

A health professional's guide for use and operation of the AccuVein AV400

AccuVein

AccuVein[®]

This AV400 User Manual and additional information can also be downloaded from www.accuvein.com

AV400 User Manual

AccuVein Inc. 2012
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Wavelength 642 nm/785 nm Peak Power 25 mW / 25 mW Pulse Energy 270 nJ / 270 nJ Pulse Length 11 µs IEC/EN 60825-1 (2001/07)



Device fully complies with European Directive 2002/364/ EC. Conformité Européenne For United States of America customers: IEC/EN 60825-1 Safety of Laser Product: Complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

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This manual last revised: October 2012

Warnings and Cautions

Read all instructions, cautions, and warnings prior to use. This product should be operated only by qualified medical professionals. The AV400 should not be used as the sole vein location method, and it is not a substitute for sound medical judgment and the visual and tactile location of veins.

Before using the AV400 on a patient, qualified medical professionals must read and understand this AV400 User's Manual. Before first use, users should compare how the AV400 detects veins with visual detection and palpation techniques.

English

◆ AccuVein AV400 AccuVein AV400 User Manual

A health professional's guide for use and operation of the AccuVein AV400





User controls and screens
Operating the AV400

English

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Setup		Charging the AV400		Warranty Summary		Specifications	
Intended Use		Cleaning and Disinfecting		Limitation of Liability		Product labels	
Product Description		Troubleshooting					

<u> </u>	Caution
	Consult operating instructions
	Refer to instruction manual/booklet
*	The AV400 emits laser radiation
<u></u>	Type B Applied Part
CE	Conformité Européenne (European Conformity). This symbol means that the device fully complies with European Directive 93/42/EEC
c C User Control Contr	ETL Classified means that most system elements conform to UL Std 60601-1
SN	Product Serial Number
REF	Reference to Catalog Model Number
UPN	Universal Product Number
EC REP	European Representative
***	Manufacturer

X	European Union Waste Electrical and Electronic Equipment Directive Logo. Return is allowed for proper disposal.		
1	Temperature limitation		
Œ	Humidity limitation		
®	Do not use if package is damaged		
*	Keep dry		
Ţ	Fragile, handle with care		
	Reusable packaging		
3	Recyclable packaging		
IPX0	No water ingress protection		
Rx Only	US federal law restricts sale of this device only to physicians or other qualified medical professionals. For external use only.		
	Direct Current. Example: 3.7 V indication of battery voltage		

Warnings and Cautions

Patient and User Safety—Warnings

WARNING: The AV400 enables location of certain superficial veins and is not a substitute for sound medical judgment based on the visual and tactile location and assessment of veins. The AV400 should be used only as a supplement to the judgment of a qualified professional.

WARNING: The AV400 should only be operated when its battery is sufficiently charged (indicated when the battery icon at the upper right of the LCD screen is green), or when the device is operated in a powered hands-free accessory to ensure AV400 is available for use

WARNING: AV400 vein location 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.

WARNING: The AV400 displays only superficial veins, and does so only to limited depths dependent on a variety of patient factors. The AV400 does not indicate vein depth.

WARNING: The AV400 emits Visible and Invisible laser radiation. Do not stare into beam. Class 2 laser product.

WARNING: Do not shine vein display light in eyes.

WARNING: Blink reflexes can be inhibited or reduced by disease, drugs, or other medical conditions. For patients who might have inhibited or reduced blink reflexes, AccuVein recommends outfitting the patient with a protective eye shield. A protective eye shield capable of blocking 642 nm and 785 nm should be used in this case.

WARNING: Stop using the AV400 if the red light does not turn on when the blue button is pushed.

WARNING: Do not hold the AV400 while performing venipuncture or other medical procedures.

WARNING: For external use only.

WARNING: Keep the AV400 and its battery out of the reach of children.

WARNING: To view vein location accurately, you must position the AV400 at the proper height, and directly over the center of the vein being assessed.

Patient and User Safety—Contraindications

WARNING: The AV400 should not be used to locate veins in or near eyes.

WARNING: The AV400 is not intended to be used as a diagnostic device or for treatment of any kind.

Patient and User Safety—Cautions

CAUTION: United States Federal law restricts this device to sale by or on the order of a physician or other qualified medical professional.

CAUTION: Operation or use of the AV400 in a manner different than specified in this AV400 User's Manual may result in hazardous radiation exposure.

CAUTION: Do not make any connections to the USB port on the AV400 device.

Equipment Care— Warnings

WARNING: Do not immerse the AV400 or the AV400 charging cradle in liquid or wet the AV400 such that liquid spills off.

WARNING: Do not attempt to open, disassemble, or service the battery pack. Do not crush, puncture, or dispose of the battery in fire or water. Do not short external contacts. Do not expose to temperature above 60°C / 140°F .

WARNING: Do not modify in any way the interior or exterior components of the AV400.

WARNING: To reduce the risk of fire or shock hazard and annoying interference, use only the recommended accessories and do not expose this equipment to rain or heavy moisture.

WARNING: Use only AccuVein accessories and replacement parts with the AV400. The use of non AccuVein accessories may degrade safety.

Equipment Care—Cautions

CAUTION: Use only AccuVein approved battery charging accessories, AccuVein BA300 and BA400 batteries, and AccuVein brand additional accessories. If the AV400 will not be used for an extended time, remove and store battery in a safe, dust-free location. The battery should be replaced only with an approved AccuVein battery. Removing or replacing the battery should not to be done in the patient environment.

CAUTION: Electromagnetic Interference (EMI) can affect the proper performance of the device. Normal operation can be restored by removing the source of the interference.

CAUTION: Do not attempt to sterilize the AV400 with heat or pressure sterilization methods.

CAUTION: The AV400 will not display veins if operated outside its temperature range.

CAUTION: The AV400 may not display veins if operated under bright light such as bright sunlight.

CAUTION: Dispose of used batteries according to manufacturer's instructions. A recyclable lithium ion battery powers the AV400. Please call AccuVein at (816) 997-9400 for information on how to dispose or recycle this battery.

CAUTION: Do not disassemble or modify the AV400 or any of its charging accessories.

CAUTION: Do not service. The AV400 contains no customer serviceable components. The AV400 and its accessories should be serviced only by an authorized AccuVein repair department.

Setup

ging it into an outlet.

The AV400 Vein Viewing System includes an AV400 vein illuminator with rechargeable battery, a charging cradle, power supply and power adaptors, and instructional documents. AccuVein recommends fully charging the AV400 before first use. Connect the charging cradle to the power supply. The AV400 comes with power supply country adaptors to ensure outlet compatibility in your country. If necessary, secure a dif-

Remove the plastic protective cover from the LCD before use

ferent power adaptor to the power supply and before plug-

- ▲ **WARNING:** Inspect power cords and supplies for damage. If any damage is found do not use until replacement is obtained
- **CAUTION:** Inspect the power adaptor on the power supply to confirm it is properly secured.

AccuVein also offers optional hands-free stands that many practitioners find useful. For information about these and other optional accessories visit the AccuVein web site www. accuvein.com.

Intended Use

The AccuVein® AV400 is a portable, hand-held instrument that helps medical professionals to locate certain superficial veins. The AV400 is intended to be used as a supplement to appropriate medical training and experience. The AV400 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 AV400, medical practitioners should always follow the appropriate medical protocols and practices as required by their medical facility, as well as exercising sound medical judgment.

When used properly, the AV400 enables users to locate certain superficial veins in connection with medical procedures, such as venipuncture.

The AV400 can be used whenever the determination of vein location is appropriate.

Product Description

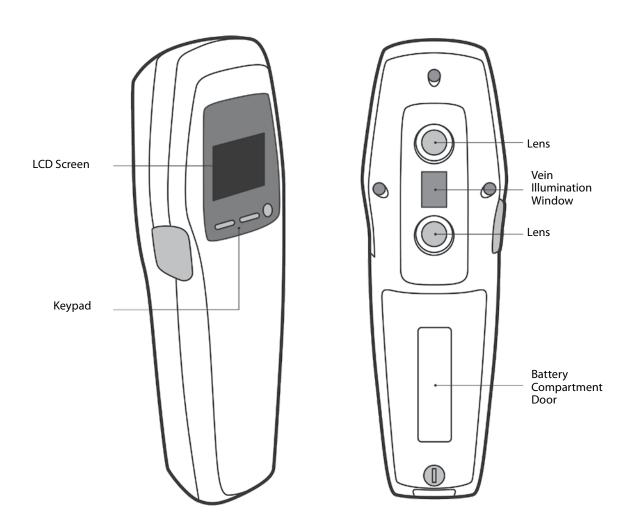
The AV400 operates by using infrared light to detect veins beneath the skin, then projecting the position of the veins on the skin surface directly above the veins. Qualified medical personnel can observe the vasculature as displayed to assist them in finding a vein of the right size and position for venipuncture and other medical procedures requiring the location of superficial veins. No training is required to operate the AV400.

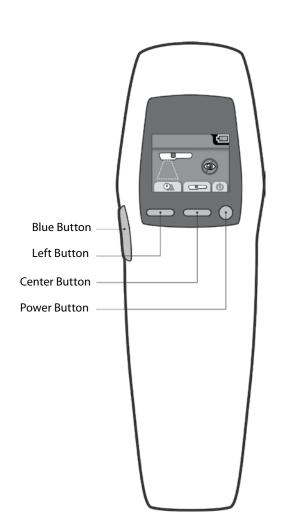
The AV400 only shows superficial vasculature. The maximum depth that veins are displayed varies by patient. In addition, some patients' veins or a portion of their veins might not be displayed well or at all. Causes for less than optimal or lack of vein display include, but are not limited to, vein depth, skin conditions (e.g., eczema, tattoos), hair, scarring or other highly contoured skin surface, and adipose (fatty) tissue.

When held directly overhead, the AV400 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.

The AV400 requires no routine or preventative maintenance. The AV400 is portable internally powered by battery and approved for continuous operation. The AV400 is considered a Type B applied part and is not protected by ingress of water. The technology in the AV400 is covered by the following patents: US 8,073,531; US 7,904,138; US 8,150,500; US 7,983,728; Mexico 0357588. Other US and international patents pending. Visit www.accuvein.com for the most current information.

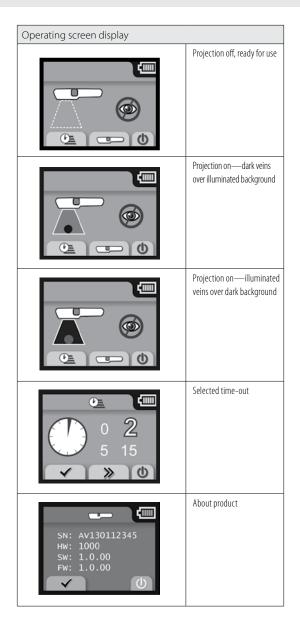
User controls and screens

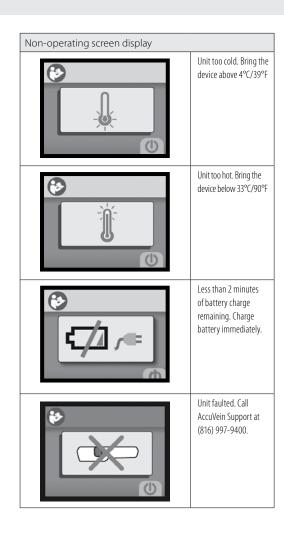




AV400 controls at a glance		
Q	Power AV400 ON or OFF	
	Turn vein display light ON or OFF	
	Invert the projection	
	About Product	
(V)	Select time-out	

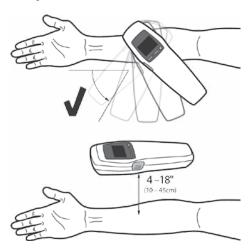
Display indications				
	Do not shine in eyes			
-	Battery charge status			
>>>	Next selection			
4	Select item			
/	Device in powered hands-free accessory			





Operating the AV400

Positioning the AV400



Hold the device from 4—18" (10 to 45 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. Don't move or tilt the device to either side of the vein or this will offset the projected vein from its true location beneath the skin. You can then 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.

▲ **WARNING:** To view vein location accurately, you must position the AV400 directly over the center of the vein being assessed.

CAUTION: The AV400 projection may not display veins if operated under bright light such as bright sunlight



Power on/off button

Press the on/off button to power on or off the AV400.



Blue button

The blue button is located on the left side of the AV400. Press the blue button to power on the AV400 and turn on the vein display light. Press the button again to turn the vein display light off. This leaves the device on so you can navigate the device settings. Press the blue side button again to turn the vein display light back on and begin locating veins again.



Time-out setting:

The time-out setting determines the amount of time until the vein display light turns off. This setting may help increase battery operation time of the AV400. To set the time, press the left button to go into the time-out menu. The time out can be set to 0 (no time-out), 2 minutes, 5 minutes, or 15 minutes.

Operating the AV400 (continued)

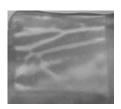


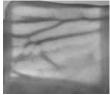
Inverse setting:

The inverse setting inverts the dark (shadow) and light (red) projection areas of the AV400 such that the veins can be depicted by either light or dark. Changing the inverse setting may improve vein visibility and eye comfort level. AccuVein recommends reversing the vein display to show light veins in cases where veins are very small. When operating the device outdoors or in bright surroundings, use the dark veins settings to enhance visibility.

WARNING: Do not shine vein display light in eyes.

⚠ WARNING: Blink reflexes can be inhibited or reduced by disease, drugs, or other medical conditions. For patients who might have inhibited or reduced bright light blink reflexes, AccuVein recommends outfitting the patient with a protective eye shield. A protective eye shield capable of blocking 642 nm and 785 nm should be used





Assess the Vasculature

While the vein display light is on, shine the AV400 over the patient's skin. You can do this before palpation, scanning quickly over the skin to help narrow down possible locations, or after palpation has confirmed vein location and suitability.

You can then often see veins better by rotating the AV400 slightly on its axis, and moving the device closer to or further away from the skin.

Confirm the Vein



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.

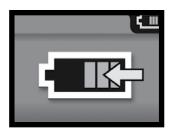
If performing venipuncture

If you are performing venipuncture, you may use an AccuVein hands-free accessory so both your hands remain free to perform the procedure. You can also hand the AV400 to an assistant during the procedure. The AV400 should be used only by qualified medical professionals and only in conjunction with appropriate visual and tactile vein assessment techniques.

Charging, Cleaning and Troubleshooting

Charging the AV400

Verify the charging cradle is properly connected (see the Setup section). Place the AV400 in the charging cradle with the LCD facing outward to begin charging. While the AV400 is in its charging cradle, the vein display light does not operate and the device cannot be used. An animated battery charge icon will display when the AV400 is charging. The light on the charging cradle will only turn on when a device is detected. If the light turns on when there is no device placed in the charging cradle please call AccuVein support for assistance.



To ensure the battery remains charged and ready for use, store the AV400 in its charging cradle or a powered Accu-Vein accessory.

CAUTION: Use only the AccuVein® PS310 power supply with the CC300 cradle and other AccuVein approved accessories.



When the AV400 battery gets low the battery indicator will flash yellow or red and beep repeatedly. Before the battery is completely depleted, an alert requesting to charge the battery will be displayed on the screen. The AV400 will resume normal operation once it has been charged.

In normal operation, the AV400 battery needs to be replaced about every two years. Longer charge cycles or shorter operating periods are indications that the battery should be replaced.

To replace the battery, open the battery compartment on the narrow end of the device's underside. Use a screwdriver or edge of a small coin to unscrew the cover. Be careful not to touch or scratch the lenses on the back of the device. Do NOT use a tool to remove the battery.

Charging, Cleaning and Troubleshooting

Cleaning and Disinfecting

WARNING: Users should inspect the AV400 and clean and disinfect the AV400 as required by their institution's policies to ensure that it is sufficiently clean before each use.



WARNING: Do not use AV400 if the vein illumination window is scratched or dirty. The AV400 should be returned to AccuVein for servicing if the vein light window is scratched.

For peak performance, the optical surfaces and lenses on the back of the AV400 should be kept clean. Use alcohol wipes or any soft lens wipe with several drops of 70% isopropyl alcohol. Dirt or scratches on the vein display window show up as dark shadows in the vein projection.

To clean the body of the AV400 and its charging cradle, you may use a cloth moistened with 70% isopropyl alcohol, a 10% dilution of chlorine bleach in distilled water, or soap and water. You can also use common household disinfectants and wipes.

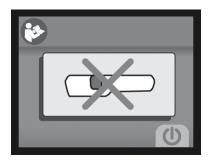
Do not immerse the AV400, the AV400 charging cradle, or the AV400 handsfree stand in liquid or get the AV400 or its components wet such that liquid spills off. Do not attempt to sterilize the AV400 with heat or pressure sterilization methods

Do not clean the AV400 while in a charging cradle or hands-free accessory.

Do not clean the AV400 when the battery cover is removed.

Unplug the charging cradle before cleaning the cradle.

Troubleshooting



Warranty and Liability

If the AV400 detects that it cannot operate properly, it turns off the vein display light and displays an alert or fault screen (See Non-Operating Display under User Screens). When the AV400 is not operating properly turn the device off using the round Power on/off button.

A yellow header on the screen indicates an alert. Alerts appear if you operate the device in an environment that is too cold (less than 4°C/39°F) or too hot (more than 33°C/90°F). Should a temperature alert occur, simply bring the AV400 back within its operating temperature range.

Other alerts indicate when the battery needs to be charged or replaced.

The fault screen has a red header and is picture above. If the fault screen appears, you should stop using the AV400 immediately. Turn off the device and contact AccuVein support via telephone at (816) 997-9400 option 3.

Warranty Summary

AccuVein warrants the AV400, when purchased new from an authorized seller, is of sound materials and workmanship and conforms to the manufacturer's specifications for a period of one year from the date of purchase from AccuVein or its authorized distributors or agents. The warranty period for accessories is as follows: Charging Cradle – 1 year; Power Supply – 1 year; Battery – 90 days. AccuVein will repair or replace any product that does not satisfy these warranties within this time limit at no cost to the customer. You must obtain a Return of Material Authorization (RMA) number from AccuVein support. The repaired unit has a 90-day warranty from the date it is received by the customer. Contact AccuVein support at (816) 997-9400 option 3 for service or additional information

These warranties do not cover any misuse or abuse. These warranties are also void if the instrument is repaired by other than AccuVein or an authorized agent. There are no other warranties, either express or implied, other than those set forth in AccuVein's written warranty.

This is only a summary of the AccuVein warranty coverage. Contact AccuVein or see www.accuvein.com/legal/warranty for full details of warranty coverage.

Limitation of Liability

In no event shall either AccuVein or the customer be liable to the other for any incidental, indirect, special or consequential damages (including without limitation lost profits or lost business opportunity) that the other party may incur by reason of its having entered into or relied on a purchase or lease agreement, or arising out of the performance or breach of such an agreement, even if the party against whom a claim is made was advised or knew of the possibility of such damages. The foregoing limitation shall apply regardless of the form of the claim in which such liability may be asserted, including breach of contract, tort (including negligence) or otherwise.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The AV400 is intended for use in the electromagnetic environment specified below. The customer or the

IMMUNITY test			Electromagnetic environment –
	test level		guidance
Electrostatic	±6 kV contact	±6 kV contact	Floors should be wood, concrete, or
discharge (ESD)	±8 kV air	±8 kV air	ceramic tile. If floors are covered
IEC 61000-4-2			with synthetic material, the relative
			humidity should be at least 30 %.
Electrical fast	±2 kV for power	±2 kV for power	Mains power quality should be that
transient/burst	supply lines	supply lines	of a typical commercial or hospital
IEC 61000-4-4	±1 kV input/output	Not applicable	environment.
	lines		
Surge	±1 kV line(s) to	±1 kV differential	Mains power quality should be that
IEC 61000-4-5	line(s)	mode	of a typical commercial or hospital
	±2 kV line(s) to	±2 kV common	environment.
	earth	mode	
Voltage dips, short	<5 % U _T	<5 % U _T	Mains power quality should be that
interruptions and	(>95 % dip in U_T)	(>95 % dip in <i>U_T</i>)	of a typical commercial or hospital
voltage variations on	for 0.5 cycles	for 0.5 cycles	environment. If the user of the
power supply input			AV400 requires continued operation
lines	40 % U _T	40 % U _T	during power mains interruptions, it
IEC 61000-4-11	(60 % dip in U_T) for	(60 % dip in U_T) for	is recommended that the AV400 be
	5 cycles	5 cycles	powered from an uninterruptible
	70.0/ 1/	70 0/ 11	power supply or a battery.
	70 % U _T	70 % U _T	
	(30 % dip in U_T) for	$(30 \% \text{ dip in } U_T) \text{ for }$	
	25 cycles	25 cycles	
	<5% U _T	<5% U _T	
	(>95 % dip in U _T)	(>95 % dip in U_T)	
	for 5 s	for 5 s	
Power frequency	3 A/m	3 A/m	Power frequency magnetic fields
(50/60 Hz) magnetic	37/111	3 74111	should be at levels characteristic of
field		1	a typical location in a typical
		1	
IEC 61000-4-8			commercial or hospital

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Recommended separation distances between

portable and mobile RF communications equipment and the AV400

The AV400 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AV400 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AV400 as recommended below, according to the maximum output power of the communications equipment

Rated Maximum	Separation distance according to frequency of transmitter m			
Output				
power of transmitter	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz	
w	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$	
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 meters (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 separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions The AV400 is intended for use in the electromagnetic environment specified below. The customer or the user of the AV400 should assure that it is used in such an environment. Compliance Electromagnetic Environment Guidance RF Emissions Group 1 The AV400 uses RF energy only for its internal CISPR 11 function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronics. RF Emissions The AV400 is suitable for use in all establishments Class A CISPR 11 other than domestic and those directly connected Harmonic Emissions Complies to the public low-voltage power supply network IEC 6100-3-2 that supplies buildings used for domestic Voltage Fluctuations purposes. Complies

IEC 6100-3-3

Guidance and Manufacturer's Declaration – Electromagnetic Immunity				
The AV400 is intended for use in the electromagnetic environment specified below. The customer or the				
user of the AV400 should assure that it is used in such an environment.				

IMMUNITY TEST	IEC 60601 TEST	COMPLIANCE	Electromagnetic Environment –
	LEVEL	LEVEL	Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the AV400, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d=1.2\sqrt{P}~80~\text{MHz}~to~800~\text{MHz}$ $d=2.3\sqrt{P}~800~\text{MHz}~to~2.5~\text{GHz}$ 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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

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

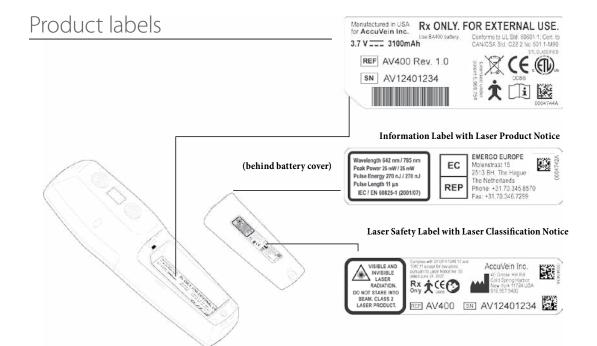
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AV400 is used exceeds the applicable RF compliance level above the AV400 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary. such as re-orienting or relocating the AV400. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Product Specification

Specifications

	(0 -)
Weight	275 grams (9.7 oz.)
Size	5 x 6 x 20 cm (2" x 2.4" x 7.9")
Battery	AccuVein® BA400 user replaceable Li-lon 3.6V. BA400 — 3,100 mAh
Continuous (vein light on) run time on full charge:	Typically 180 minutes
Number of standard viewing procedures that can be performed using a fully charged battery	90
Charge time (full)	Typically 3 hours

Operating	Temperature	4°C to 33°C (39°F to 90°F)
	Humidity	5% to 85% RH non-condensing
Transport	Temperature	-20°C to 50°C (-4°F to 122°F)
	Humidity	5% to 85% RH non-condensing
Storage	Temperature	-20°C to 50°C (-4°F to 122°F)
	Humidity	5% to 85% RH non-condensing







AccuVein Inc.

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Cold Spring Harbor, NY 11724

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www.accuvein.com/av400um