veinsite

Redefining the standard for vascular imaging.

Operator User Manual

VueTek
SCIENTIFIC

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Introduction

The Veinsite, from VueTek Scientific, is a near infra red (NIR) vein imager that is worn on the head to improve the viewing of superficial, subcutaneous vasculature. The device works by contrasting the vasculature from surrounding tissue while providing portable and hands-free operation.

The Veinsite is designed to provide a non-diagnostic, enhanced visual aid that is used alongside standard visual and tactile methodology. Video of the vasculature is viewed by the user in the headset display. The headset and display combination facilitates both visualization in the display and an open field of view directly to the subject's anatomy and practitioner's surroundings.

Safety & Clinical

Warning: U.S. Federal Law restricts this device to the sale by or on the order of a licensed physician or other qualified medical professional.

The Veinsite is for use by a qualified medical professional only. Read all Warning and Cautionary Statements and instructions in their entirety before operating the Veinsite.

Conventions Used

This manual and device packaging uses internationally accepted conventions in describing information requiring further attention by the user.

WARNINGS: Indicate a hazardous situation which, if not avoided or adequate precautions taken, could result in loss of life or serious injury to the user or patient and potential device damage.

CAUTIONS: Indicate a hazardous situation which, if not avoided or adequate precautions taken, could result in minor or moderate injury to the user or patient, or device damage.

Caution, consult accompanying documents

Manufacturer

Consult instructions for use

Fragile, handle with care

Temperature limitation

Qty

Quantity

Keep dry

Dispose of accordingly

Allowable humidity range

Allowable temperature range

MRI Unsafe

Unit Power Switch

Contrast Mode

Indications

The Veinsite is a non-invasive, electronic device to aid in the visualization of superficial, subcutaneous vasculature.

It is indicated for use in procedures requiring vascular or peripheral vessel access.

It is intended for use in settings such as hospitals, ambulatory surgery centers, blood drawing centers (diagnostic or donation), clinics/outpatient treatment centers and office-based physician practices.

Users of the Veinsite must be medical professionals qualified to perform vascular access procedures.

Contraindications

The Veinsite is not intended to be used as a diagnostic device or as a form of treatment

It is not intended for imaging eyes, vasculature in the eye, or other structures of the eye

It is not intended for tissue differentiation

It is not intended to enable direct or indirect medical procedures

Patient and User Safety

WARNINGS

The Veinsite is for use by qualified medical personnel only.

The Veinsite is a visual aid and is not intended to replace the medical judgment of a qualified healthcare professional or the standard visual and tactile vascular access location confirmation process.

The Veinsite is a visual aid and should not be solely relied upon when performing vascular access procedures as a slight delay and difference in actual size of the vasculature in the display may be experienced.

The Veinsite does not distinguish between arteries and veins. Use conventional visual and tactile methods to discriminate between arteries and veins.

The Veinsite does not display the depth of veins which can vary based on patient physiology, condition, and location of the anatomy being examined. Standard visual and tactile methods and professional training should be used to confirm the vein depth and location.

Certain veins may appear larger than they actually are due to patient characteristics such as vein depth and amount of adipose (fatty) tissue. Standard visual and tactile methods and professional training should be used to confirm vein size, depth and location.

What is displayed by the Veinsite can be affected by factors including: patient's vein depth, amount of adipose tissue, age, physical condition and skin condition/traits (e.g. scarring, tattoos and hair). These factors may completely prohibit veins from being displayed. Standard visual and tactile methods and professional training should be used to confirm vein depth and location. Deep veins in excess of about 7mm may not be visible.

Using Veinsite on subjects in a bassinet or incubator while viewing through the acrylic or polycarbonate (such as Plexiglas) may cause artifacts such as rings or patches of blurring that block out part of the displayed image. This is caused by ambient conditions such as a heating lamp and the reflective properties of the plastic. In an attempt to correct this, the user may try changing the viewing angle of the Veinsite. In all cases, do not rely solely on the Veinsite display for performing the venipuncture or vascular access procedure. Follow standard conventional clinical verification and implementation of the procedure using direct line of sight to the subject.

The VGA compatible video monitor must be certified for use with medical equipment (IEC 60601-1). Furthermore all configurations shall comply with the medical system requirements (IEC 60601-1:2005, Clause 16, or IEC 60601-1-1:2000). A user connecting additional equipment to data ports configures a medical system, and is therefore responsible that the system complies with the medical system requirements. If in doubt, consult your facility's technical service department or your local Vuetek representative.

Do not operate machinery, equipment or vehicles with the Veinsite positioned on the head and do not walk or climb stairs while wearing the Veinsite to avoid a tripping or falling accident.

The Veinsite headset and battery charger are not safe for use in harsh electromagnetic environments such as those exhibited with MRI equipment.

CAUTIONS

Do not examine eyes, vasculature in the eye, or other structures of the eye.

Do not look or have patients look directly into the illuminator at close range.

If the user cannot see the displayed image clearly and without strain, continued use may cause eye discomfort and fatigue.

Although no known increased risks of exposure to near-infrared energy at levels emitted by this product have been identified, exposure to the eyes should be avoided at all times. Appropriate patient eye protection is recommended if the instrument is to be used to view vessels near the eyes, such as the face or scalp.

In extremely bright conditions such as would occur in direct sunlight, the image's contrast may be reduced. If this occurs, shading the area to be imaged will improve the overall contrast in the display.

It is recommended that the Veinsite be used with sanitary head covering, such as a bouffant, to reduce the chance of cross contamination between users.

Do not wear the headset for a prolonged period or if you experience any strain including to the neck or eyes.

Always keep the unit, charger, and battery out of the reach of children.

General Equipment Safety

WARNINGS

To avoid the risk of electrical shock, inspect the battery charger cable and plug for damage before use. Do not use the Veinsite or accessories if damaged.

Use only VueTek Scientific supplied batteries, chargers, and accessories. In the event of visible damage, do not use and contact VueTek Scientific for replacement.

Do not use the battery charger, or insert or remove the battery pack from the Veinsite in an oxygen enriched environment.

CAUTIONS

Do not scratch the Veinsite protective lens cover or internal LCD display screens. Use only non-abrasive, lint free materials to clean the device.

Clean the Veinsite between users.

If prior to or during the procedure, no contrast between the vascular system and surrounding tissue is noted or if other anomalies are detected, discontinue use of the device and contact VueTek for assistance.

Do not immerse any component of the Veinsite (including battery charger, batteries and remote monitor cable, if used) in water or other liquids.

Do not insert any objects into any opening on the Veinsite.

Dispose of batteries and accessories per your facility policy or local regulations.

There are no user serviceable components on this device. Servicing is to be performed only by the manufacturer or their authorized service centers. Other servicing voids the warranty.

Read and observe all electro-magnetic compatibility (EMC) limits as outlined in Appendix A in this manual.

Do not use this device near equipment with strong magnetic or electromagnetic fields such as MRI or CT equipment.

Remote Monitor Safety

CAUTIONS

Follow all user instructions that accompany the monitor regarding safe product use.

Route cable to avoid contact with the patient and all sterile fields.

Route cable to avoid accidental tangling, pulling, or tripping.

Disconnect the Veinsite from external monitor when cleaning.

When using the external monitor feature, the connected monitor may experience a momentary flicker due to AC electrical disturbances. The internal display of the Veinsite will not be affected.

Clinical Analysis

Clinical study results demonstrated that when using the Veinsite at least two (2) additional suitable IV sites were observed that had not been seen by the eyes and tactile feel. This was demonstrated at above a 99.5% confidence level. The study also demonstrated that subject gender, subject group, subject weight (normal or overweight), subject ethnicity, subject skin tone, or the viewing order did not affect the results (i.e., ability to observe additional potential suitable IV sites versus the eye and tactile feel) of using the device. This was demonstrated at above a 95% confidence level.

When further comparing the study results with subject age groups, weight, (normal or overweight as a function of BMI), ethnicity, and skin tone that the number of potential IV sites observed was greater ("more beneficial") when compared to visual methods with the following results:

- The observation of adult/elderly subjects was more beneficial (i.e., more suitable IV sites identified with the Veinsite) than observing IV sites of neonate/toddlers and adolescents;
- Observing IV sites of subjects with BMI equal or greater than 25 was more beneficial (i.e., more suitable IV sites identified with the Veinsite) than to observe IV sites of subjects with BMI less than 25. Observing IV sites of subjects with BMI equal or greater than 30 is more beneficial (i.e., more suitable IV sites identified with the Veinsite) than to observe IV sites of subjects with BMI less than 20;
- Observing IV sites of Black or African American subjects was more beneficial (i.e., more suitable IV sites identified with the Veinsite) than to observe IV sites of White or Caucasian subjects.

Light Emissions

The Veinsite infra-red (IR) light emissions do not pose a potential hazard to the eye under any conditions of intended use and is exempt in accordance with ANSI RP27.3 and IEC 62471:2006 standards addressing optical safety hazards associated with LED IR Radiation. However, as with any bright light source, needless staring into the LEDs should be avoided. Although there are no known increased risks of exposure of infants to near-infrared energy at levels emitted by this product, needless exposure of the eyes of infants should be avoided, and eye patches could be applied if the instrument is to be used to view vessels of the face.

The Veinsite display does not pose a potential hazard to the eye of the user under intended use and is also exempt in accordance with ANSI RP27.3 and CIE-S009/IEC-62471:2006.

Use in Oxygen Enriched Environment

The Veinsite has been designed and tested to be used in an oxygen enriched environment. The power source does not exceed 10 volt-amperes nor does the surface temperature of any component exceed 300°C.

Oils and grease should not be used on this device and the device should be kept clean while in an oxygen enriched environment.

Do not insert or remove the battery pack or use the charger while in an oxygen enriched environment. Move the device to a normal atmosphere before performing any battery handling operations.

The charger is not to be used in an oxygen enriched environment and should not be located in any area where a higher level of oxygen may be encountered.

Setup & Use of Device

Unpacking & Inspection

The Veinsite kit contains everything necessary to get started with enhanced vein viewing. Please carefully remove all of the kit contents, ensure that your kit contains all of the items and visually inspect for any damage or missing items. Contact VueTek prior to use if any items are missing or appear to be damaged.

Item	Qty
Veinsite Head Set	1
Carrying Case	1
Headband Replacement Pad	1
Operator's User Manual (OUM)	1
Battery	1
Battery Charger System*	1

*Includes charger base and wall transformer

WARNING: Do not use the Veinsite or its accessories if damaged.

Setting up the Battery Charger

The battery charging system consists of a charging cradle to accept the battery and a wall mounted power supply to provide power to the cradle.

The power supply comes standard with several different terminal adapters to be compatible with many international power configurations. Select the proper adapter for the appropriate power outlet and insert the adapter into the power supply housing. There should be an audible click when the adapter is correctly mated with the power supply.

The charging cradle can be either wall or table top mounted. If the cradle is to be wall mounted, self-adhesive pads are supplied that can be attached to the back of the cradle to hold the device to the wall. For a more secure attaching method, screws and anchors are also supplied for permanent mounting. A detailed diagram can be found in the cradle's shipping package.

Connect the power supply with the correct power adapter in place to a suitable (110-240 VAC, 50/60Hz) wall outlet. The indicator light in the base will glow red indicating power is available but no battery is detected.

Charging the Battery

WARNING: Do not perform battery operations (inserting/removing/charging) in an oxygen enriched environment.

Batteries are shipped in a partially charged state. Prior to first use, it is recommended that a full charge be done to ensure full use of the device.

Insert battery into charger cradle which causes the indicator light to blink green indicating that charging has begun. Charging is complete when the indicator light turns steady green, approximately five hours for full charge.

A fully charged battery will provide approximately 4 hours of continuous operation.

The indicator light can have four possible states as follows:

Solid Red	No battery detected
Blinking Red	Fault condition, battery or charger defective
Blinking Green	Charging
Solid Green	Fully charged

To ensure that you always have a fully charged battery pack available, it is recommended that a second battery pack be acquired to allow the use of the Veinsite while the depleted battery is being charged.

Installing/Removing the Batteries

CAUTION: Do not use batteries if visibly damaged or the charger station indicated a faulty battery.

Inspect the battery and contacts for contamination such as dust and dirt that could prevent proper electrical contact. If necessary, clean with a non-abrasive, lint free wipe or cloth.

Install the battery pack by pressing the blue tab on the battery and pivoting the battery into the unit's pocket (see Figure 1 below). Removal is the reverse of the installation process.

When installing a battery pack, make sure that the blue tab securely locks in place to retain the battery pack.

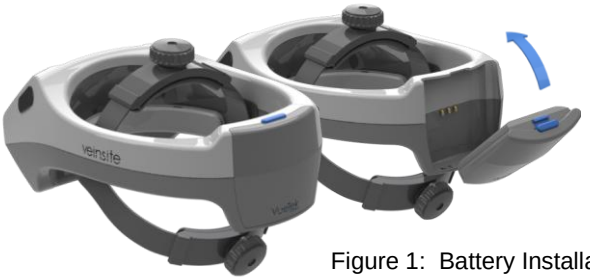

Figure 1: Battery Installation

Device Controls and Important Features

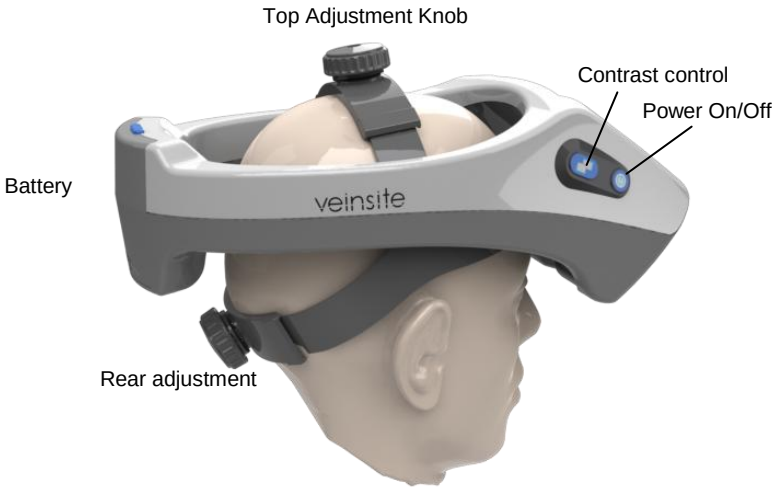

Figure 2: Parts and Controls

Removing Protective Lens Covering

The Veinsite is shipped with a protective film covering the front IR lens material and must be removed prior to use. Gently peel this covering off and discard. The device is now ready to be used.

Turning the Device On/Off

Once the charged battery is installed, press the blue power button on the right hand side of the unit to turn on the unit. Pressing the button again will turn off the unit.

The unit may be turned on prior to donning the device or once the device is positioned on the user's head.

If the device sounds three beeps after turning on, there is insufficient charge remaining in the battery to continue. Change or charge the battery to continue to use the device.

CAUTION: Applying power to the Veinsite activates the infra-red (IR) illuminators. Use normal precautions as listed in the Patient and User Safety section of this manual.

Wearing the Device

CAUTION: To reduce the potential of contaminant transmission, it is recommended that the Veinsite be cleaned and/or the disposable headband pads be replaced between users. It is also recommended that sanitary head covering such as a disposable bouffant be used while operating the device.

After placing the Veinsite device on the head, the head basket fit is adjusted by grasping the adjustment knobs and turning clockwise to tighten and counter-clockwise to loosen (see Adjustment Knobs: Figure 3).

With the device powered on, place the unit onto your head. Adjust the top adjustment knob so that the display is aligned horizontally with your eyes.

Hold the unit in position to maintain horizontal alignment and adjust the rear knob of the device so that the strap will fit easily onto your head. Increase the tension of the rear adjustment knob to achieve a snug and secure fit.

For a more precise view of the display, repeat previous steps making minor adjustments of the entire unit up or down on the forehead.

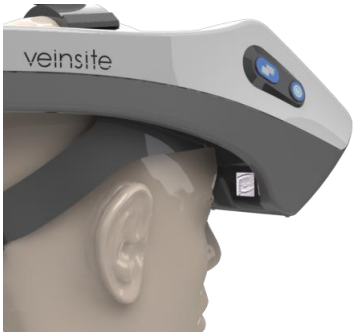

Figure 4: Representation of Screen to Eye Positioning

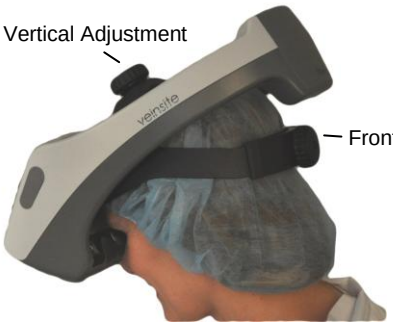

Figure 3: Headband Adjustments

The Veinsite is a visual aid designed to be used in conjunction with conventional clinical practice. With a working distance of approximately 10 to 20 inches [25 to 50 cm] from the patient's anatomy, the device provides hands free operation to complement current methods of vein identification.

a) Look into the display for an enhanced view of the vasculature (see Figure 5).

b) Look below the unit to allow normal vision and follow normal clinical practice.

c) Alternate between (a) and (b) as necessary

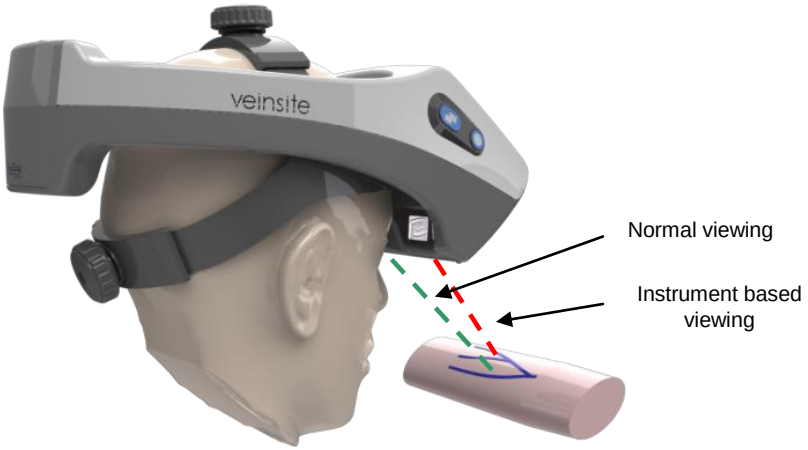

Figure 5

WARNING: Do not rely solely on the Veinsite display for performing the venipuncture or vascular access procedures.

If prior to or during the procedure, no contrast between the vascular system and surrounding tissue is noted or if other anomalies are detected, discontinue use of the device and contact VueTek for assistance.

The Veinsite is designed to be used in a wide range of lighting conditions including fluorescent, incandescent and natural lighting. As the device provides its own light source, a dimly lit room will not affect the efficacy of the Veinsite. In extremely bright conditions such as would occur in direct sunlight, the image's contrast may be reduced. If this occurs, shade the area as much as possible to improve the image quality.

Controls & Indicators

The Veinsite contains a LCD display that presents the image to the user as well as several informational icons.

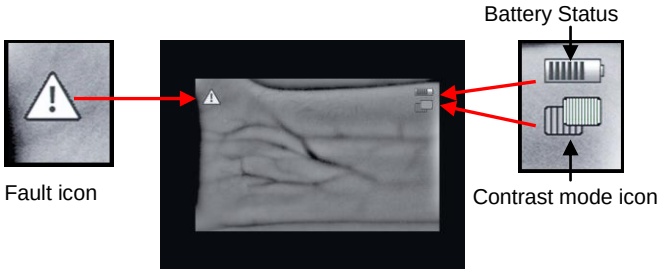

Image with enhanced contrast
Note: All icons are shown for display purposes only

Contrast Selection

The Contrast Control Button (Figure 2) will alternate the display between low contrast and high contrast. This selection alters the way the image is processed where fine detail may be enhanced or suppressed. The user may find that one mode is preferred over the other when factors such as patient age, condition, skin tone, and physiology (such as hair) are considered. An indicator in the display will show which mode is currently active.

Auto Shutoff

The Veinsite is equipped with a detector that will turn off the device after approximately 10 minutes if no motion of the headset is detected.

Battery Status

The visual indicator appearing in the upper right hand corner of the display will show eight bars when fully charged with each segment of the icon representing approximately 30 minutes of useful battery life remaining.

If the remaining battery life is insufficient to continue operation, the device will sound 3 beeps and turn off. The battery must be charged or changed at this point to continue using the device.

Fault Indicator

If an internal fault is detected during use, the imaging will be disabled and an icon in the form of an exclamation mark will be shown on the display. Contact VueTek or your distributor for further information.

Using the Device with a Remote Monitor

The Veinsite provides a video output port for connecting an optionally supplied VGA Cable, part number VTS1000-VGA to an external display monitor. By using this cable with a suitable monitor, observers can view, in real time, what the user of the Veinsite is seeing through the device.

To connect the Veinsite to an external display:

a) Slide the cable's molded clip onto the top ridge of the Veinsite as shown in Fig. 6. Loop the cable through the clip, allowing additional safety in the event the cable is pulled.

b) With the Veinsite turned OFF, gently pry open the protective cap on the left side of the unit, exposing the VGA connection.

c) Insert the molded connector on the cable into the receptacle in the unit. The molded connector should fit snugly into the recess where the protective cap fits. Do not force the connector or twist after insertion.

d) Attach the other end of the VGA cable to an appropriate input of a monitor and secure the support screws. Note that the Veinsite transmits a VGA compatible signal to a monitor capable of receiving such a signal. This includes all standard LCD, Plasma, and projector devices. PCs and laptops are not typically capable of receiving a signal and therefore are not compatible with the Veinsite device.

e) Turn the Veinsite on. The image will be simultaneously shown in the headset and the external monitor. The image on the monitor may differ from what is visible in the Veinsite's display due to monitor settings and external lighting conditions.

CAUTION: When using the remote monitor feature, refer and adhere to all instructions, paying special attention to the warnings and cautions found in the section on Remote Monitor Safety.

Figure 6: Use of Remote Monitor Cable

Maintenance & Support

The Veinsite does not require any periodic maintenance other than routine cleaning. There are no user serviceable components within the device other than battery replacement. Order replacement and additional batteries from your distributor.

Replacing Disposable Headband Pads

The pads located on the head basket straps can be removed and replaced as desired. Replacement pads may be ordered from your distributor and are available in varying quantities.

The pads are attached to the head basket with Velcro™ strips. To remove the pads, simply peel away the old pads and discard.

Replacing the pads consists of simply pressing the new pads into the areas indicated in figure 7. Observe the correct side of the pad to attach to the Velcro strip. The rough side should be against the strap, the smooth side to the user's head.

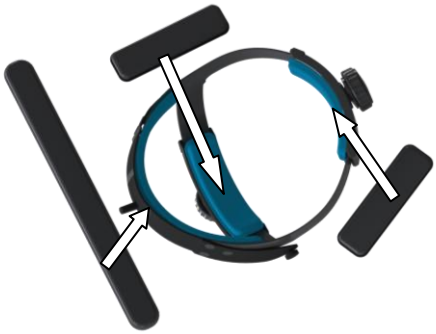

Fig. 7

VueTek Handling and Storage

CAUTION: Always keep the Veinsite and charger out of reach of children.

When not in use, power off the Veinsite to preserve battery life.

If the Veinsite is not to be used for an extended period of time, VueTek recommends removing the battery prior to storage.

Always store the unit in a safe, secure location per your institution's guidelines.

Operate at 32°F to 90°F [0°C to 32°C] and 0-80% relative humidity.

Store at -4 °F to 122 °F [-20°C to 50°C] and 0-95% relative humidity.

If carrying the unit for an extended distance, it is recommended that the device be placed into its carrying case.

Store the device where it will not be accessible by children and untrained individuals.

Cleaning

As the Veinsite is an optical instrument, it is important to keep the optical surfaces clean of contamination for optimum image quality.

Periodically inspect the device and if necessary, gently clean the front window that houses the camera and light sources. Any cleaner that is recommended for glass is acceptable; do not use cleaners that will leave a residue or abrasive as these will degrade the optical surfaces.

The device's housing can be wiped down using any common non-abrasive chlorine or alcohol based cleaners normally found in a medical environment.

Do not allow any liquids to enter into any connectors or into the device itself. Use only a cloth dampened with the cleaner to clean the device.

The headband pads may be cleaned or replaced as desired. Additional headband pads may be purchased through VueTek Scientific or your supplier.

CAUTIONS:

Do not immerse any portion of the unit or its accessories in liquids or disinfectants.

Do not sterilize the Veinsite or its accessories using heat, steam or pressure.

Do not allow any liquids to enter into any connectors or into the device itself. Use only a cloth dampened with the cleaner to clean the device.

Veinsite Specifications

Unit weight	35 oz / 1.0 Kg		**Battery charge time**	300 minutes typical
Approx. system ship wgt	7 lbs / 3.2 Kg		**Display type**	LCD
Working distance	10-20 inches (25 –50 cm)		**Display resolution**	640x480
Illumination wavelength	850 nm		**External display output**	VGA compatible
Battery type	Sealed 7.4V lithium ion		**Exposed materials**	Nylon, ABS, polycarbonate
Battery run time	240 minutes (4 hours) typical		**Battery charger input voltage**	100-240 VAC, 50/60 Hz
Min/Max operating temperature	32˚F / 90˚F (0˚C / 32˚C)		**Humidity Operating**	0-80% RH
Min/Max storage temperature	-4˚F / 122˚F (-20˚C / 50˚C)		**Humidity Storage**	0-95% RH

Veinsite Standards

CIE-S009/IEC-62471:	Photobiological Safety of Lamps and Lamp Systems
ANSI RP27.3:	Recommended Practice for Photobiological Safety for Lamps - Risk Group Classification
IEC 60601-1:	Medical Electrical Equipment Performance and Safety
IEC 60601-1-1:	Medical Electrical Equipment Safety
IEC 60601-1-2:	Medical Electrical Equipment Electromagnetic Compatibility

Veinsite and Accessories Ordering Information

VEINSITE	Headset Vein Viewing System
VTS1000-BAT	Battery Pack
VTS1000-CHARGER	Battery Charger Base / Power Supply Set
VTS1000-VGA	4.8 meter Remote Monitor Video Cable
VTS1000-CASE	Carrying Case
VTS1000-PAD2pk	Replacement Headband Pad Set (2 pk of 10 ea)
VTS1000-PAD10pk	Replacement Headband Pad Set (10 pk of 10 ea)
VTS1000-OUM	Operator's User Manual (this document)

Note: This manual is available at www.vuetekscientific.com and selecting the 'Manuals' button on the menu bar or by calling +1-207-657-6565

Service and Support

CAUTION: The Veinsite and its accessories are not field-serviceable. Do not attempt to repair or use a malfunctioning unit. Doing so could result in injury and will void the product warranty.

Customer and Technical Support within the U.S. and Canada:

Telephone: **207-657-6567**
Facsimile: **207-657-6569**

Warranty

VueTek Scientific ("VueTek") warrants that the Equipment conforms to any specifications provided in writing by VueTek to Customer for that Equipment, is of sound materials and workmanship, is new and unused, unless otherwise specified.

Except as provided in the above paragraph, VueTek is not making, and the Customer is not relying on, any representations or warranties with respect to the Equipment, including without limitation any implied warranty or merchantability, fitness for a particular use, or arising from course of performance, course of dealing or usage of trade.

Standard Warranty

1. **Standard Warranty Period**. The Warranties with respect to any Equipment shall remain in effect for the following period of time after delivery of the Equipment to the Customer (the "Warranty Period"): (1) Twelve (12) months for each Veinsite vascular imaging device; and (2) Ninety (90) days for any Veinsite battery.

2. **Notice of Warranty Claim**. If at any time during the applicable Warranty Period, the Customer believes that the Equipment does not comply with any of the Warranties, the Customer shall promptly notify VueTek of a Warranty Claim. If the Customer does not provide notice of Warranty Claim within the Warranty Period, the Customer shall not have any right to claim that the Equipment does not comply with the Warranties. The Customer shall inspect the Equipment promptly after delivery to the Customer and promptly notify VueTek of any alleged breach of any Warranties or any errors relating to the delivery of the Equipment.

3. **Repairs and Replacements**. If within the applicable Warranty Period the Customer notifies VueTek that any Equipment does not comply with any of the Warranties and if in fact the Equipment does not comply with any of the Warranties (not caused by misuse or abuse), VueTek shall, at VueTek's election and expense, either repair or replace the Equipment. The Customer shall not return any Equipment to VueTek without first obtaining a return authorization number from VueTek or VueTek's authorized distributor. If Customer fails to follow all of VueTek's return instructions, including the packaging of the Equipment, the repair will not be covered by this Warranty.

Appendix A

Electro-magnetic Compatibility Declarations

Emissions All Equipment and Systems

The Veinsite is intended for use in the electromagnetic environment specified below. The customer or user of the Veinsite should ensure that it is used in such an environment**.**

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	The VTS1000 (Veinsite) 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	Group 2	N/A
RF Emissions CISPR 11	Class A or B	B
Harmonics IEC 61000-3-2	Class A,B,C,D or N/A	Class A when using VGA cable and external monitor. Class B otherwise
Flicker IEC 61000-3-3	Complies or N/A	Complies
The VTS1000 (Veinsite) is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.		

CAUTION: When using the external monitor feature, the connected monitor may experience a momentary flicker due to AC electrical disturbances. The internal display of the Veinsite will not be affected.

Immunity All Equipment and Systems

Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
ESD EN/IEC 61000-4-2	±6kV Contact, ±8kV Air	±6kV Contact, ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30% RH
EFT EN/IEC 61000-4-4	±2kV Mains ±1kV I/Os	±1kV Mains ±1kV I/Os (see justification)	
Surge EN/IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential	Mains power quality should be that of a typical commercial or hospital environment
Voltage Dips/Dropout EN/IEC 61000-4-11	>95% Dip for 0.5 cycle, 60% dip for 5 cycles, 30% dip for 25 cycles, >95% dip for 5 seconds	>95% Dip for 0.5 cycle, 60% dip for 5 cycles, 30% dip for 25 cycles, >95% dip for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency 60/60Hz magnetic field EN/IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment

Recommended Separation Distances between portable and mobile RF Communications equipment and the Veinsite Equipment and Systems that are NOT Life-supporting

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

Max Output Power (Watts)	Separation (m) 150kHz to 80MHz D=(3.5/V1)(Sqrt P)	Separation (m) 80 to 800MHz D=(3.5/E1)(Sqrt P)	Separation (m) 800MHz to 2.5GHz D=(7/E1)(Sqrt P)
0.01	.1166	.1166	.2333
0.1	.3689	.3689	.7378
1	1.1666	1.1666	2.3333
10	3.6893	3.6893	7.3786
100	11.6666	11.6666	23.3333

Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Portable and mobile communications equipment should be separated from the VTS1000 (Veinsite) by no less than the distances calculated/listed below:			
Conducted RF EN/IEC 61000-4-6 Radiated RF EN/IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	(V1)Vrms (E1)V/m	D=(3.5/V1)(Sqrt P) D=(3.5/E1)(Sqrt P) 80-800MHz
D=(7/E1)(Sqrt P) 800 MHz to 2.5 GHz where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.			

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