

English



 **AccuVein[®]**

**AccuVein AV600
Instructions For Use (IFU)**

A health professional's guide for use
and operation of the AccuVein AV600

AV600 Vein Visualization System

Instructions For Use (IFU)

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SECTION 1 - INTRODUCTION

1.1 Overview

This Instructions for Use (IFU) document introduces the AccuVein AV600 Vein Visualization System, along with step-by-step information to guide qualified medical professionals in the safe and effective operation and proper maintenance of the AccuVein AV600 Vein Visualization System.

The AV600 facilitates assessment of certain superficial veins and is not a substitute for sound medical judgment, and standard clinical procedures for venous assessment, such as visual and tactile evaluation of the superficial venous system. The AV600 should be used only as a supplement to the clinical judgment of a qualified medical professional.

Before using the AV600 on a patient, qualified medical professionals must read and understand this AV600 Instructions for Use (IFU), in its entirety. All users must pay careful attention to the Warnings and Precautions throughout the IFU.

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AV600 is manufactured for AccuVein Inc.

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520nm / 808nm
 440nJ / 220nJ
 EN/IEC 60825-1:2014

IEC/EN 60825-1:2014
Class 1 laser device
Wavelength: 520nm and 808nm
440nJ and 220nJ per pulse in train

For United States of America customers: Complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007

1.2 Device Identification

GTIN and GUDI#'s

Device Name(s)		AV600 Vein Visualization System					
Development Code(s)	Product	GMDN Term	GMDN Code	CND Term	CND Code	Basic UDI-DI	UDI-PI
	AV600	Infrared-light Vein Locator		Instrumentation for general medicine not otherwise classified	-	199284148536	Date of Manufacture*: (11)YYMMDD Serial Number*: (21)AVYYWWNNNNX
	HF580	Powered, Hands-Free Wheeled stand	42513	Devices for Blood Transfusion and Hematology – others	B99	00850019808025	Date of Manufacture*: (11)YYMMDD Serial Number*: (21)HF580YYMMNNNN

**YY = Year, MM = Month, DD = Day, NNNN = Unique Serial Identifier, X = Facility Identifier*

1.3 Product Description

The AccuVein AV600 medical device is a portable, easy to operate, hand-held instrument that helps medical professionals to visualize and assess superficial veins.

The AV600 uses near-infrared (NIR) light to detect superficial veins beneath the skin and uses visible light to project their location onto the skin surface directly above them. Qualified medical personnel can observe the vasculature to assist in finding a vein of the right size and position for venipuncture and other medical procedures requiring the location and assessment of superficial veins.

The AV600:

- Is a Class 1 (US) Medical Device and is a Class IIa (EU) Medical Device.
- Requires no routine or preventative maintenance.
- Is portable, internally powered by a battery.
- Is a Type B applied device complying with specified requirements for protection against electric shock.
- Does not contain a medicinal substance, tissues or cells of human origin, tissues or cells of animal origin.
- Is not sterile and does not require sterilization before use; disinfection is recommended if device is contaminated with biohazards.
- Is non-contact, non-invasive and does not deliver a medicinal or biologic product; therefore the “Qualitative composition of the device and quantitative information on the main constituent(s) responsible for achieving the principal intended action” is not applicable to the device.

1.4 Intended Use

The AV600 is intended to display the superficial venous system to help medical professionals visualize and assess superficial veins. The AV600 enables users to visualize and assess certain superficial veins in connection with medical procedures, such as venipuncture. Additionally, vein visualization can be utilized for the avoidance of certain veins during aesthetic or operative procedures.

1.5 Intended Users

Qualified healthcare professionals/providers and clinical practitioners with experience and knowledge of the indications and methods required for assessment of superficial veins, including but not limited to, physicians, nurses and phlebotomists.

- United States Federal law restricts this device to sale by, or on the order of a physician, or another qualified medical professional.

Note: End users may not offer this device for resale to others, regardless of their qualifications. Sales of AccuVein AV600 Vein Visualization Systems are only available from AccuVein or AccuVein authorized Distributors.

- When using the AV600, medical practitioners should always follow the appropriate medical protocols and practices as required by their medical facility, as well as exercise sound medical judgment.

1.6 Intended Patients (Patient Target Groups)

Patients undergoing a procedure where visualization and/or assessment of superficial or subcutaneous veins is required.

The AccuVein AV600 device is suitable for treating both pediatric and adult patient populations. There are no patient restrictions based on age or gender.

1.7 Indications for Use

The AV600 can be used by clinicians to visualize and assess superficial veins in connection with medical procedures that involve accessing or avoiding superficial veins.

The AV600 can be used whenever visualization and assessment of a superficial vein is appropriate, in physical locations such as hospitals, clinics, and other surgical and aesthetic facilities.

The AV600 can be used for the following medical and aesthetic indications:

- Vein visualization and assessment for Venipuncture
- Vein visualization and assessment for Cannulation
- Vein visualization and assessment for Surgery
- Vein visualization and assessment for Avoidance of Veins

1.8 Contraindications

A Contraindication indicates when a device should not be used, generally when the risk of use clearly outweighs any possible benefit. There may be persons with whom the device should not be used because of the health status, patient characteristics, accompanying therapy, disease state, or continued use in the face of unacceptable hazardous adverse event.

- The AV600 should not be used to locate veins in the eyes.
- The AV600 is not intended to be used as a diagnostic device or for treatment of any kind.

1.9 Introduction to Warning and Precautions

Warnings and Precautions are signals for Hazard Alerts. Warnings and Precautions represent different levels of potential Severity of Harm, as described below:



Warning: A warning alerts the reader about a situation which, if not avoided, **could result in death or serious injury**. It may also describe potential serious adverse reactions and safety hazards. The designation of a hazard alert as a “warning” is reserved for the most significant problems.



PRECAUTION:

Precaution: The term precaution is used for the statement of a hazard alert that warns the reader of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property. It may also be used to alert against unsafe practices. This includes the special care necessary for the safe and effective use of the device and the care necessary to avoid damage to a device that may occur as a result of use or misuse.

Note: Warnings and Precautions for Use of the AV600 are covered in detail in Section 2 - Safety Information.

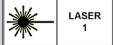
1.10 Special Facilities Required for Device Use

The Device can be operated in normal clinical settings; no special facilities are required for device use.

1.11 User Assistance/ Support Information

AccuVein Support can be reached at: at www.accuvein.com/support, by email at service@accuvein.com, or via telephone at +1 (888) 631-8160 or 1(816)997-9400.

1.12 Symbols Used in This Device's Labeling and Instructions for Use

Symbol	Meaning / Description	Standard Reference
	Voltage – Direct Current (DC)	IEC 60417
	Voltage – Alternating Current (AC)	IEC 60417
	Class 1 Laser Product	IEC 60825-1
	Manufacturer	ISO 15223-1:2021, 5.1.1
	Catalog Number	SO 15223-1:2021, 5.1.6
	Serial Number	ISO 15223-1:2021, 5.1.7
	Unique Device Identifier (UDI) data carrier	ISO 15223-1:2021, 5.1.10
	Do not use if the package is damaged	ISO 15223-1:2021, 5.2.8
	Temperature Limitations	ISO 15223-1:2021, 5.3.7
	Humidity Limitations	ISO 15223-1:2021, 5.3.8
	Consult Instructions for Use	ISO 15223-1:2021, 5.4.3
	Do not immerse in any liquid	IEC 60417
	Do Not Dispose / WEEE	Directive 2012/19/EU
	Medical Device	EU MDR 2017/745
	Class II Equipment	IEC 60601-1
IP54	Ingress Protection Rating (Dust-protected / Splash-resistant)	IEC 60529
	Certifications	
	Safety Compliance - Intertek	

SECTION 2 - SAFETY INFORMATION

This Section will provide the following AV600 Clinical and Safety Information:

- Clinical Benefits
- Adverse Events (AEs) and Serious Adverse Events (SAEs)
- Residual Risks
- Warnings and Precautions (Organized into the following Categories)
 - Basic Safety/Usage Environment
 - Device Malfunction
 - Patient Safety
 - Laser Safety
 - Biological Safety
 - Operator Safety
 - Electrical and General Equipment Safety
 - EMI/IEC Equipment Protection
- Expectations of the Device for the Patient
- Disease and Self-Care

2.1 Clinical Benefits

The AV600 Vein Visualization System improves visualization of superficial veins, enabling clinicians to identify optimal sites for venous access or vein avoidance (e.g., during cosmetic and microsurgical procedures). By enhancing visualization, [1-3] the device supports more accurate and efficient procedures via:

- Reducing the time exploring / assessing veins and undertaking procedures ^[1]
- Increasing the success rate of venipuncture attempts and peripheral IV catheter placement ^[3]
- Increasing clinician satisfaction ^[2]
- Enhancing the knowledge and skills of clinicians ^[3]

^[1] Tamura, F. and J. Oshima, *Identification of recipient subcutaneous veins in limb trauma flap surgery by use of Accuvein(R)*. *J Clin Orthop Trauma*, 2022. 30: p. 101916.

^[2] Renno, I., et al., *Vein Visualization With a Near Infrared Imaging Device and Its Impact on Students' and Nurses' Skills in an Academic Teaching University Hospital*. *J Infus Nurs*, 2024. 47(4): p. 249-254.

^[3] Yilmaz, H., et al., *Does the use of infrared technology (AccuVein AV-500(R)) for Peripheral Intravenous Cannulation (PIVC) increase the success rate in nursing students? A randomized controlled trial*. *Nurse Educ Today*, 2022. 108: p. 105179.

2.2 Adverse Events (AEs) and Serious Adverse Events (SAEs)

The AV600 does not contact the patient and does not introduce direct clinical risks. However, the clinical procedures in which the device is used (such as venipuncture, IV catheter placement, injections, or other vascular access procedures) carry inherent risks, including hematoma, infiltration, extravasation, pain, thrombosis, or other access-related events. These events are associated with the clinical procedure and not caused by the AV600.

Notice is given to the user and/or patient that Serious Events (SE) and Serious Adverse Events (SAE) should be reported to AccuVein (manufacturer) (see Section 12 – Service and Serviceability) and the cognizant National Competent Authority (FDA, Medicaid, etc.) in the region or country where in user is located.

2.3 Residual Risks

Residual risks include any undesirable side effects that could be experienced by the patient.

An AV600 malfunction, such as a misalignment of vein projection, could result in missing the venous target and potentially causing infiltration, hematoma formation, nerve damage, pain, hemoconcentration, extravasation, arterial puncture, petechiae, fear and phobia, infection, syncope and fainting, excessive bleeding, edema, and thrombosis.

2.4 Basic Safety/ Environmental Usage



WARNING:

- The AV600 must not be used as the sole method for locating veins. Always confirm vein location using appropriate clinical assessment techniques and follow all facility protocols. The device must be operated only by qualified healthcare professionals.
- Do not use the AV600 until all the materials in this IFU have been reviewed and fully understood.
- The AV600 should be used in an appropriate setting with safe, clean, and hygienic conditions, and should meet defined standards of environmental safety. **See also Section - 16 System Specifications** for further information.
- Do not dispose of an AV600 device or accessories in a litter bin or at a public waste disposal site. To avoid the negative impacts of disposal of the AV600 device on the environment, please contact AccuVein customer service for waste recovery instructions. See also **Section 14 - Disposal and Recycling** for further information.



PRECAUTION:

- Device shall be maintained, and error codes adhered and tended to.
- To achieve optimal performance device should be used within temperature limits. **Section 16 - System Specifications** for further information.
- The AV600 will not display veins if operated outside its temperature range. See also **Section 16 - System Specifications** for further information.

2.5 Device Malfunction



WARNING:

- If the AV600 detects that it cannot operate properly, it turns off the vein display light and displays an alert or fault screen.
- When the AV600 is not operating properly, turn the device off using the side blue power On/Off button. Do not attempt to charge the unit.
- Alerts may appear if the device operates in an environment that is too cold or too hot (**Section 16 - System Specifications** for further information). Should a temperature alert occur, simply bring the AV600 back within its operating temperature range, but not artificially through heating or cooling.
- If the fault screen appears, stop using the AV600 immediately. Turn off the device and contact AccuVein Customer support. Provide the fault code that appears on the fault screen.
- Improperly securing the AccuVein Vein Visualization System to the HF580, HF550, or HF510 mount may result in the device detaching from the mount.
- Overloading the HF580, HF550, or HF510 or improper mounting of the AccuVein device may lead to instability and tip-over.
- Use of third-party devices or accessories may compromise safety or performance.
- For all customer service needs inside the USA, contact AccuVein customer support at www.accuvein.com/support, by email at service@accuvein.com, or via telephone at +1 (888) 631-8160 or 1(816)997-9400. For customer inquiries outside the United States, please contact your local approved distributor.

2.6 Patient Safety



WARNING:

- The AV600 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 AccuVein AV600 is intended for use by competent users capable of interpreting image quality, diagnosis, and clinical utility of the system.
- Stop using and charging the AV600 if the projection does not turn on when the side blue button is pushed. (Also see Laser Safety).
- The AV600 should only be operated when its battery is sufficiently charged (indicated when the battery icon on the AV600 display is green), or when the device is operated in a powered hands-free accessory, to ensure AV600 is available for use.
- The AV600 displays only superficial veins and does so only to limited depths, dependent on a variety of patient factors.
- AV600 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.
- AccuVein AV600 does not distinguish between venous or arterial vessels.
- Avoid using the AV600 in bright light, such as direct sunlight, as vein projection may be impaired or undetectable.
- Store the AV600 and its battery out of the reach of infants and children. Failure to do so could result in a choking hazard caused by swallowing a small part that has become detached. (See also Basic Safety section)
- Do not use to locate veins in the eyes. (See also Laser Safety)
- Do not shine the AV600 directly into patient eyes. (See also Laser Safety)
- The AV600 is not intended to be used to diagnose, treat, or verify the presence of a medical condition.
- Clinician using device shall not deviate from its intended use. **Section 1 – Intended Use** for further information.
- AV600 is intended to be used by trained Health Care Professionals such

as, but not limited to, Licensed Doctors, Nurse Practitioners, Emergency Medical Technicians, Registered Nurses, Anesthesiologists, Vascular Access Technicians, Phlebotomists, Infusion Nurses, to perform vascular access.

2.7 Laser Safety



WARNING:

- The AV600 emits visible and invisible laser radiation for medical purposes. Do not stare directly into the beam. (See also Patient Safety)
- The AV600 should not be used to locate veins in the eyes. (See also Patient Safety)
- Operation or use of the AV600 in a manner different than specified in this AV600 IFU may result in hazardous laser light exposure.
- The AV600 Laser is a Class 3R Laser; however, its attenuated output is Class 1.

2.8 Biological Safety



WARNING:

- Ensure to routinely inspect and disinfect the device before, as required by your institution's policies and procedures, before and after use, to ensure there is no blood or human tissue splatter on the device, which could be a source of human contamination. This will also help prevent spread of infection.
- If you see biological tissue or fluid, take extra measures to cleaning the device and don gloves prior to touching the device.
- When cleaning and disinfecting the housing of the AV600 and its accessories, use an AccuVein-approved cleaner and follow the instructions listed in **Section 10 - Maintenance, Cleaning and Disinfection**, or on the AccuVein website.
- When cleaning any AccuVein device or accessory, use an approved wipe and firmly squeeze the wipe to remove excess cleaning fluid. This helps to prevent the pooling of liquid in crevices and depressions, which can damage the plastic.

The following wipes and cleaner are approved for use: Isopropyl Alcohol (maximum 70%), PDI Sani-Cloth Plus, PDI Super Sani-Cloth, Pre-moistened bleach wipes (10% or less), Caviwipes1, Cavicide1, Cidex Plus, EcoLab Incidin Plus, EcoLab Incidin Pro, EcoLab SaniCloth Active.

For a full list of approved and unapproved cleaners for products, accessories and procedures visit: www.accuvein.com/clean.

- Do not attempt to sterilize the AV600 with heat or pressure sterilization methods. (See also Electrical or General Equipment Safety)
- Do not clean the AV600 while it is in the CC500 Charging Cradle or in a hands-free accessory.
- Do not clean the AV600 when the battery cover is removed.
- Unplug the CC500 Charging Cradle before cleaning.

Note: *The AV600 device is a non-contact device and is not intended to deliver or support the delivery of the following:*

- *Medicinal substances*
- *Human Blood/Plasma Derivatives*
- *Tissues/Cells/Derivatives of Human origin*
- *Tissues/Cells/Derivatives of Animal origin*

2.9 Operator Safety



WARNING:

- The AV600 should not be incorrectly handled, thrown, or brandished. This could result in injury or impairment to the patient or operator.

2.10 Electrical and General Equipment Safety



WARNING:

- Do not crush, puncture, or dispose of the battery in fire or water or use a damaged battery, signs of which are leaking, an odor, or noticeably swollen.
- To reduce the risk of fire, shock hazard, and interference, use only AccuVein-approved accessories. Use only AV600-approved and branded battery charging accessories and additional approved accessories. If other batteries are used, the device will fault and not function.
- Do not short external contacts, including through application of excess cleaning agents.
- Do not touch the CC500 charging contacts and the patient simultaneously.
- Do not expose AV600 to temperatures above 55°C/130° F.
- Do not immerse the AV600 or the CC500 Charging Cradle in liquid or wet the AV600, such that liquid spills off.
- Do not attempt to open, disassemble, modify or service the battery pack or any of the AV600 charging accessories.
- Do not modify, in any way, the interior or exterior components of the AV600.
- Do not self-service. The AV600 contains no customer serviceable components. The AV600 should only be serviced by an authorized AccuVein repair department.
- Do not modify the interior or exterior components of the AV600.
- Do not expose the AV600 or its accessories to rain or heavy moisture.
- No external cables should be connected to the AV600. This could cause performance loss or device failure.

2.11 EMI/IEC Equipment Protection

EMI/IEC Equipment Protection includes the following considerations:

- 1) The risk of an AV600 malfunction causing electromagnetic interference emissions, which may affect other equipment; and
- 2) The risks of AV600 exposure to environmental conditions, such as

magnetic fields; external electrical and electromagnetic effects; electrostatic discharge; radiation associated with diagnostic or therapeutic procedures, or other devices; or excessive pressure, humidity, or temperature.



WARNING:

- Avoid use of the AV600 adjacent to, or stacked with, other equipment, including other NIR devices because it could result in improper operation. If such use is necessary, this equipment and other equipment should be observed to verify that they are operating normally.
- Use of accessories other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emission, decreased electromagnetic immunity of this equipment, or result in improper operation. (See also Electrical Safety)
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be no closer than thirty (30) cm to any part of the AV600, CC500 or HF570. Disregarding this recommendation could result in degradation of product performance.
- Electromagnetic Interference (EMI) can affect the proper performance of the device.

Note: *Normal operation can be restored by removing the source of the interference.*

2.12 Expectations of the Device for the Patient

Tell the Patient the following (or equivalent statement):

“As a first step, before this [name procedure}, I will be using the AV600 device to visualize and assess the peripheral veins in [location]. I will be placing the AV600 device above the surface of your skin and you will see a colored projection of your veins on your skin surface. You will not feel anything when the AV600 is used. The AV600 will make it easier for me to choose the most optimal vein to perform the procedure. The use of AV600 will not require any post-procedural care.”

2.13 Disease and Self-Care Information

The AV600 helps the clinician to perform Peripheral Intravenous (PIV), which is a medical technique that administers fluids, medications, and nutrients directly into a person's vein via a needle/catheter.

2.14 Importance of the Need to Adhere to a Care Regimen

The use of the AV600 does not require adherence to a specific care regimen.

SECTION 3. EXPECTED FAILURE TIME, FAILURE MODES, DEVICE REUSABILITY, AND POTENTIAL EFFECTS ON PATIENT

3.1 Device Monitoring and Malfunction Indicators

The AV600 should be monitored before and during operation to ensure vasculature is clearly visible and no additional risk is imposed by operating the AV600 during the procedure.

- a. Refer to ***Section 6 - Inspection and Setup Instructions*** for additional information.
- b. If you suspect your AV600 or any of its accessories are malfunctioning, contact AccuVein Customer Support for guidance.

Observe OLED display for any deviations, which may include blank OLED display, cracks or gouges, non-square shape/misalignment of graphics, or 2-digit Fault Code.

Observe housing for any cracks or signs of battery damage like leaking, an odor, or swelling.

Observe projection for any stray artifacts.

The AV600 will be able to project veins for approximately two (2) hours when the battery is fully charged. If a fully charged AV600 battery drains from full charge to dead within two (2) hours, please contact AccuVein support for assistance.

If the AV600 battery does not fully charge within three (3) hours of charging in an approved AccuVein charging cradle or stand, refer to **Section 15 - Troubleshooting**.

3.2 Fault Codes (Description and Table)

When the AV600's self-monitoring system encounters an error, the AV600 will display a 2-digit Fault Code on the AV600 display, and an indicator to review the IFU. If a Fault Code event occurs, the AV600 will cease operation and turn off the vein projection. Please contact AccuVein Customer Support when a Fault Code is present on the AV600 display.

NOTE: *The AV600 is not Field Serviceable. Contact AccuVein Customer Support at www.accuvein.com/support, when you suspect your device is not operating to specifications.*



WARNING: Do NOT attempt to open, engrave, adulterate, service, or repair the AV600 or its accessories. Do not use a cover over the device. Do not place labels over windows, heatsink, or charging connections which can interfere with the operation of the device. Do not obstruct the projected light.

The following table includes the Fault Codes the user may encounter, along with a brief description of the fault:

Table 3-1 Fault Codes and Descriptions

Fault Code	Description	Resolution
01	FPGA Fault	The AV600 is not User or Field-Serviceable. Contact AccuVein Customer Support
02	FPGA Fault	
03	Visible Laser Fault	
04	IR Laser Fault	
05	Failed to boot (MCU)	
06	FPGA Fault	
07	FPGA Error	
08	FPGA Fault	
09	FPGA Fault	
10	FPGA Fault	
12	Configuration Error	
13	Initialization Error	
14	Boot Error	
16	FPGA Fault	
17	FPGA Fault	
18	FPGA Fault	
20	Laser Safety Disabled	
21	Synclock Lost	
22	Mirrors Fault	
23	WDT Timeout.	
24	Laser Power Too Low.	
25	Laser Power Too High.	
26	Missing Heartbeat.	
29	Error reading Battery Charger	
30	Error reading Fuel Gauge	
31	Error reading MCU ADC	
32	Device On Time	
33	Lasers On Time	
36	Cradle ID	

NOTE: *If a Fault Code is present on the AV600 display, or the device is not operating call AccuVein Customer Support Immediately. The AV600 is not field-serviceable nor field-repairable.*

3.3 Device Failure

Device failure may impact the chance of successful venous access in all patient populations, resulting in delays in care and/or multiple needle sticks as well as complications with the intravascular access procedure, including but not limited to infection, bleeding, local tissue damage requiring medical intervention or embolism.

3.4 Reusability of the Device

1. The AV600 is a reusable device and should be cleaned or disinfected between each use.
2. The AV600 should not be reused if the external housing of the device is damaged, or if internal components are exposed as this poses an infection-control risk for the user and patient.
3. The AV600 should not be reused if any biological or chemical contaminants are present on the device until thoroughly cleaned by the user.
 - a. Follow the cleaning instructions outlined in **Section 10 - Maintenance Cleaning and Disinfection** of this IFU.
 - b. These instructions are also available on our website at www.accuvein.com/cleaning-instructions.

SECTION 4 – SUMMARY OF CLINICAL AND SAFETY INFORMATION

It is concluded that the AV600 has been suitably designed to meet its intended purpose, taking into consideration all the relevant risk reduction measures, the target population and the user group. The Instructions for Use (IFU), which is packaged with the AV600 is designed to minimize risk. It lists all relevant handling instructions, risks, warnings, precautions, and contraindications.

Finally, based on this review of clinical data, scientific literature and post-marketing safety data, it can be concluded that the benefits to patients of AccuVein’s AV600 device outweighs the potential risks. Furthermore, the device is considered to be “State-of-the-Art.” Considering that:

- The design and technology of the device, the materials used, the principle of operation and the medical indications treated with the device are not novel;
- No new risks have been identified from the results of previous clinical investigation or from Post Market Surveillance activities, from the literature, or for similar marketed devices; and
- Adequate PMS systems and product risk management are in place to monitor safety and performance of the product on an ongoing basis

This alignment underscores our commitment to upholding the highest standards of safety and efficacy as required under current regulations.

SECTION 5 - SYSTEM OVERVIEW

5.1 Overview

The AV600 Vein Visualization System is a laser-driven imaging device, which includes the AV600 Vein Visualization Device; the CC500 Charging Cradle, the PS510 Power Supply, the pre-installed BA500 Battery, and optional accessories for hands-free operation of the device (the HF580 Powered Goose Neck Wheeled Hands-Free Stand and the HF510 Unpowered Hands-free Arm with Clamp).

5.2 System Components

For the technical specifications of each of the system components below, refer to *Section 16 - System Specifications*.

5.2.1 AV600 Vein Visualization Device – The AV600 is a hand-held medical device that operates by using near-infrared (NIR) to detect superficial veins beneath the skin and using visible light to project their location onto the skin surface directly above them. Visual depictions of each of the AV600 Device and Components are in Tables 1 – 5 on the following pages.

Table 5-1. AV600

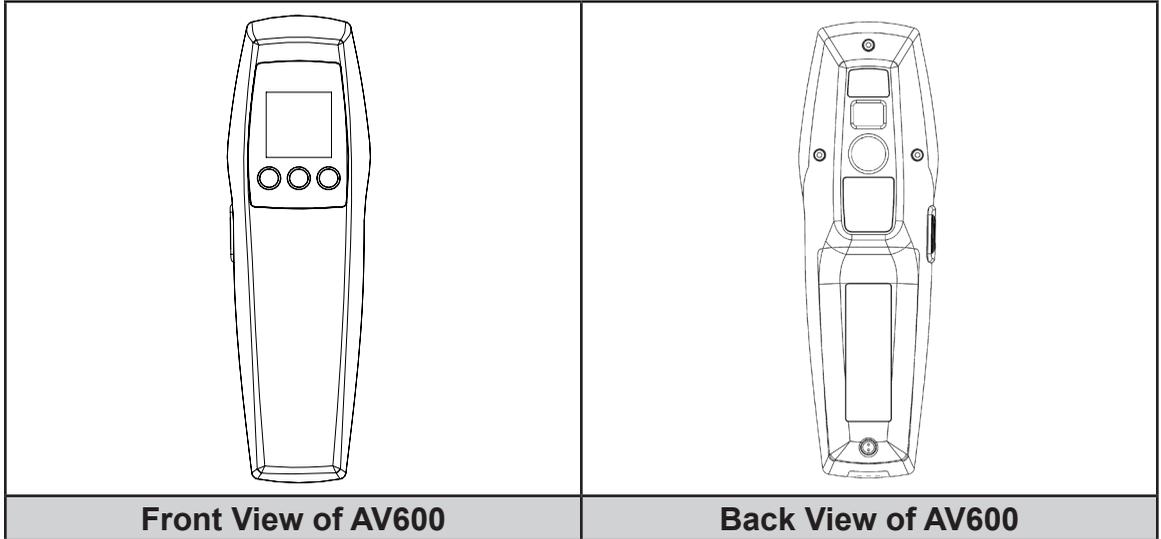
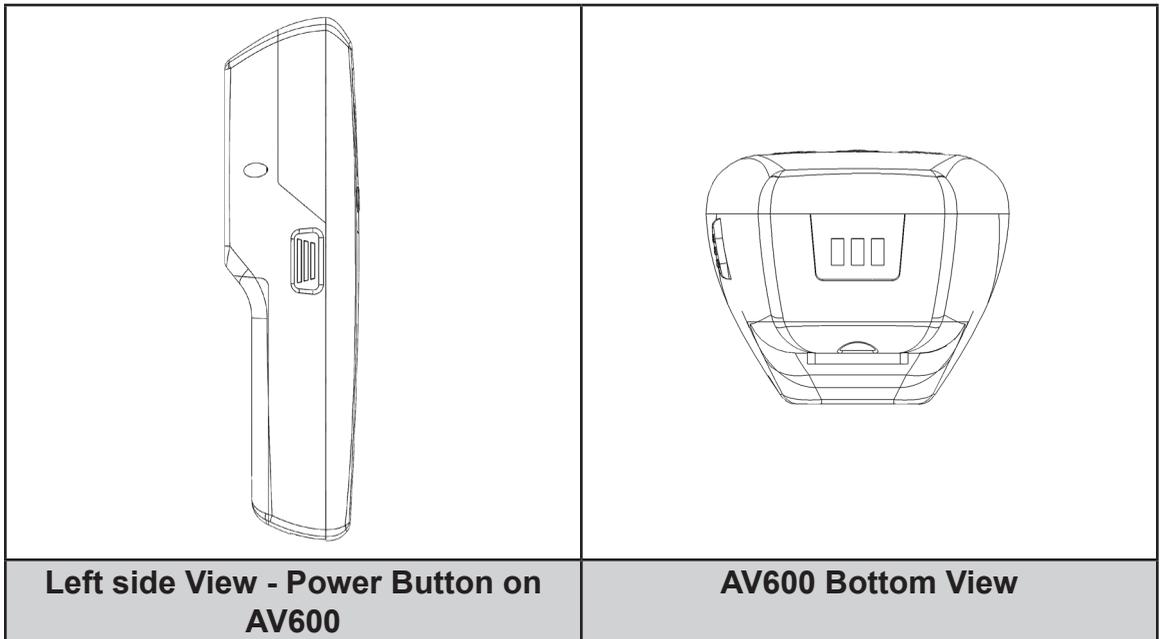
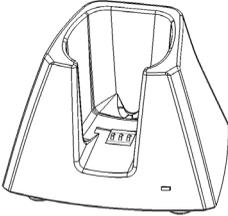
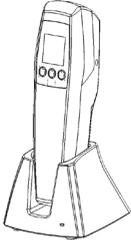


Table 5-2. Side View and Bottom View of AV600



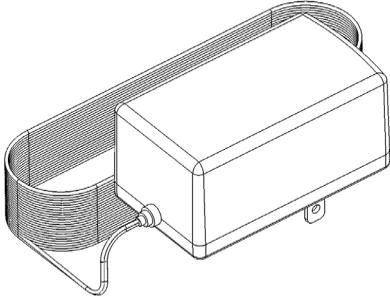
5.2.2 CC500 Charging Cradle – The CC500 Charging Cradle is a desktop charger that works along with the PS510 power supply. The AV600 can be charged by placing it into the CC500 Charging Cradle, see *Section 6. Inspection & Setup Instructions*.

Table 5-3. CC500 Charging Cradle

		
<p>CC500 Charging Cradle – Front</p>	<p>CC500 Charging Cradle - Back</p>	<p>AV600 Mounted in the CC500 Charging Cradle</p>

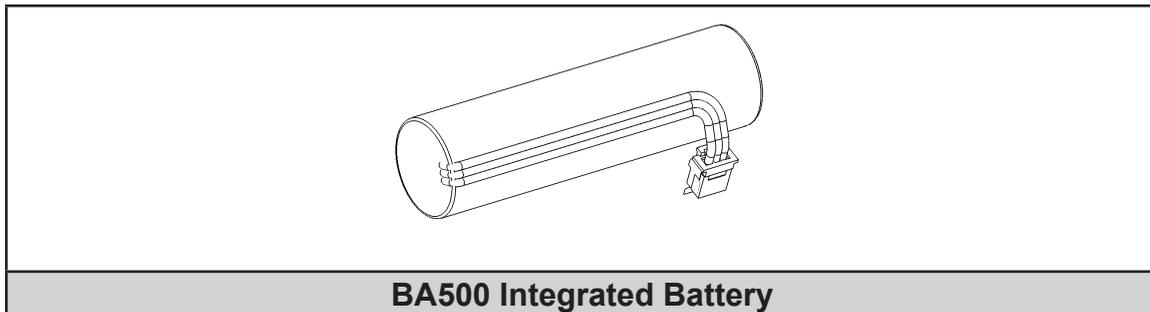
5.2.3 PS510 Power Supply – The PS510 power supply connects to the back of the CC500 Charging Cradle and is plugged into a standard electrical wall outlet. For use outside of North America, use the appropriate electrical adapter for the region of use.

Table 5-4. PS510 Power Supply

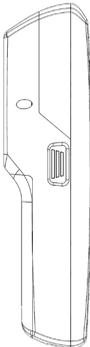

<p>PS510 Power Supply</p>

5.2.4 BA500 Integrated Battery - The BA500 Integrated Battery is a Lithium-ion battery.

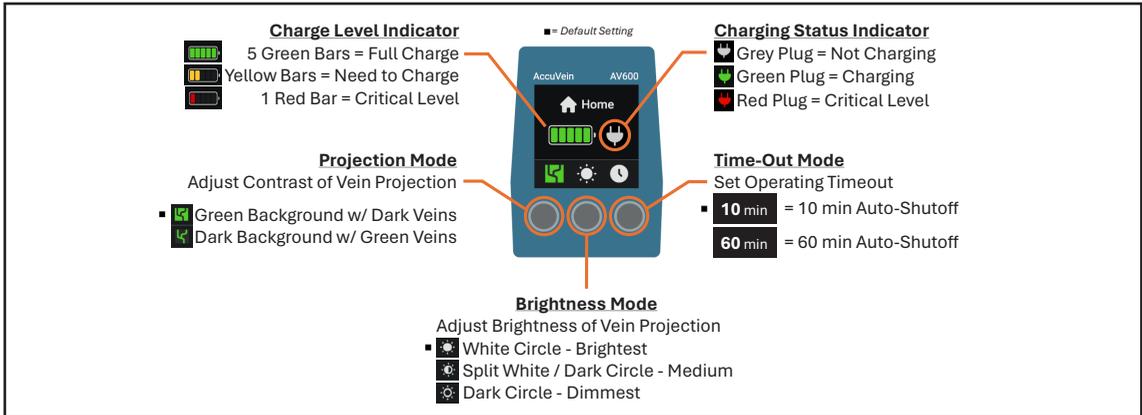
Table 5-5. BA500 Integrated Battery



5.3 Device Controls and Indicator Displays

<p>Power On/Power Off Button</p> <p>The blue button on the left side of the AV600 will power on the AV600 and turn on the Vein Display Light. Press the button again to turn the Vein Display Light and power off.</p>	
<p>Startup Screen</p> <p>During power up, the AccuVein logo will appear for approximately 3 seconds.</p>	
<p>Home Screen</p> <p>This is the normal default view after AV600 has powered up.</p>	

5.4 AV600 Controls at a Glance



5.5 Description of Device Settings

<p>Default / Inverse Setting (Contrast Setting)</p>		<p>The device can toggle between the Default Setting and the Inverse Setting.</p> <p>In the Default Setting, the projection will show Dark veins on a Green background.</p> <p>In the Inverse Setting, the projection will show Light Green Veins on a Dark Background.</p>
<p>Brightness Setting (Projection Intensity)</p>		<p>The device can toggle through three (3) Brightness Settings:</p> <p>White Circle = Brightest Split White / Dark Circle = Medium Dark Circle = Dimmest</p> <p>Note: The Default Setting is Brightest (White Circle)</p>

<p>Time-out Setting:</p>		<p>The device can toggle between two (2) Time-out options:</p> <p>10 - Minute Timeout (Automatic Turn Off After 10 minutes)</p> <p>60 - Minute Timeout (Automatic Turn Off After 60 minutes)</p> <p>Note: <i>The Default Setting is 10-Minute Timeout</i></p>
<p>AccuVein Training QR Code:</p>		<p>While the device is displaying the Time-out screen, by pressing the center button (QR Code icon) the “AccuVein Training” QR Code will be displayed.</p> <p>Note: <i>While on this screen press the right button to return to the Home screen.</i></p>
<p>Device Info:</p>		<p>While the device is displaying the “AccuVein Training” QR Code screen, by pressing the center button (Information icon) the Device Info screen will be displayed.</p> <p>Note: <i>While on this screen press the right button to return to the Home screen.</i></p>

5.6 Fault Alerts and Displays

If the AV600 does not function properly, a fault alert or numerical code will be displayed on the device screen.

Please see *Section 3.1 and 3.2, and Table 3-1* for Device Monitoring and Malfunction, Indicators, Fault Codes and Descriptions, and further information.

5.7 Description of Fault Codes and Alerts



WARNING:

Numerical Fault Code		<p>AV600 displays a Numerical Fault Code (2-digit number).</p> <p>Note: See Section 3 for Fault Code description.</p>
Low Temperature Alert		<p>AV600 displays a “Low Temperature” Fault (Blue Thermometer). Return device to proper Operating temperature range (above 5C/41F min).</p>
High Temperature Alert		<p>AV600 displays a “High Temperature” Fault (Orange Thermometer). Return device to proper Operating temperature range (below 33C/90F max).</p> <p>If system is not physically Hot, Contact AccuVein Customer Support at www.accuvein.com/support, by email at service@accuvein.com, or via telephone at (888) 631-8160 or 1(816)997-9400.</p>

If a Fault Code or Temperature Alert is displayed, the projection will turn off and lasers will cease to function. See Laser Safety. If this occurs, power the device off, and contact AccuVein Customer Support at www.accuvein.com/support, by email at service@accuvein.com, or via telephone at +1 (888) 631-8160 or 1(816)997-9400.

NOTE: The “Build XXXX” identifies the device’s firmware version and is information that should be provided to Customer Support.

SECTION 6. INSPECTION & SETUP INSTRUCTIONS

6.1 Determine Suitability for Use

6.1.1 Clinical Setting Considerations

- The AV600 can be used whenever the determination of vein location is appropriate, such as in hospitals and other clinical settings.
- The AV600 is not suitable for use in clinical departments involving high levels of Electro-Magnetic Interference/frequencies (EMI/EMF), for example, rooms with active MRI Machines (Zones 3 or 4).
- Suitable clinical environments should meet the specifications outlined in **Section 16 - System Specifications** section.

6.1.2 Patient Considerations:

The AV600 is suitable for locating superficial vasculature of the human body. The maximum depth that veins are displayed is approximately 10mm.

- Some patients' vasculatures, or a portion thereof, might not be displayed well or at all due to vein depth, skin conditions (e.g., eczema, tattoos), hair, scarring or other highly contoured skin surface, and adipose (fatty) tissue.

6.2 Inspection and Setup Instructions

6.2.1 Charging the AV600

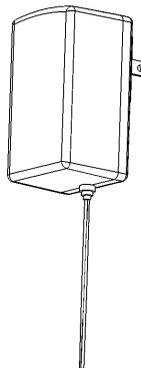
- a. Connect the PS510 power supply into the facility mains outlet. If using the device outside of North America, connect the appropriate electrical adapter (not included) in between the PS510 and mains outlet for the region of use.



WARNING:

Use only the appropriate electrical adapter for the region of use (outside of North America).

Ensure the facility mains voltage complies with the PS510 voltage range listed in **Section 16 - System Specifications**.

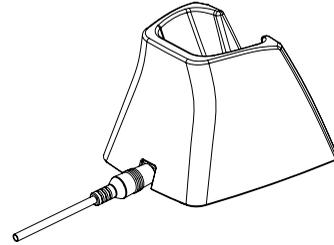


- b. Connect the PS510 power supply barrel connector into the CC500 Charging Cradle. Ensure that the connector is pushed fully in.



PRECAUTION:

Do not use excessive force to avoid breaking the PS510 or CC500.

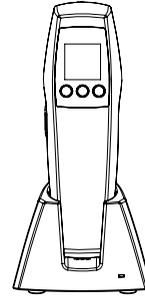


- c. Place the AV600 in the CC500 Charging Cradle with the AV600 display facing outward to begin charging before first use. Remove the display protective cover.



PRECAUTION:

Do not place objects such as labels or RFID tags on the AV600 or CC500 which can obstruct the AV600 from being fully inserted into the CC500.

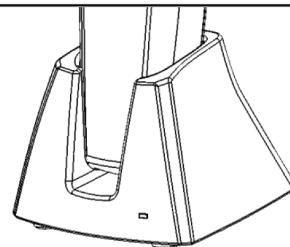


- d. Confirm the device is connected to the charger. A green plug on the AV600 display means that the device is charging. If there is a gray plug on the AV600 display, the device is not charging and the AV600 should be checked if it is properly seated and that the CC500 Charging Cradle and PS510 are properly connected.

Note: The AV600 display will go dark after a few minutes of undisturbed charging.

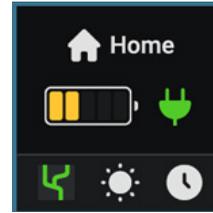


- e. Confirm the device is connected to the charger by observing the amber LED illumination on the CC500 Charging Cradle. If the LED does not come on, check that the AV600 is properly seated and the CC500 Charging Cradle is plugged in.



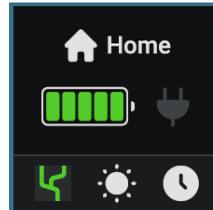
f. Inspect the charge level on the AV600 display by pressing the blue side button on the AV600 or unseating and reseating the AV600 in the CC500 Charging Cradle. You should observe a visible increase in the battery's charge level on the AV600 display within one (1) hour of inserting the AV600 into the CC500 Charging Cradle. Power off the AV600 and allow charging to continue.

Note: if the charge level on the AV600 display does not increase after one (1) hour, do not continue attempting to charge and contact customer service, see Section 12 – Service and Serviceability.



g. Fully charging the AV600 before first use.

Full charge is signified by five (5) green bars in the battery icon on the AV600 display and should be achieved after three (3) hours of continuous charge when the device is not powered on.



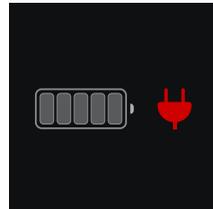
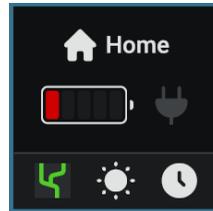
Critical battery level is shown in three progressing notifications, as 1 red bar in the battery icon (10% - 20%), 1 red bar on the battery icon flashing red (5% - 10%), and a gray battery icon with a red plug (less than 5%) on the AV600 display. DO NOT use the device when battery level is “Critical”.



WARNING:

Only charge the AV600 with the approved AccuVein CC500 Charging Cradle or the HF580 Powered Goose Neck Wheeled Hands-Free Stand

Only use PS510 Power Supply with the CC500 Charging Cradle.



6.2.2 Cleaning and Disinfecting the AV600:

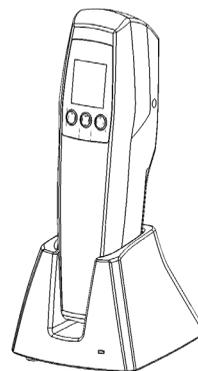
Clean and disinfect the AV600 and its accessories before and after each use. Please see **Section 10- Maintenance, Cleaning, and Disinfection** for further instruction.

SECTION 7 - STARTUP INSTRUCTIONS

7.1 Startup Instructions

This section includes all sequential steps for AV600 Startup, prior to Use.

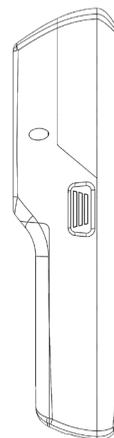
1. Remove the AV600 from the CC500 Charging Cradle after confirming it has achieved a full charge.



2. **Power On/Power Off Button**

Locate the Power Button (blue button on the left side of the device) and press it one (1) time to power on the AV600. There will be a tactile response (a detent accompanied by a clicking sound) and an auditory response (beeping) when pressing the Power button initializing start-up.

Note: The AV600 is not designed to power up while charging in the CC500 Charging Cradle. Pressing the Power button while in the CC500 will only display battery charge status.



<p>3. Startup Screen</p> <p>Confirm the AV600 display presents a black background with the word “AccuVein” in white.</p> <p>Note: <i>The AccuVein logo will appear for approximately 3 - 5 seconds.</i></p> <p>If the device does not power up, please contact AccuVein Customer Support.</p>	 <p>The image shows the AccuVein AV600 device with a black screen displaying the white AccuVein logo in the center. The device has three circular buttons at the bottom.</p>
<p>4. Home Screen – This is the normal default view after AV600 has powered up. The green projection will be displayed.</p>	 <p>The image shows the AccuVein AV600 device with a green home screen. At the top, it says 'Home' with a house icon. Below that is a battery level indicator with four green bars. At the bottom, there are three icons: a green square with a white 'L', a sun icon, and a clock icon. The device has three circular buttons at the bottom.</p>



WARNING:

Cease operation if the AV600 display presents a Fault Screen, power off the AV600, and Contact AccuVein Customer Support at www.accuvein.com/support, by email at service@accuvein.com, or via telephone at +1 (888) 631-8160 or 1(816)997-9400.

7.2 Device Verification

The following Functional Testing Steps on the AV600 are performed before use:

- Review Vein Visualization Projection
- Review Device Control Buttons
- Review the AV600 Display
- Review the Device Settings (Contrast, Time-Out, and Brightness Settings)

Note: *The AV600 is continuously performing automatic self-diagnostics (checkout activities) during startup and operation. If the AV600 detects a fault, a fault code will automatically present on the AV600 display.*



WARNING:

If a Fault Code is presented on the AV600 display, cease operation, turn the AV600 off, and contact AccuVein Customer Support at www.accuvein.com/support, by email at service@accuvein.com, or via telephone at +1 (888) 631-8160 or 1(816)997-9400.

7.3 Checkout Functional Testing Steps (After AV600 is turned on)

7.3.1 Review the Projection

- a. Before clinical use, verify the functionality of the AV600 by scanning the vein visualization projection across known veins.
- **Normal Operation:** Veins will remain stationary in the image while moving the device.
 - **Abnormal Artifacts:** Any visible artifacts (e.g., smudges or contamination on the windows) will move with the projection and may indicate a need for cleaning.

Important Notes:

- **Lighting Conditions:** For optimal performance, avoid using the device under bright lighting.
- **Projection Window Shape:** The AV600 projection window is not a perfect square. Slight curvature or bending of the green projection edges is not a defect.
- **Incorrect Testing Methods:** Do not test the projection on blank paper, walls, or other non-biological surfaces. These do not provide accurate feedback on vein visualization.

- b. **If Abnormal Artifacts Are Observed**, clean the Exit/Entrance Windows following the steps outlined in **Section 10 - Cleaning Disinfection, and Maintenance**.

- c. If the problem persists after cleaning, contact AccuVein Customer Support at www.accuvein.com/support, by email at service@accuvein.com, or via telephone at +1 (888) 631-8160 or 1(816)997-9400.

Need Help?

For any concerns or questions regarding projection quality, please contact **AccuVein Customer Support** at www.accuvein.com/support, by email at service@accuvein.com, or via telephone at +1 (888) 631-8160 or 1(816)997-9400.

7.3.2 Review the Device Control Buttons

Confirm Buttons for Device Controls are working:
Press each one of the three (3) buttons listed below, one at a time:

- Inverse Mode Setting Button
- Timer Setting Button
- Brightness Setting

When each button is depressed, there should be a tactile response (a click) and an auditory response (a beep).



WARNING:

If no tactile response or auditory response is found for any of the three (3) button controls, contact AccuVein Customer Support.

Refer to **Section 5 - System Overview** for an explanation of these controls.



7.3.3 Review the Time-Out Setting Function:

a) Press the right button of display fascia to access the Time-Out Setting. There are two (2) possible selections: 10-Minute Time-Out “10 min” and 60-Minute Time-Out “60 min”.

b) When the Time-Out Setting screen appears, press the left button to toggle between “60 min” & “10 min”, and press the right button to confirm, which presents a check mark on the AV600 display above the button.

Note: All AV600s are shipped on “10 min” (Auto-shut-off after 10 minutes). AccuVein recommends ensuring the timer setting of the device displays “10 min”.

Note: When the time-out setting is set to “10 min”, the auto-shut-off feature will shut down the device after 10 minutes by indicating to the user with an audio alert, turning the projection off, and then powering the AV600 down.



Note: Confirming the timer setting is strongly recommended for use in Aesthetics or Surgical environments, or if used when accessing vasculature on or near the face.

Note: The AV600 will retain memory of the last Timer Setting used when device is turned off. **Always** double-check this setting.

7.3.4 Review the Inverse Setting (Contrast Adjustment) Function:

<p>a. When the AV600 is powered on, and projecting veins, the projection will default to a Green Background with Dark Veins.</p> <p>Note: The Contrast Button allows you to toggle between the Default Contrast Setting and the Inverse Contrast Setting.</p>		Default 
<p>b. Press the Inverse Setting Button one (1) time to change the projection to a Dark Background with Green Veins.</p> <p>Note: The Inverse Contrast Setting = Green Veins on Dark background. This setting is shown by the white semi-circle on top with the green semi-circle on bottom.</p>		Inverse 
<p>c. Press the Inverse Setting Button once more to revert to the Green Projection with Dark Veins.</p> <p>Note: The AV600 does <i>not</i> retain memory of the Display setting chosen at prior usage. The default Green Background with Dark Veins is projected on startup.</p>		Default 

7.3.5 Review the Brightness Setting Function:

Confirming the Brightness Setting:

- 1) There are 3 total brightness levels to choose from. The AV600 defaults to the brightest setting (*White Circle*).
- 2) Press the Brightness Setting Button one (1) time, and the brightness will adjust to Medium Brightness (half White / half Dark Circle); press the same button again (two (2) presses total) to achieve the dimmest setting (Dark Circle).
- 3) To achieve brightest level (White Circle) again, press the Brightness Setting Button one (1) more time (for a total of 3 presses).

Note: *The AV600 does not retain memory of the Brightness setting chosen at prior usage. The default of setting of the brightest level (White Circle) is displayed on startup.*



7.3.6 Personal Optimization of Brightness and Contrast Settings

Test all combinations of Brightness Level Settings WITH the two different Contrast Settings (Default Setting Vs. Inverse Setting) to find the Optimal Personal Settings for Visualizing Patient Veins.

Note: *Testing these Brightness and Contrast Setting should result in a clean green projection. If the projection is not clean, clean the Exit Window.*

7.3.7 Review the AccuVein Training QR Code and Device Info Displays:

<p>Locating the AccuVein Training QR Code and Device Info:</p> <p>1) With the Time-out screen displayed, press the center button (QR Code icon) to display the “AccuVein Training” QR Code screen</p>	 The image shows the AccuVein AV600 device screen. At the top, it says "AccuVein AV600". Below that, there is a "Timer" icon and the text "10 min". At the bottom of the screen, there are three circular buttons: a left button with a blue arrow, a center button with a QR code icon, and a right button with a checkmark icon.
<p>2) The QR Code displayed provides a link to www.accuvein.com/educate.</p> <p>3) With the AccuVein Training QR Code screen displayed, press the center button (Info icon) to display the Device Info screen</p> <p>Note: While on this screen press the right button to return to the Home screen.</p>	 The image shows the AccuVein AV600 device screen. At the top, it says "AccuVein AV600". The main area of the screen is filled with a large QR code. Below the QR code, there are two icons: an information icon (i) and a home icon (house). At the bottom, there are three circular buttons: a left button, a center button with the info icon, and a right button with the home icon.
<p>4) The Device Info screen provides the following information:</p> <ul style="list-style-type: none">• The Device Firmware version (“Build XXXXX”)• The AccuVein Customer Service Number – 1(816)997-9400 <p>Note: While on this screen press the right button to return to the Home screen.</p>	 The image shows the AccuVein AV600 device screen. At the top, it says "AccuVein AV600". Below that, there is an information icon (i) and the text "Device Info.". Underneath, it displays "BUILD 01234" and "Customer Service +1(816)997-9400". At the bottom right, there is a home icon (house). At the bottom, there are three circular buttons: a left button, a center button, and a right button with the home icon.

7.3.8 Instructions for Accessory Startup

For Detailed Start-Up Instructions for the AccuVein Accessories (e.g., HF580 and HF510), refer to their respective IFUs available on <http://www.accuvein.com/product-manuals>.

SECTION 8. OPERATING INSTRUCTIONS

This section includes **Warnings, Precautions and Steps for Operating the AV600**



WARNING:

Do NOT Operate the AV600 if you suspect or observe any damage to the device or any of its accessories.

Do NOT attempt to operate or charge the AV600 if a Fault is presented on the AV600 display. Power the AV600 off and Contact AccuVein Customer Support if a Fault Code is displayed.

Do NOT Operate the AV600 prior to cleaning the device.



PRECAUTION:

Do NOT Operate the AV600 outside of normal operating temperature, humidity, or atmospheric pressure specifications. Refer to Section 16 - System Specifications for information about proper operating environments.

The AV600 should NOT be operated in MRI Zones 3 or 4. Approval by the MRI Safety Officer may be required for MRI Zones 1 & 2.

8.1 Operating Steps

1. **Power On** - The blue button located on the left side of the AV600 will power on the AV600 and turn on the projection.
2. Adjust the preferred Default/Inverse (Contrast) Setting by pressing the Left Button below the AV600 display.
3. Adjust the preferred Brightness Setting by pressing the Center Button below the AV600 display.
4. Adjust the preferred Time-Out Setting by pressing the Right Button below the AV600 display.

NOTE: *Confirming the timer setting is strongly recommended for use in Aesthetics or Surgical environments, or if used when accessing vasculature on or near the face.*

5. Hold the device from 6" – 10" (150 to 250 mm) over the surface of the skin.
6. Enhance the display quality by slightly adjusting the height and angle to the skin.
7. 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.
8. 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.
9. Device should be held parallel to the area you are scanning; tilting the device in any direction may offset the projected vein from its true location beneath the skin.
10. Powering off the AV600 - When ending operation, press the Blue Side Button again to turn the AV600 and the projection off.



WARNING:

To view vein location most accurately, the clinician should position the AV600 directly over the center of the vein being assessed.

Vein projection width is most accurate when the AV600 is positioned closest to the body, within the device's range of operation.

Avoid using the AV600 in bright light, such as direct sunlight, as vein projection may be impaired or undetectable.

NOTE: *Accessing the Timer Setting (Right Button) will turn the vein projection OFF, but the AV600 will remain ON; confirming the timer setting will turn the projection back ON.*

8.2 Battery Life

- | |
|---|
| a. To ensure the battery remains charged and ready for use, store the AV600 in the CC500 Charging Cradle or in a powered AccuVein hands-free accessory. Ensure the AV600 power is off. |
| b. The AV600 battery cannot be overcharged when approved charging devices are used. |
| c. The AV600 has a continuous run-time of approximately 2 hours (120 Minutes) when removed from the charger. |
| d. When the AV600 battery gets low, the battery indicator will turn yellow. |
| e. Before the battery is completely depleted, an alert showing the battery at critical level will be displayed on the screen, see <i>Section 6. Inspection & Setup Instructions</i> . At this point, the AV600 must be charged. |
| f. The AV600 will resume normal operation once it has been charged. |

SECTION 9 - HANDLING

9.1 Hand-Held Usage

1. The AV600 is a precision, hand-held medical device with internal electronic components which may be damaged if improperly handled.
2. The AV600 should be handled with disinfected, sterilized, sanitized, or otherwise cleaned and protected hands, or appropriate PPE.
3. The AV600 should be thoroughly cleaned prior to handling. Refer to ***Section 10 - Maintenance, Cleaning And Disinfection*** for cleaning instructions which are also available on our website at www.accuvein.com/cleaning-instructions.
4. The AV600 should not be handled outside of normal operating temperature, humidity, or atmospheric pressure. Refer to ***Section 16 - System Specifications*** for information regarding proper environmental conditions for storage/operation of the AV600 and its accessories.



WARNING:

Do **NOT** drop, throw, or brandish the AV600 or its accessories.

Do not pierce the unit or battery with any sharp objects, strike the unit with a hammer, tools, heavy object, step on the unit, or otherwise damage the unit.



DO NOT IMMERSE the AV600 and its accessories in any liquid.



WARNING:

If a spill occurs, promptly disconnect any accessory connected to a power source (if applicable) and remove the AV600/accessory from the affected area. Dry thoroughly before attempting to operate the AV600.

Do not use excessive force or in a manner not consistent with normal device use.

Do not place the device on or near fires, heaters, high or cold temperature locations, or apply heat or cold directly to the unit. Do not try to artificially heat or cool the unit.

Do not subject the unit to impacts or shocks.

Do not leave the unit in direct sunlight and avoid storing it in vehicles in hot weather where temperatures could exceed storage conditions.

Handling of Lithium Batteries -**DO NOT PUNCTURE** the unit or battery with any sharp objects, strike the unit with a hammer, tools, heavy object, step on the unit, or otherwise damage the unit.

9.2 Handling the AV600 Attached to the Approved Stand

Refer to HF580 Instructions for Use (IFU) for further information. The HF580 IFU is located on the AccuVein website at: www.accuvein.com/product-manuals.

1. The AV600 can be used with the HF580 Wheeled Powered Stand, and other approved AccuVein Stands (HF550, HF510).
2. For Assistance, contact AccuVein Customer Support at service@accuvein.com or by telephone at +1 (888) 631-8160 or 1(816)997-9400
3. The AV600 should be inserted into the cup of the approved hands-free mobile stand (HF580) and should securely click into the HF580 cup, with no excess room for movement when the clip is closed.
4. If the AV600 does not fit securely into the HF580 cup, contact AccuVein Customer Support for assistance.



WARNING:

Do not handle the AV600 by the neck of the HF580 stand.

SECTION 10 - MAINTENANCE, CLEANING, AND DISINFECTION



WARNING:

Do not use any materials listed below under Harmful Cleaning Agents. These agents will degrade the plastics of our products.

Do not use AV600 if the vein illumination window is scratched or dirty. The AV600 should be returned to AccuVein for servicing if the vein light window is scratched.

Do not immerse the AV600, the CC500 Charging Cradle, or the AV600 hands-free accessories in liquid or get the AV600 or its components wet, such that liquid spills off.

Do not attempt to sterilize the AV600 with heat or pressure sterilization methods. Do not clean the AV600 while it is in the CC500 Charging Cradle or other hands-free accessory.

Do not clean the AV600 when the battery cover is removed.

Be sure to unplug the CC500 Charging Cradle before cleaning.

Do not apply excessive force when cleaning or disinfecting the AV600 or its accessories.

10.1 Maintenance

The AV600 requires no periodic, routine, or preventative Maintenance, except for changing the battery, depending on usage. If you suspect your device requires a replacement battery, contact AccuVein Customer Support for assistance.

10.2 Cleaning and Disinfection

Users should inspect the AV600; and clean and disinfect the AV600, as required by their institution's policies to ensure that it is sufficiently clean and disinfected before each use.

AccuVein recommends cleaning and disinfecting the AV600, before and after each use to ensure the removal of biohazards (such as blood) from previous use.

The AV600 should be cleaned and disinfected **IMMEDIATELY**, if biological or chemical contaminants are present.

When cleaning any AccuVein device or accessory, the wipe used (see approved wipes below) should be firmly squeezed to remove excess cleaning fluid. This helps to prevent the pooling of liquid in crevices and depressions, which can damage the plastic.

10.2.1 Cleaning the AV600 Optical Surfaces and Windows

For peak performance, the optical surfaces, and lenses on the back of the AV600 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. If coloring of the window changes, cease operation and contact AccuVein customer support.

10.2.2 Cleaning the AV600 Body and Accessories

To clean the body of the AV600 and its accessories, you may use an AccuVein approved cleaner, using AccuVein's and the manufacturer's instructions. See Table 10-1 below for Approved Cleaners and Disinfectants for the AV600 and Table 10-2 for Cleaning Agents NOT to be used for the AV600.

Table 10-1 Approved Cleaners and Disinfectants

Approved Cleaning/Disinfecting Agents
Isopropyl Alcohol (maximum 70%)
PDI Sani-Cloth Plus
PDI Super Sani-Cloth
Pre-moistened bleach wipes (10% or less)
Caviwipes ¹ or Cavicide ¹
Cidex Plus
EcoLab Incidin Plus
EcoLab Incidin Pro
EcoLab SaniCloth Active

Table 10-2 Harmful Cleaning Agents NOT to be Used

Do NOT use ANY of the following:
Bleach Solutions > 10% concentration
Hydrogen Peroxide (H ₂ O ₂)
Virex

For further information, refer to www.accuvein.com/cleaning-instructions/

SECTION 11 - TRAVEL OR INTERNATIONAL USE

The AV600 can be used globally, provided the appropriate electrical adapters (not included) are used for the country in which the device will be operated.

For further information, refer www.accuvein.com/support or your local distributor.

SECTION 12 – SERVICE AND SERVICEABILITY

Service is performed exclusively by AccuVein.

There are no serviceable components in the device, except for battery replacement.

For Service, contact the AccuVein Complaint Handling Unit (CHU) at service@accuvein.com or by telephone +1 888 631-8160 or 1(816)997-9400.

SECTION 13 – STORAGE

The AV600 should be stored with the power off in a controlled healthcare environment to ensure the efficacy and longevity of the device.

13.1 When device is not currently in use

Power off device and place the AV600 in the CC500 Charging Cradle, or in HF580 Cup or HF580 Basket, as needed.

13.2 When device is in longer-term storage

Place in a protected location which meets the Transport and Storage Conditions below.

Table 13-1 Transport and Storage Conditions

Transport	Temperature	-20°C to 55°C (-4°F to 131°F)
	Humidity	5% to 90% RH non- condensing
Storage	Temperature	-20°C to 55°C (-4°F to 131°F)
	Humidity	5% to 90% RH non- condensing

SECTION 14 – DISPOSAL AND RECYCLING

14.1 Disposal

As required by the Waste Electrical and Electronic Equipment (WEEE) directive of the European Community and other national laws, AccuVein offers all end users the possibility to return “end of life” units without incurring disposal charges.

- The offer is valid for AccuVein electrical and electronic equipment.
- The unit needs to be complete, not disassembled and not contaminated.

If you wish to return an AccuVein product for waste recovery, please contact AccuVein Customer Support or your Local Distributor.

14.2 Recycling and Waste Treatment

Recycling and Waste Treatment is Your Responsibility

If you do not return an “end of life” unit to AccuVein you must hand it to a company specialized in waste recovery. Do not dispose of a unit in a litter bin or at a public waste disposal site.

14.2.1 Ecological Background

It is well known that certain materials pollute the environment by releasing toxic product during decomposition. The aim of the RoHS directive is to reduce the content of toxic substance in electronic products in the future. AccuVein’s business practice is for all product to meet the RoHS directive.

The intent of the WEEE directive is to enforce the recycling of electrical/electronic waste. By controlling recycling of end-of-life products AccuVein seeks to avoid the negative impacts of its products on the environment.

SECTION 15 - TROUBLESHOOTING

NOTE: The AV600 is not User- or User Facility-Serviceable

When the AV600 is not operating properly, turn the device off, using the side blue power on/off button, do not charge or use the device and contact the AccuVein Complaint Handling Unit (CHU) at service@accuvein.com or by telephone at: +1 (888) 631-8160 or 1(816)997-9400.

All Troubleshooting for the AV600 is performed by AccuVein Complaint Handling Unit (CHU), in conjunction with AccuVein Servicing. Many malfunctions will result in a Fault Code being presented in the AV600 display. The purpose of Fault Code is to facilitate communicating the potential malfunction to the CHU.

Note: *Reference Section 3 for Fault Code description.*

Note: *The Fault Code is not exhaustive. Some malfunctions will not result in a Fault Code. In either case, contact the CHU for support.*

SECTION 16 - SYSTEM SPECIFICATIONS

16.1 The AV600 Device Specifications

Table 16-1 Product Specifications

Weight	275 grams (9.7 oz.)
Size	5 x 6 x 20 cm (2" x 2.4"x 7.9")
Ingress Protection (IP) Rating	IP54
BA500 Integrated Battery	Product contains an integrated Li-Ion battery: 3.635V, 3,500 mAh, 13Wh
Continuous (vein light on) run-time on full charge	120 minutes (standard settings and environmental operating conditions)
Maximum charging time	3 hours 45 minutes (AV600 not powered on)
CC500 Charging Cradle	Input: 5V  2.0A
PS510 Power Supply	Input: 100V-240V  50Hz-60Hz 0.32-0.19A Output: 5V  2.0A

16.2 Lifetime of the Device

The Expected Lifetime of the device is the time period, the number of uses, or both, in which the device is expected to be functional, safe, effective, and serviceable after being placed into use, assuming the device is subjected to the stresses which can occur in normal conditions of use and proper storage and maintenance.

Therefore, the lifetime of the AV600 is five (5) years subject to storage conditions, projection intensity and time-out settings, the runtime of each use, and operating environment variables such as temperature and humidity.

The shelf-life of the AV600 is six (6) months from the date of receipt when stored at a temperature range of -20°C (-4°F) to 20°C (68°F) and a humidity range of 5% to 85% RH non-condensing. After six (6) months of storage, it is recommended that the device's battery be recharged to ensure optimal performance. Upon recharging, the shelf-life period will restart and will be valid for an additional six (6) months. The device does not require reconditioning and

does not need to be sent back for service. Only recharge the battery as needed; no further actions are required

The lifetime of the BA500 integrated battery is one (1) year subject to storage conditions, operating environment variables such as temperature and humidity, and the number of charge cycles.

The shelf-life of the BA500 integrated battery is one (1) year if stored external to the AV600 and at a temperature range of -20°C (-4°F) to 20°C (68°F) and a humidity range of 5% to 85% RH non- condensing.

16.3 Software

AV600 software is considered “Firmware” and the software is hard coded into the device. AV600 software cannot be affected by the user.

The AV600 Vein Visualization System has been designed in compliance with applicable Cybersecurity regulations, guidances, and standards, when operated within its Intended Use and without tampering or modification of the medical device, to be secure from Cybersecurity threats.

16.4 Measurement and Calibration

The AV600 has no measurement or user calibration functions.

16.5 Environmental Operating Conditions

Table 16-2 Operating Conditions

Operating	Temperature	5°C to 33°C (41°F to 91°F)
	Humidity	5% to 85% RH non-condensing
	Pressure	66kPa to 106kPa

16.6 EMI/EMC

Table 16-3 EMI

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The AV600 is intended for use in the electromagnetic environment specified below. The customer or the user of the AV600 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	Voltage Dips 30% reduction, 25/30 periods At 0°	Voltage Dips 30% reduction, 25/30 periods At 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the AV600 requires continued operation during power mains interruptions, it is recommended that the EQUIPMENT be powered from an uninterruptible power supply or a battery.
	Voltage Dips > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Voltage Dips > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	
	Voltage Dips > 95% reduction, 1 period At 0°	Voltage Dips > 95% reduction, 1 period At 0°	
	Voltage Interruptions > 95% reduction, 250/300 periods	Voltage Interruptions > 95% reduction, 250/300 periods	

Table 16-3 EMI (con't)

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The AV600 is intended for use in the electromagnetic environment specified below. The customer or the user of the AV600 should assure that it is used in such an environment..			
Power frequency magnetic field (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity Magnetic Fields IEC 61000-4-39	65 A/m, PM at 2.1 kHz, 50% duty cycle, 134.2 kHz; 7.5 A/m, PM at 50kHz, 50% duty cycle, 13.56 MHz	65 A/m, PM at 2.1 kHz, 50% duty cycle, 134.2 kHz; 7.5 A/m, PM at 50kHz, 50% duty cycle, 13.56 MHz	Proximity magnetic fields should be that of a typical hospital 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 (6 Vrms in ISM radio Bands within 150kHz – 80MHz) 3 V/m 80 MHz to 2.7 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the AV600, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 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 ^a , should be less than the compliance level in each frequency range ^b
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.			
^a 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 AV600 is used exceeds the applicable RF compliance level above, the AV600 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the AV600. ^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

NOTE: UT is the ac. mains voltage prior to application of the test level.

Table 16-3 Electromagnetic Emissions

Guidance and Manufacturer's declaration – Electromagnetic Emissions		
The AV600 is intended for use in the electromagnetic environment specified below. The customer or the user of the AV600 should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1	The AV600 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The AV600 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions	Complies	

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential ENVIRONMENT (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Table 16-5 Device Separation Distance

Recommended separation distances between portable and mobile RF communications equipment and the AV600			
The The AV600 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AV600 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AV600 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 to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 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 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.			

Table 16-6 RF Immunity

Immunity to RF Wireless Communications Equipment						
Test Frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum Power (W)	Distance (m)	IMMUNITYTEST LEVEL (V/m)
385	380 – 390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0.3	28
870						
930						
1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0.3	28
1845						
1970						
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0.3	28
5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9
5500						
5785						
<p>a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.</p>						

