelor în timp real, neinvaziv Acumulator intern (Li-ion)</p> <p>Materialul - plastic Sursa de lumină-două lămpi infraroșii Distanța optimă a imaginii 200 mm ±50 mm</p> <p>Rezoluție imagine $\geq 1024 \times 768$</p> <p>Precizia alinierii ≤ 0.5 mm Energia radiațiilor infraroșii $\leq 108 \mu\text{W}/\text{m}^2$ Luminozitate reglabilă</p> <p>Adâncime de recunoaștere vasculară între 0-10 mm Opțiune de montare podea</p>	<p>Dispozitiv pentru vizualizarea venelor DA Descriere. Dispozitiv pentru vizualizarea venelor în timp real, neinvaziv DA Acumulator intern (Li-ion) DA pag.4 din User Manual</p> <p>Materialul – plastic DA Sursa de lumină-două lămpi infraroșii DA Distanța optimă a imaginii 220 mm ± 20 mm DA pag. 12 din User Manual Rezoluție imagine pe display - 420*480 px se folosește doar pentru controlul dispozitivului. Insași vizualizarea venelor se face pe suprafața pielii. Rezoluția camerei este de 600 de linii</p> <p>Precizia alinierii ≤ 0.5 mm DA Energia radiațiilor infraroșii $\leq 108 \mu\text{W}/\text{m}^2$ DA Luminozitate reglabilă – DA și posibilitate de schimbare în a culorii de vizualizare a venelor din Verde în roșu sau alb (cu nuanța slabă de orange)</p> <p>Adâncime de recunoaștere vasculară între 0-3 mm DA Opțiune de montare podea DA In standard vine cu suport pentru masa</p>

Vein Detector Model: VD80



Class & code	Class I Type B Medical Device GMDN Code: 48040
Certificate	CE & FDA approved UK MHRA Reference No.: CA016564
Product Hotspots	Real-time accurate vein display Light, Flexible Multi-application Wide adjustment of distance and direction
Principle	For different wave-length near-infrared, the absorption between blood hemoglobin and periphery tissue is different. Through photoelectric conversion and image processing, to show the vein clearly by machine.
Features	Windows system provide a stable prompt function performance. Fully digital image acquisition provides a high screen frame with excellent fluent continuity of image. Various color display mode provides vein's identification effectively and image resolution, indicate vein's depth. Advanced optical structure design assures an excellent vein recognition rate and provides original position projection. High quality patent products, anti-interference and reduce the radiation effectively, stable and safe.
Application	Injection section, Lab blood collection room, Pediatrics, Micro plastic department, Peripheral vascular Department ex laser therapy, sclerotherapy, thrombosis observation, etc

Company Profile

AHT INC founded with mentality of "Advanced Health-care Tech Services A Better Life of Mankind."

As a professional manufacturer of vein detector, AHT INC has been dedicated in its research, production and distribution almost 5 more years. With abundant experience of medical industry and professional services team, we've been strive to provide our customers best cost-effective products with cutting-edge advanced features.

We are ISO13485 quality system approved company. Our product vein detectors are CE & FDA approved and registered in UK MHRA (MHRA Reference Number CA016564).

With orientation of Appropriate Product, Affordable Price, Quality Service, we build a long-term reciprocal symbiosis relation with our customer.



Working Mode



Color adjustment: Switch color among Green, White and Red according to different skin condition. It provides true image of vein in high accuracy.



Brightness adjustment: change projection's brightness according to circumstance and provide user-friendly operation.



Background change: Change projection background by pressing "BWCC" (black & white) button to provide flagrant contrast and locate vein more accurately.



Depth recognition: Place cross "+" on target vein to have reference of vein's depth according to filling ratio of signal bar + □□□.



KIDS mode: Apply small projection size for kid's tiny vein to display kid's vein with appropriate scale and reduce interference of large size projection.



Pause: stand-by function

Clinical Application Gallery



Company: AHT INC

Address: 8th Floor 805, Blilding D1, Huameiju, Xinghu Rd, 82 District, Baoan area, Shenzhen, Guangdong P.R. China 518133

Tel: +86 (755) 2163 5832

Fax: +86 (755) 2359 6190

Email: info@ahtmed.com.cn

Website: www.ahtmed.com.cn

Subject to change without notice in advance



Compliance Report

Applicant: AHT INC
Address: Floor 8th 805, Building D1, Huameiju, Xinghu Rd, 82 District,
Baoan Area, Shenzhen, P.R. China Post Code 518133

Product: Vein Detector
Type: VD80, VD82, VD88, VD90, VF70, VF77, VF78

Product Classification: Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. **02866**

Initial Issue Date: **16 Mar 2018**

A handwritten signature in blue ink that reads 'Tony Chen'. The signature is written in a cursive, flowing style.

General Manager (Signature)

EC Declaration of Conformity

Manufacturer:

Company name: AHT INC

Address: Floor 8th 805, Building D1, Huameiju, Xinghu Road, 82 District, Baoan area, Shenzhen, P.R. China

We, the manufacturer, hereby declare that the product

Vein Detector / Vein Finder

Model: VD80, VD82, VD88, VD90, VF70, VF77, VF78

meets the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark



The product concerned has been manufactured according to Annex VII of Directive 93/42/EEC following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

The above mentioned declaration of conformity is exclusively under responsibility of company AHT INC.

Signed by: Qisheng Lee

Designation: General Manger

Place & date: Shenzhen China, Jan. 21th, 2018



Vein Detector
Operator's Manual
Model: VD80



AHT INC

Preface

Product Name: Vein Detector

Model: VD80

Manufacturer: AHT INC

Address: Floor 8th 805, Bld. D1, Block A, Huameiju, Xinhu Rd, 82 District, Baoan area, Shenzhen, P.R. China Post Code 518133

Thanks for purchasing VD80 Vein detector.

This Operator's Manual is the necessary instructions for the safe use of this product. Before using the product, please carefully read and understand the contents of this Manual, and abide by the method of operation stated in this Manual in order to ensure the safety of patients and operators.

All the illustrations in this Operator's Manual are for reference only. The menus, settings and parameters of the illustrations may be different from the machine.

This Operator's Manual is a major component of the product, please keep this Manual properly for future reference.

Version: 1.0

Date of Issue: April. 2018

Content

Chapter 1	Summary.....	1
Chapter 2	Principle.....	1
Chapter 3	Application.....	2
Chapter 4	Structure.....	3
Chapter 5	Technical Specification.....	5
Chapter 6	Installation.....	6
Chapter 7	Instruction.....	8
Chapter 8	Charging.....	12
Chapter 9	Maintenance and cleaning.....	13
Chapter 10	Troubleshooting.....	14
Chapter 11	Transportation and storage.....	14
Chapter 12	Packing.....	15
Chapter 13	Warranty.....	15

Chapter 1 Summary

This machine is used to position the outer peripheral veins of superficial parts and a complementary to qualified medical staff as assistance, especially for those patients whom vein is difficult to locate.

It should not be the only method to locate vein and can not replace the traditional intravenous location judge method based on vision & touch.

This machine is only used to assist in identifying the location of the vein, it's not for diagnostic or therapeutic purpose.

***Warnings:

① **Please connect AC and recharge as soon as Li-ion battery indicator flashing, to avoid power supply faulty.**

② Do not use near the eyes or inside the eye. Do not irradiate to eyes directly or do not look directly at projection port during machine running.

③ Do not use in flammable gases environment.

④ Use in clean area and away from high/low temperature or humid environment.

⑤ Please put on a flat surface when adding support bracket. Avoid vibration during operation and away from corrosive and flammable environment.

⑥ Please do not use in conjunction with other machines.

⑦ Do not frequently slide the power switch to turn on or turn off machine, this avoid errors to inside embedded Windows operation program. Restart machine after shutdown for 20 seconds at least.

⑧ Please stop use machine if "PS" power supply indicator doesn't on when slide switcher to "ON" position.

Chapter 2 Principle

For different wave-length near-infrared, the absorption are different between patient's physiological parameter (blood hemoglobin in vein)

and body periphery tissue.

Through photoelectric conversion and image processing, display the vein's project in its original position clearly.

The machine detect the superficial skin vein by near infrared firstly, then locate the vein's position with different color light. The blood hemoglobin absorb the near infrared preferentially and the displayed image is inside part of vein, instead of whole vein.

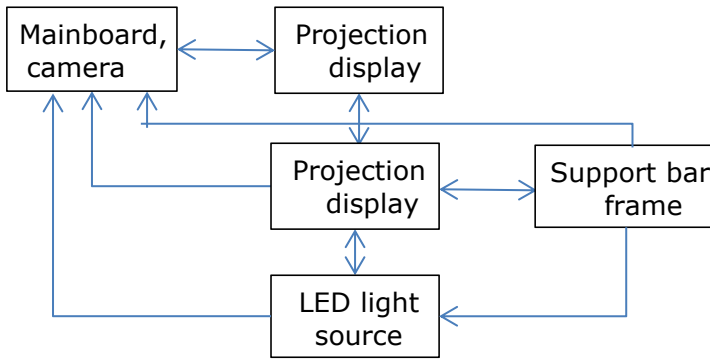


Illustration 1 Working principle diagram

Chapter 3 Application

For observation and search a subcutaneous superficial blood vessels and auxiliary puncture. Ex thrombus's laser therapy, Injection section, plastic and cosmetic surgery, Dialysis section, Clinical laboratory, Peripheral vascular section, Surgery , Cardiovascular department, Geriatric department, Universities, laboratories, etc.

To help & support the observation of venous imaging.

*****Note:**

- The maximum vein's positioning is different according to different patient vein's condition and physiological parameter (blood hemoglobin in vein).
- The vein may not be positioned efficiently if patient is weak pulse

rate and there's low blood hemoglobin in vein, ex vein of cold hand). The other factors include vein's depth, skin conditions ex as tattoos, hair density & color on skin surface, skin scar, highly rugged skin surface and adipose (fatty) tissue, etc.

- c. The machine can detect the vein's center if machine projection port is right above. There's deviation from displayed vein image and actual vein position if move from right above to oblique above.

Chapter 4 Structure

The machine mainly consist of main board, optical system, display camera, LED light source, power cable, adapter, extension cable, intensifier, surgical mark pen and/or optional moving trolley, etc.

4.1 Main unit and base Charger:

1. Main unit
2. Switcher
3. Base charger
4. Projection display (backside)
5. Function keyboard
6. Operation indicators
7. Charging indicators



Illustration 2 Vein detector handheld

4.2 Intensifier and its switcher:

- 1. Intensifier
- 2. Switcher for intensifier
- "OFF"(left side)
- "ON"(right side)

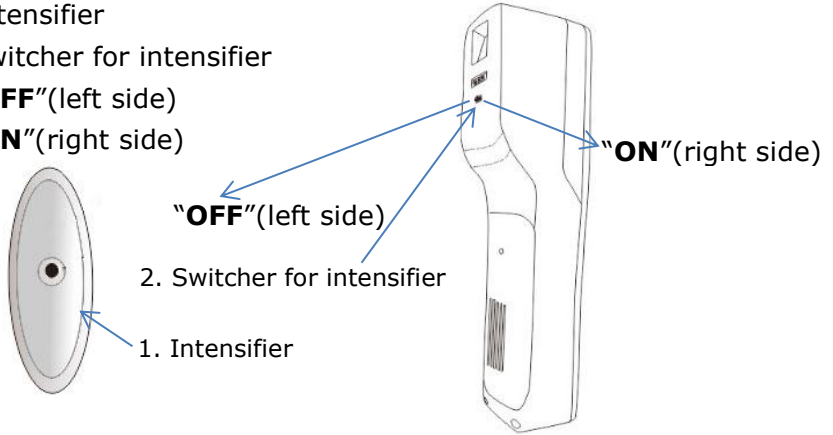


Illustration 3 Intensifier and its switcher

4.3 Trolley

- 1. Main unit;
- 2. Base charger with base-plate;
- 3. Telescopic arm;
- 4. Basket;
- 5. 5-wheel trolley base

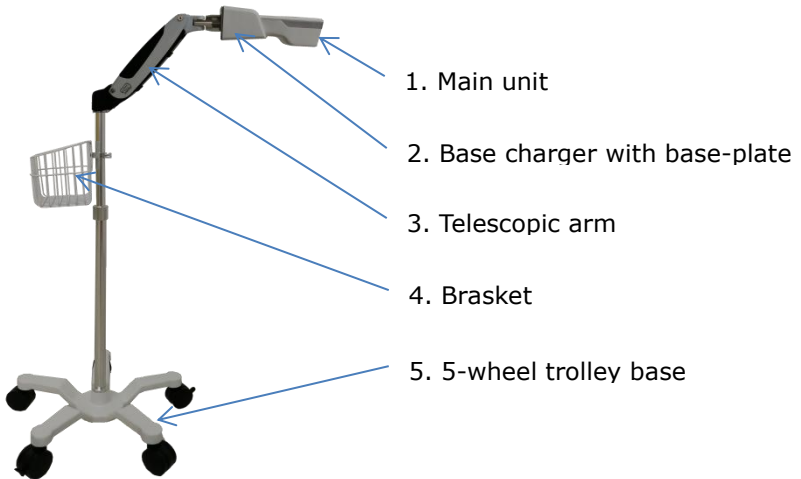
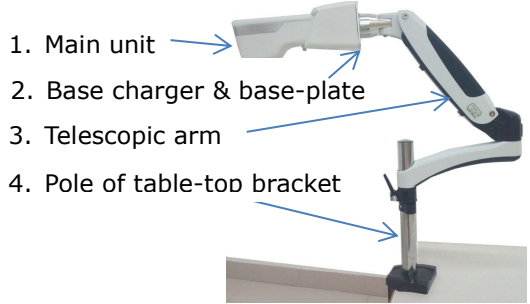


Illustration 4 Vein detector with trolley

4.4 Table-top Bracket

1. Main unit;
2. Base charger with Base-plate;
3. Telescopic arm;
4. Pole of table-top bracket



4.5 Power supply



Illustration 5 Power cable, power adapter and extension cable

Chapter 5 Technical Specification

Item	Spec
Display resolution	420*480TVL
Main wavelength of light source	750nm~940nm
Charger	DC +12V 4A
Battery backup time	Up to 3.5 hours
Surface temperature	Increase 10°C or less after 30 minutes running
Camera resolution	≥600Lin
Operation mode	Run continuously
Atmospheric pressure	86kPa~106kPa
Charging time	4 hours
Power supply	DC+12V, 10W

Working environment	Temperature	10℃~40℃
	Humidity	≤80%
Transportation environment	Temperature	5℃~40℃
	Humidity	≤80%
Storage environment	Temperature	5℃~40℃
	Humidity	≤80%
Safety classification	class I type B	
Machine net weight	0.53KG	
Machine size	22cm*5cm*7cm	

Chapter 6 Installation

6.1 Unpacking & installation

6.1.1 handheld type

Please operate as below:

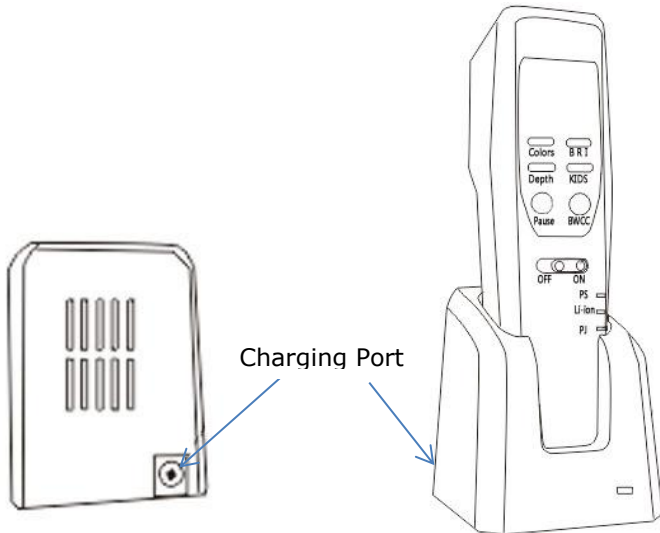


Illustration 6 Charging port

Step 1	Open the carton to take out main unit and base charger
Step 2	Put the base charger on stable flat table
Step 3	Put main unit inside of base charger

Step 4 | Connect power cable to base charger from charging port

6.1.2 Installation of Trolley

Open the carton to take out the machine vein detector main unit and trolley components, then assemble the trolley as per below guidance:

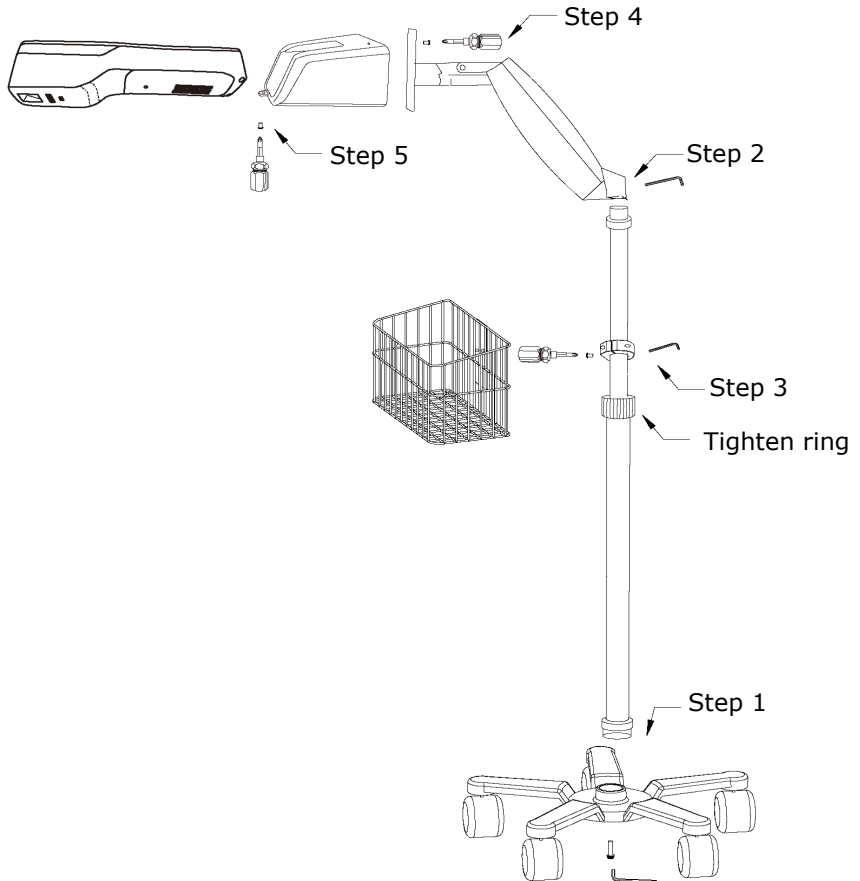


Illustration 7 Installation of 5-wheel trolley

<p>Step 1: Main part installation</p>	<p>a. Insert Ø32mm stainless pipe/pole's threaded end into central hole of 5-wheel base. b. Screwing in M8*70mm Inner Hexagonal screw and its shim from below of 5-wheel base. c. Lock with M6 inner hexagon spanner.</p>
---	---



Step 2: Telescopic arm	a. Put telescopic arm into stainless steel pipe. b. Lock with M3 inner hexagon spanner.
Step 3: Height adjustment and basket fixing	a. One hand hold the stainless pole and another hand screw off tighten ring counter-clockwise director. Adjust trolley's height then lock by tighten ring clockwise direction . b. Loose M3*10mm screw with M3 cross screwdriver and adjust height. Loose M4*8 screw and install basket.
Step 4: base charger fixing	Make charging port of base of base charger downward ,fix base charger to base-plate with M4*7mm screws.
Step 5: main unit installation	a. Put main unit into base charger and make projection window downside. b. Fix the main unit with base charger with M4*8mm screw.

Chapter 7 Instruction

7.1 Start-up

Before using machine first time, please charge machine till charging indicator off.

Slide the power switcher button to turn on machine. The boot process need about 10~20 seconds due to embedded Windows system.

7.2 Intensifier

According to depth condition of vein, you can use machine individually or together with intensifier. The machine working individually if put intensifier's switcher on "OFF" side; the machine working together with intensifier if put intensifier's switcher on "ON" side.

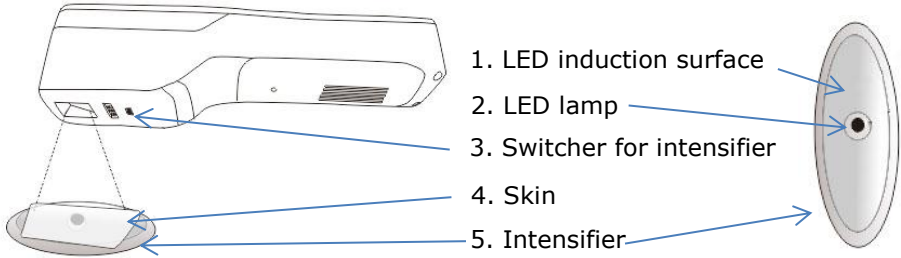


Illustration 8 Application of intensifier

Intensifier is LED induction mode. When machine working together with intensifier, please make skin surface touch the induction side of intensifier and let LED light transmit skin tissue.

7.3 Operation indicators

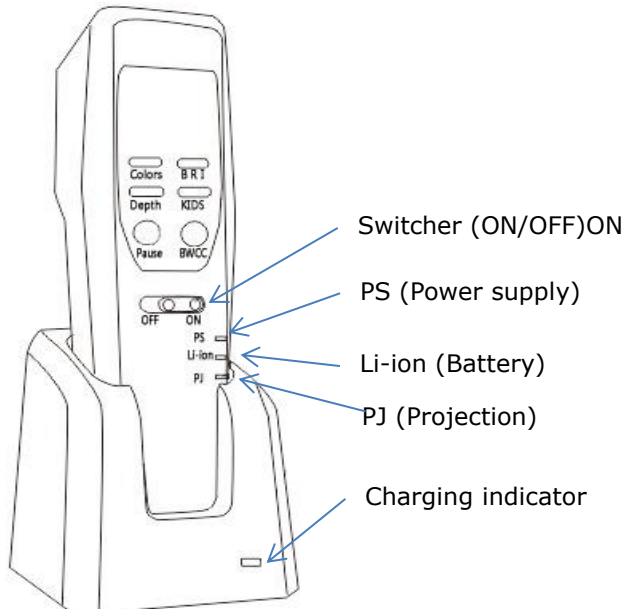


Illustration 9 Operation button/indicators

7.3.1 Switcher button:

Slide the switcher to turn on or turn off machine. Due to embedded

Windows operation system, it needs around 10 seconds to turn on or turn off machine. Please do not slide the switcher repeatedly in short time to avoid system error. Restart machine after shutdown for 20 seconds at least.

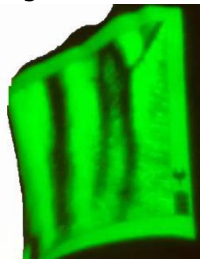
7.3.2 "PS" indicator: this is indicator for power supply and keep on all through machine operation.

6.3.3 "Li-ion" indicator: this indicator is on during operation and would flashing if low battery.

7.3.4 "PJ" indicator: this is indicator for projection working condition. During working state, press "Pause" key and the projection will be shut down (PJ indicator off too); press "Pause" key again and restart projection.

7.3.5 "Charging" indicator

Charging indicator keeps on during charging and flashing when battery is low. Meanwhile low battery icon will showing in projection area border-side. Please recharge the batteries in time and maintain the battery.



← Charging icon
← Battery icon

Illustration 10 Battery & Charging Icon

During charging, the charging indicator is on. The battery icon and charging icon also showing in projection border.

7.4 Function buttons

7.4.1 Color: Total 3 kind of color mode include Green, Red and White. The vein image's color can be adjusted by press "Color" button.

7.4.2 Brightness: Facilitate observation contrast and highlight the superficial veins.

Suggestions combined with black and white color conversion model

transformation.

Using image black and white conversion + red + brightness, display of superficial vein images more rounded.

*****Notes:**

- ① For normal environment light, recommend to use "Green color" pattern.
- ② If environment high brightness, it is recommended to use "White color" pattern.
- ③ If environment is low brightness, it is recommended to use "Red color" pattern.
- ④ If environment is dark, it is recommended to use "Red color +low Brightness" pattern.
- ⑤ If want to highlight vein clearly particularly, it is recommended to use "White color +BWCC" pattern.
- ⑥ If want to exposure smooth vein image, it is recommended to use "Red color +BWCC + low Brightness" pattern.

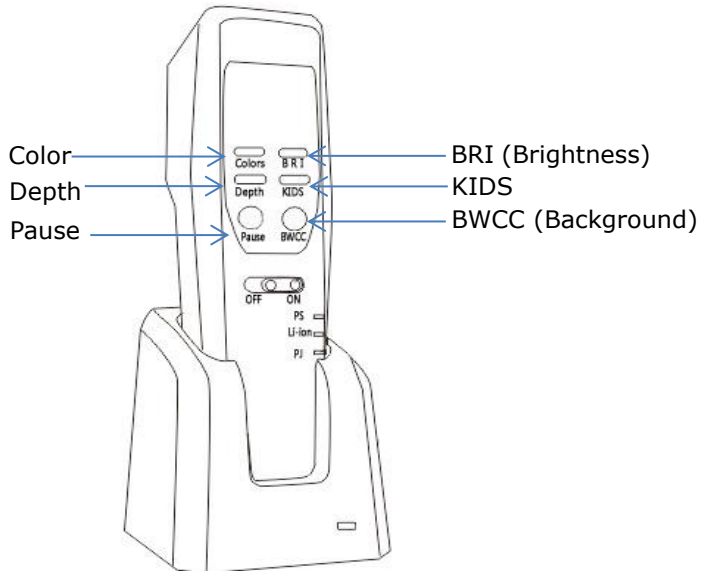



Illustration 11 Function buttons

7.4.3 Depth recognition:

"+" should focus on the target vein need to detect.

Signal bar  :

3 full bar means vein about 1mm under skin.

2 full bar means vein about 2mm under skin.

1 full bar means vein about 3mm under skin.

3 empty bar means no veins or veins not found.

7.4.4 Kids: Kids mode is with small size projection display area. It reduces eye irradiation and exposure kids vein with appropriate projection scale.

7.4.5 BWCC: BWCC is background change for vein image. Use "BWCC" function with 3-color mode to have real, clear & accurate clinical vein image, as below:

Color mode	Vein image's background	Vein's color in vein image	Vein's color in vein image after press BWCC
Green	Green	Black	Green
Red	Red	Black	Red
White	White	Black	White

7.4.6 Pause:

It's standby mode and will suspend the projection. It effectively save electricity. Press "Pause" button again to awake the machine.

7.5 Detection distance

Choose appropriate detection distance which around 22 ± 2 cm averagely to have a best clear vein's exposure. Reduce detection distance appropriately for relatively small superficial blood vessels; increase detection distance appropriately for general or more bulky skin-surface blood vessels.

Chapter 8 Charging

Please turn off machine or connect AC and recharge as soon as Li-ion battery indicator flashing, to avoid battery damage. The machine can connect directly to DC12V/4A charger.

The battery provides about 3 hours battery backup after fully charged around 3 hours.

In case of AC disconnected, please assure the battery is enough power so machine can work normally. Please avoid machine operation under low battery.

It may cause feed and unable to switch on the machine if long time NO use of the machine. Suggest to charge machine 5~10 minutes firstly, then switch on the machine.

Chapter 9 Maintenance and cleaning

Please check and ensure machine in clean condition before use.

The machine should be cleaned regularly. In the heavily polluted environment, increase the frequency of cleaning. Before cleaning, please turn off the machine and disconnect the AC power.

The cleaning of projection window and lens:

To ensure a best performance, please keep clean of the projection window and lens all through. The dirty or scratch will cause the shadow in projected vein image and influence machine performance. Only lens cloths with ethanol (70%) is allowed to clean the projection window and lens.

Please do not scratch projection window and lens.

*****Notes:** Please do not use machine if there's scratch or dirty in projection window or lens. Please contact your supplier for maintenance if the projection window scratched.

The cleaning of other parts:

Use the regular cleaning fluid of a clean soft cloth to clean, wipe with clean cloth and take a small amount of cleaning fluid.

Appropriate cleaning agents include: Soft soap water, Ethanol (70%), 10% dilutions of Chlorine bleach and distilled water, Chlorhexidine.

Dry the device naturally in a ventilated cool environment.

It is forbidden to immerse the machine in any liquid, or the instrument or its parts with fluid retention. It is prohibited to disinfect by the method of

heating or pressure machine.

Please clean strictly according to above method. On the contrary, the damage the machine.

Chapter 10 Troubleshooting

10.1 The machine may not start-up properly due to feed if long time NO use of the machine. In this case:

- a. Please check whether the battery is enough or AC is connected.
- b. Please charge machine 5~10 minutes then turn on the machine.

10.2 The machine may not start-up properly due to internal Windows system crashed which caused due to below situations:

- a. extreme weather (too hot/cold) or too high/low temperature
- b. Switch on/off machine frequently
- c. Be interfered with other big machine/systems noise.

In above cases, please switch off machine for some time (ex 1 hour) in suitable air condition, then turn on again.

10.3 Display image is not clear or position deviation.

- a. Check whether the working distance too far or too short.
- b. Check if machine were impacted violently during transportation or using.

10.4 Please contact your supplier for maintenance if machine trouble is not caused due to battery or power supply.

*****Notes:** Please do not open the machine without authorization. No professionals please do not disassemble the machine.

Chapter 11 Transportation and storage

Transportation: Please use original general transportation packing and shipping material, please handle with care and do not shock or fall violently.

Storage: clean the machine and cover the dust mask, then store in safe,

dry, clean place.

Environment temperature: $-10^{\circ}\text{C}\sim 40^{\circ}\text{C}$. Relative humidity: $\leq 80\%$.

Chapter 12 Packing

The machine packed in plastic bags, lined with foam, fixed in the corrugated paper box. The contents as below:

S.N.	Contents	Quantity
1	Main unit	1
2	Base charger	1
3	Intensifier	1
4	Moving trolley & tools kit (optional)	1
5	Power cable and adapter(12V 4A)	1
6	Surgical skin marker	1
7	Operator's Manual	1
8	Gross weight (handheld)	2.5kg
9	Dimension (handheld)	31*22*10(cm)
10	Gross weight (Table-top)	5kg
11	Dimension (Table-top)	51*35*14(cm)
12	Gross weight (trolley)	17kg
13	Dimension (trolley)	61*61*22(cm)

Chapter 13 Warranty

In order to protect the interest of customers and to give customers better after sale service, please read the following carefully.

1. The content and period that need to be warranted:

1.1 The content: Manufacturer/Supplier will be responsible for defects in workmanship & materials and the problem is due the quality of the product if the user use product exactly according to the manual and in the period of warranty. Manufacturer/Supplier's obligation under this warranty is limited to repair, any part that upon Manufacturer/Supplier's

examination proves defective.

1.2 The period: 12 months (6 months for accessories and exclude expendable) from shipment date.

1.3 The designed lifespan is 5 years.

2. In the following cases, Manufacturer/Supplier do not provide quality warranty of our product

2.1 Not operate product according to the manual.

2.2 Product is damaged due to violently impact.

2.3 Beyond the warranty period.

2.4 Caused by modification or repair by anyone except Manufacturer/Supplier or without Manufacturer/Supplier authorization; from which Manufacturer/Supplier's original serial number tag or product identification markings have been altered or removed.

2.5 Not use the parts that were not manufactured by Manufacturer/Supplier.

2.6 Without the permission of Manufacturer/Supplier, restructure the product.

2.7 Product is damaged due to typhoon, flood, fire, earthquake, war and other force, which cannot be resisted by human power.

3. The method of validity

If find any problem, please contact your supplier. The sales are responsible for informing the problem to Manufacturer/Supplier's technical department and it will valid after the technician confirm.

4. Return and Freight

Be sure confirmed with Manufacturer/Supplier before any return machine and/or parts, to avoid problem.

4.1 Within Warranty: The customer is responsible for freight & insurance charges, includes custom charges when the equipment and/or parts is shipped to Manufacturer/Supplier for service. Manufacturer/Supplier are responsible for the freight & insurance charges from Manufacturer/Supplier's to the customer.

4.2 After Warranty: The customer is responsible for any freight & insurance charges.

5. Technical Training

Manufacturer/Supplier provides free service training to the technical personnel from the Agent/Distributors with respect to the products and will further provide technical assistance via e-mail or fax as requested by the Agent/Distributors. The training will be performed at site in Shenzhen China. The transportation and accommodation expenses are on the Agent/Distributors' account.