Vein Finder System
User Manual

Document No.	Rev. No.
ZD-JM09	A/0

Contents

01. Related Information

1.1 Manufacturer

Name	ZD Medical Inc.
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02. Product Overview

2.1 Name

Vein Finder System

2.2 Model

Model	Main Unit Figure
ZD-JM-260-04	

2.3 Structure

Model	Structure
ZD-JM-260-04	ZD-JM-260-04 consists of main unit. Main unit consists of light source, image processing module, battery, case, function buttons and indicator lights.

2.4 Intended Use

The Vein Finder System is used to assist the clinical personnel to find subcutaneous veins.

2.5 Contraindications

No contraindications are known.

2.6 Operating Principle

Vein Finder System acquires image of subcutaneous veins, the image which results from dealing with image signal is projected onto the surface of the skin. Thus, subcutaneous vein image will be displayed on the skin surface of the corresponding position.

2.7 Technical Parameter

Effective forward projection distance	29 cm to 31 cm
Projection illuminance	300 lux to 3,000 lux
The wavelength of active irradiation light	750 nm to 980 nm
Error	the accuracy error should be less than 1mm
Power supply	a. Internal battery: Lithium-ion polymer battery, 3.7Vd.c.; b. Power Adapter Input: 100-240Va.c., 50/60Hz, 0.8A; Output: 5Vd.c., 3A.

2.8 Environmental Information

Use Information	● Temperature: 5℃～40℃; ● Humidity: ≤80%; ● Atmospheric Pressure: 700hPa～1,060hPa.
Storage Information	Store in the cool, dry, dark place: ● Temperature: 5℃～40℃; ● Humidity: ≤90%; ● Atmospheric Pressure: 700hPa～1,060hPa.

2.9 Symbol and Description

Symbol	Description	Symbol	Description
	Consult accompanying documents.		Serial Number
	Type B applied part		Do not discard randomly, for professional disposal
	Manufacture		Date of manufacture

2.10 Service Life

The service life of the product is 5 years. The buyer needs to carry out regular maintenance and pay attention to the daily cleaning and dust-proof work.

When the product is out of service, it should be disposed according to the regulations of local environmental protection department.

03. Method of Application

Before using the product, medical staff should be familiar with how to correctly locate in order to get the best detection effect. In the process of use, it is recommended that the medical staff take touch and visual observation information for reference, combined with the projected image results to determine the actual location of veins. Please try to keep the observed of skin smooth and tight, give priority to choose areas of the organization with less scars, spots or hair.

3.1 Open the Package

Open the package box of the vein finder system and store the package box for re-transportation and use.

The product is a handheld portable vein finder system, which can be used after taking out from the packaging.

Warning:

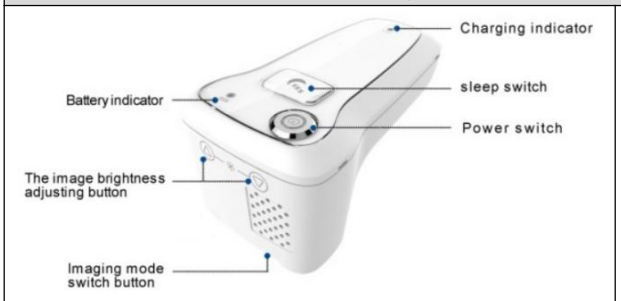
- If the product is transported again, please use the original packing materials.

3.2 Charging

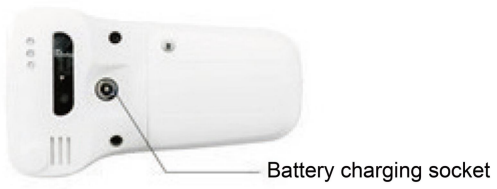
The buttons of the main unit are shown in Figure 3.2. Press the power switch of the main unit, observe the battery indicator, judge whether the battery is enough. When battery indicator is white, the battery is full. If battery indicator is blue, the battery is low. The battery needs to be recharged when it is low. The power adapter (charger) attached with the product is used for charging.

When charging the main unit, connect the power adapter to the charging socket at the bottom of the main unit, as shown in Figure 3.2 b). The charging indicator will keep flashing during charging, and will stop flashing when it is fully charged.

Figure 3.2 Marks of Main Unit Function



a) Main unit front function symbol



b) Main unit back function symbol

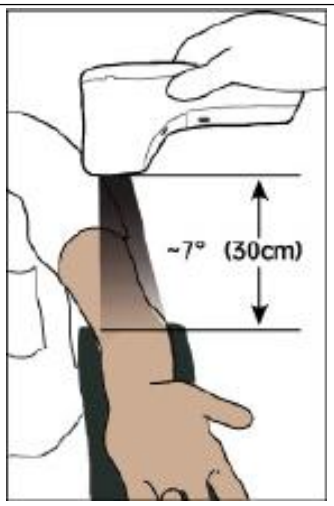
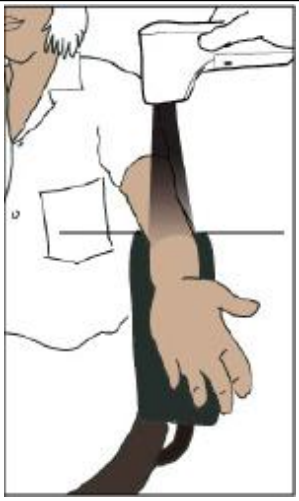
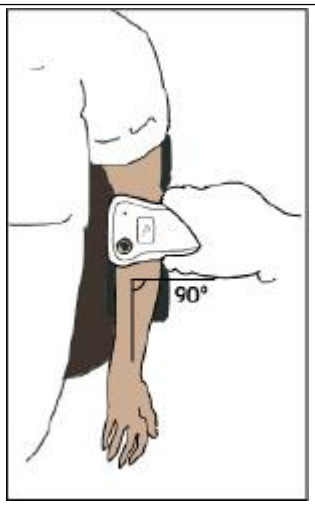
3.3 Status of use

After the main unit starts working, the projection window of the main unit will project a picture, which is corresponding to the texture of the object. This image will be projected on the surface of the projected object, which indicates that the main unit enters into the status of use.

3.4 Height Adjustment

When using the main unit, the suggested position is about 30cm from the arm to the main unit. The center point of the main unit and the puncture vessel are the same. The suggested angle between the equipment and the blood vessel is 90 degrees. Shown as Figure 3.4.

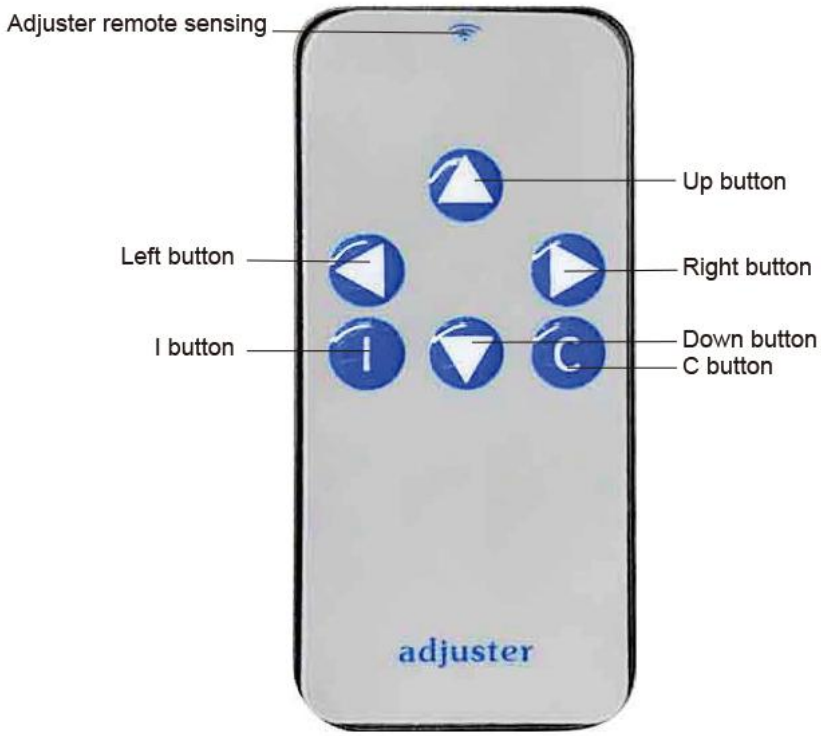
Figure 3.4 Height Adjustment

Height	Centering	Angle
		
The best development is about 30cm.	Set the same center point as the puncture blood vessel.	The angle is 90 ° perpendicular to the blood vessel.

3.5 Adjuster

The Adjuster contains adjuster remote sensing, up button, down button, left button, right button, I button, C button. See Figure 3.5.

Figure 3.5 Adjuster



The functions are as follows:

Button	Function
up button, down button, left button, right button	These four buttons use to reconcile projecting vein image for the first long transportation after manufactured. See 3.2.10 Calibration for details. **Warning:** ● Please don't use these four buttons in daily use.
I button	Inversion mode, which means the skin is colorful, while the vessels are white.
C button	Color mode, which means the vessels are colorful, while the skin is white.

3.6 Image Mode

The operator can adjust the image mode according to the patient's skin color to display a clearer image. The image mode adjustment for the product is realized by the C button and I button of the adjuster.

a. Inversion mode: Seven colors of skin (blue, yellow, green, rose red, fluorescent green, red and black) and one color of vessels. See Table 3.6 for details.

b. Color mode: One color of skin and seven colors of vessels (blue, yellow, green, rose red, fluorescent green, red and black). See Table 3.6 for details.

Table 3.6 Image Mode

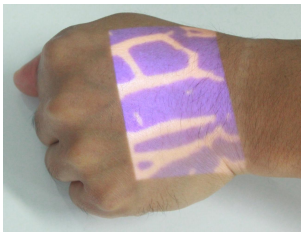
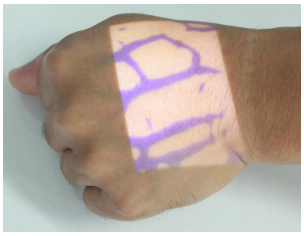
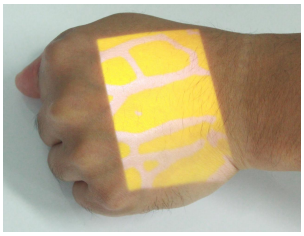
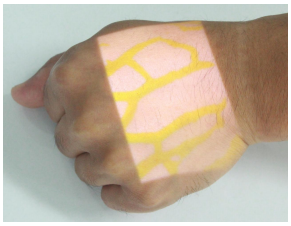
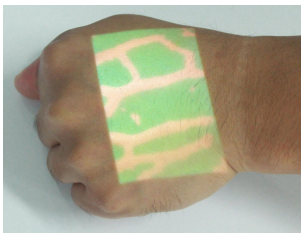
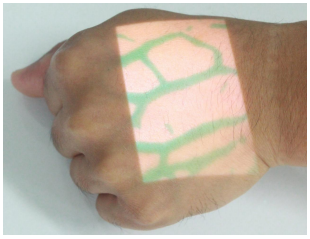
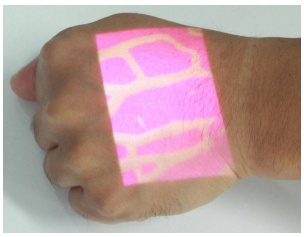
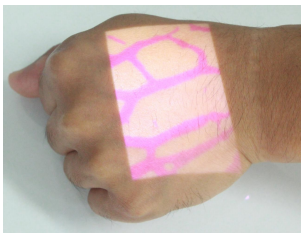
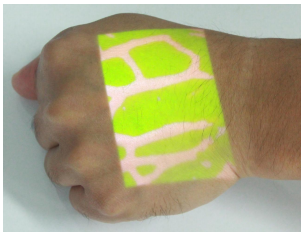
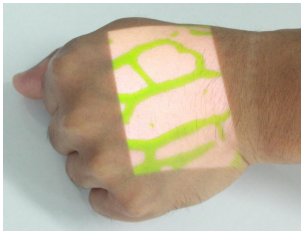
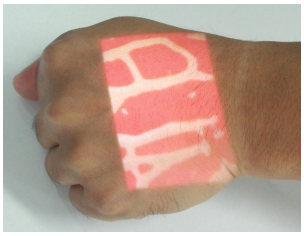
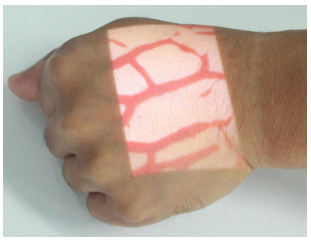
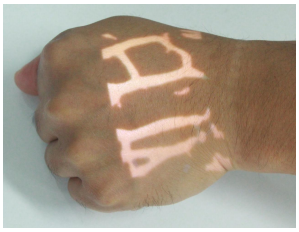
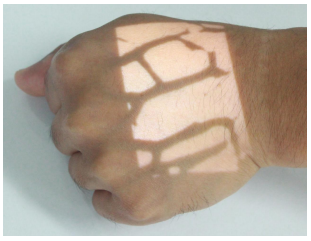
Mode / Color	Inversion mode	Color mode
blue		
yellow		
green		
rose red		

Table 3.6 Image Mode		
Mode / Color	Inversion mode	Color mode
fluorescent green		
red		
black		

3.7 Image Brightness

The image brightness adjusting button is located on the front of main unit, as shown in Figure 3.2 a).

Button	Description
▽	Decrease the brightness
△	Increase the brightness

In the process of use, the operator can adjust the image brightness according to the use environment, location, patient's skin color and amount of body hair.

3.8 Product Sleep

The product starts sleep mode when touch sleep switch. The image is off. Meanwhile, the product saves electricity. If you touch the sleep switch again, the image restores.

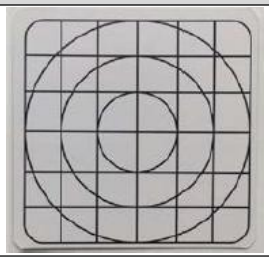
3.9 Shut down

After using, press the power switch, the product is turned off and battery indicator is extinguished.

3.10 Calibration

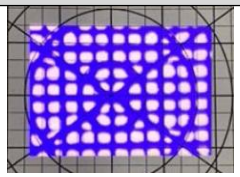
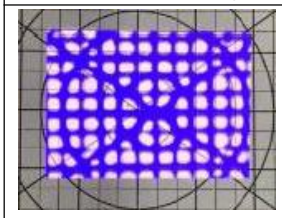
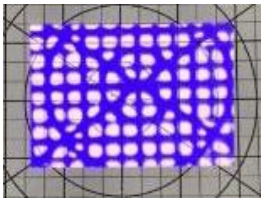
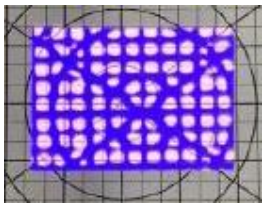
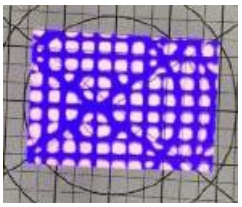
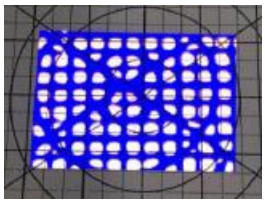
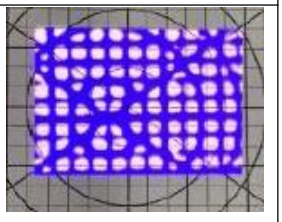
In order to ensure the accuracy of product display, the product needs to be calibrated before first use after long transportation. The calibration card (see Figure 3.10) and adjuster (see Figure 3.5) are used for calibration.

Figure 3.10 Calibration card



The image calibration method is as follows:

Place the calibration card horizontally at a position more than 30cm below the main unit.

<table>
<tr><th colspan="2">Results</th><th>Description</th><th>Calibration Measures</th></tr>
<tr><td colspan="2"> 
Image coincidence</td><td>The projected image of blue circle and lines completely coincides with the calibration card image.</td><td>The product is accurate. There is no need for calibration.</td></tr>
<tr><td> 
Image too right</td><td> 
Image too up right</td><td rowspan="3">Image is offset and does not coincide, including too right, too up right, too down right, too left, too up left and too down left.</td><td rowspan="3">Use the adjuster button (up, down, left, right) to adjust until the images completely coincide.</td></tr>
<tr><td> 
Image too down right</td><td> 
Image too left</td></tr>
<tr><td> 
Image too up left</td><td> 
Image too down left</td></tr>
</table>

3.11 Suggestions for use

a. Medical staff can begin venipuncture directly while using the product. Medical staff also can draw lines towards along the projection image of targeted veins by a medical skin marker firstly, then begin venipuncture. It is convenient for venipuncture after shutdown the product.

b. Sunlight or indicator light illume: While you are using the product, please do not make the measured surface of skin towards to the sun. Otherwise, the vein image is incomplete. It is necessary to adjust the indoor illumination which can help medical staff to examine the vein display better.

c. Optimized vein display: after selecting the vein to be observed, it is also possible to rotate the observed part slightly to locate the vein better. And in order to accurately examine the position of the vein, it is suggested put the product at the proper height and angle, and keep the product located in the center of the target vein.

d. Target at the center of the vein: the projected vein pattern will be slightly wider than the real vein, but the center of the projected vein is coincident with the center of the real vein. If you want to puncture, please try to be close to the center of the image line.

e. Please try to keep the skin of the observed area as smooth and taut as possible during the operation, and give priority to the tissue area without scar, stain or hair.

04. Warning and Caution

4.1 Infrared Vein Finder is a kind of medical equipment which it forms the subcutaneous vein image in situ for contactless.

4.2 This product can only display peripheral veins. According to various patient factors, veins in a certain depth range can be detected. This product does not indicate vein depth.

4.3 In order to accurately view the position of the vein, the product must be kept in a relative position to the area being observed, and the skin used to display the observed image must be perpendicular to the axis of the projected light.

4.4 The use of the product is helpful to find and locate peripheral veins, but it cannot replace the visual and tactile based vein location and other clinical vein location methods. The product can only be used as an aid to the visual or tactile judgment of medical professionals.

4.5 Don’t look straight at the light source when it is working.

4.6 Keep away from other equipment when using, as the product is an electronic device. There could be outside interference by electromagnetic signal.

4.7 It is suggested that the product should not be used when it is charging.

4.8 The product has no waterproof function, please keep it from liquid.

4.9 Do not open, disassemble or repair the product by yourself. Except for the qualified service personnel and technicians authorized by the ZD Medical Inc.

4.10 Do not replace product components or original system components with components not approved by the ZD Medical Inc. Otherwise, it may lead to abnormal operation of the product or injury to operators and patients.

4.11 If the product is expected to be not used for a long time, please charge the product fully, clean and package it in a dry, shady and cool place to store by the original packaging materials.

4.12 Avoid putting the product upside down or under heavy stuff when storing.

4.13 This product contains lithium polymer batteries; it is strictly prohibited to put the product into the fire. Don't discard at will and recycle according to local government regulations.

05. Maintenance

It is recommended to maintain the equipment regularly to ensure it is clean enough before use.

5.1 Daily Cleaning

a. Please turn off the power switch to avoid injury before cleaning the product.

b. Please use a soft and clean rag dipped in alcohol to clean the surface of the product.

c. Clean the lens by touching the optical component with gloved hands. Wipe the optical surface of the bottom of the product with a soft and clean object, such as lens paper and lens cloth. Drop a few drops of 70% isopropyl alcohol on a piece of lens paper and slowly rub the surface of the lens in one direction.

d. After cleaning, it must stay dry condition before use.

Warning:

- Please turn off the power switch when the product is not working.
- Do not allow any liquid low into the product and affect the power connection.
- Do not sterilize the product by heating, UV irradiation or pressurizing. The main unit needs to be removed from the bracket when being cleaned.
- It is not allowed to wipe the product directly with any detergent containing abrasive materials.
- The solvent should evaporate evenly and without any stains. Use only after the solvent has evaporated completely and the product is completely dry.

5.2 Daily Maintenance

a. Please try to keep the battery fully charged.

b. Do not charge the product when it is working.

c. When the product is not in use, please check whether the power is off.

d. When the product is not in use, please do a good job in dust prevention.

Warning:

- Please do not disassemble the product for maintenance and repair.
- If the product cannot work normally, please contact the professional technicians and maintenance personnel in time.
- It is suggested that do not charge the product when it is maintained.

06. Electromagnetic Compatibility Information

Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (IEC 60601-1-2:2014)

Note: For this instrument, special precautions for electromagnetic compatibility (EMC) need to be taken, and needs to be installed and put into service according to the EMC information provided herein of the manual.
Note: Portable and mobile RF communications equipment can affect the medical electrical equipment.

The cables and accessories provided by the manufacture with the equipment must be used.

Warning:

- The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity of the equipment.

Basic performance:

Item	Detail
Acquire images	Imaging subcutaneous veins.

Guidance and manufacturer's declaration - electromagnetic emissions		
The vein finder system is intended for use in the electromagnetic environment specified below. The customer or user of the vein finder system should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The vein finder system uses RF energy only for its internal function. Therefore, its RF emission are very low and are not likely to cause any interference in nearby electronic Equipment.
RF emissions CISPR 11	Class B	The vein finder system is suitable for use in all establishments other than domestic establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC/EN 61000-3-2	Class B	
Voltage fluctuations/ flicker emissions	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The vein finder system is intended for use in the electromagnetic environment specified below. The customer or user of the vein finder system should assure 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%.
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 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 or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines. IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the vein finder system requires continued operation during power mains interruptions, it is recommended that the vein finder system be powered from an uninterruptible source.
Power frequency (50/60 Hz) magnetic field IEC/EN 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage before application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The vein finder system is intended for use in the electromagnetic environment specified below. The customer or user of the vein finder system should assure that it is used in such an environment			
Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the vein finder system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ 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: 
Note 1: At 80 MHz and 800 MHz, the higher frequency applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the vein finder system is used exceeds the applicable RF compliance level above, the vein finder system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the vein finder system. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the vein finder system

The vein finder system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the vein finder system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the vein finder system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter/W	Separation distance according to frequency of transmitter/m		
	150 kHz ～ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ～ 800 MHz $d = 1.2\sqrt{P}$	800 MHz ～ 2,5 GHz $d = 2.3\sqrt{P}$
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 recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the higher frequency applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.