



Vave Wireless Ultrasound

User Manual



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About This Manual

This manual describes the safe installation, operation, and maintenance of the Vave Wireless Ultrasound System.

Install, operate, and maintain the Vave Wireless Ultrasound System only in accordance with the safety and operating procedures in this manual, and only for its intended purpose. Always apply sound clinical judgment and best clinical practice.

The latest revision of this manual is available on the [Vave Health website](#).

Devices Covered by This Manual

The Vave Wireless Ultrasound System includes compatible ultrasound probes, associated hardware accessories such as the battery and charger, and the Vave Health Software Application.

The Vave Universal Ultrasound (REF VA-0327) is the hardware kit for the Universal Probe, comprising the Vave Universal Probe (REF VA-0133) and the accessories Vave Battery (REF VA-0175) and Vave Battery Charger (REF VA-0252).

The Vave Phased Ultrasound (REF VA-0182) is the hardware kit for the Phased Probe, comprising the Vave Phased Probe (REF VA-0116) and the accessories Vave Battery (REF VA-0175) and Vave Battery Charger (REF VA-0252).

The Vave Health Software Application (REF VA-0330) is the software component of the system.

Only product configurations bearing the CE mark on their label are CE marked.

How This Manual Is Organized

- Chapter 1 — System Overview: description, intended use, indications for use, contraindications, essential performance, and cybersecurity.
- Chapter 2 — Safety: warnings, precautions, biological safety, acoustic output, electromagnetic compatibility, and incident reporting.
- Chapter 3 — Using the System: environmental conditions, setup, software updates, charging, power, exam workflow, data management, and malfunction response.
- Chapter 4 — Cleaning, Disinfection, and Maintenance: probe, battery, charger, display device, storage, and service life.
- Chapter 5 — Troubleshooting: conditions that may arise during use and when to contact support.
- Chapter 6 — Specifications and References: classifications, EMC, and disposal.

Intended Audience

This manual is written for qualified and trained healthcare professionals.

Related Resources

This manual contains only the information required for the safe and effective use of the Vave Wireless Ultrasound System. Additional resources, which are updated independently of this manual, are available online:

- In-App help and guided walkthroughs, accessible from within the Vave Health App.
- Online user guide and support articles at [Vave Health Customer Support](#).
- Release notes at [Vave Health Release Notes](#).

Document Conventions

The following conventions are used throughout this manual:

CONVENTION	MEANING
DANGER	Indicates a hazard that, if not avoided, will result in death or serious injury.
WARNING	Indicates a hazard that, if not avoided, could result in death or serious injury.
CAUTION	Indicates a hazard that, if not avoided, may result in minor or moderate injury, or in damage to the device.
NOTE	Provides information that is useful for effective use of the device but is not safety critical.

Symbols Glossary

The following symbols may appear on the Vave probe, its accessories, packaging, or in this manual. Symbols are applied in accordance with ISO 15223-1 and other applicable standards.

General Symbols

SYMBOL	TITLE AND DESCRIPTION	REFERENCE
	Legal medical device manufacturer's name and address.	ISO 7000-3082
	Indicates the date on which the medical device was manufactured.	IEC 60417-6049
	Indicates the need for the user to consult the instructions for use.	ISO 7000-1641
	Indicates the user must read the instruction manual before operating the device.	ISO 7010-M002
	Indicates the device catalogue (model) number.	IEC 60417-6050
	Indicates the device serial number.	ISO 7000-2498
	Unique Device Identifier. Indicates a carrier that contains Unique Device Identifier information.	ISO 15223-1
	Indicates the item is a medical device.	ISO 15223-1
	Indicates the Authorized Representative in the European Community.	ISO 15223-1
	Indicates conformity with European Medical Device Regulation (EU) 2017/745.	Regulation (EU) 2017/745
	Indicates a medical device that has not been subjected to a sterilization process.	ISO 15223-1
	Indicates a medical device that poses unacceptable risks to patients, medical staff, or others in the MR (magnetic resonance) environment and must not be brought into the MR environment	
	Caution: United States federal law restricts this device to sale by or on the order of a physician.	21 CFR 801.109
	Caution is necessary when operating the device close to where the symbol is placed.	ISO 7000-0434A
	Recycle according to local custom and regulation.	—

SYMBOL	TITLE AND DESCRIPTION	REFERENCE
	Waste electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately.	EN 50419
	Type BF applied part.	IEC 60417-5333
	Class II equipment (double insulated).	IEC 60417-5172
	Battery Charger.	—
IP67	Enclosure is dust-tight and protected against temporary immersion in water up to 1 m for up to 30 minutes.	IEC 60529
IP22	Enclosure is protected against the ingress of solid foreign objects larger than 12.5 mm and against vertically falling water drops when the enclosure is tilted up to 15°.	IEC 60529
	Federal Communications Commission Identification and IC (Canadian) certification identifier.	FCC Part 15; CRSS-247
	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 7000-0632
	Indicates the range of humidity to which the medical device can be safely exposed.	ISO 7000-0224

1 System Overview

This chapter describes the Vave Wireless Ultrasound System, its intended use, indications for use, contraindications, essential performance, and cybersecurity information.

1.1 System Description

The Vave Wireless Ultrasound System is a wireless, portable diagnostic ultrasound system consisting of a handheld ultrasound probe ("Vave Probe"), a removable lithium-ion battery, a battery charger, and a mobile software application ("Vave Health App") that runs on non-proprietary commercial smart devices (iOS or Android tablets or phones, not supplied with the system).

The Vave Probe uses a piezoelectric transducer and houses the components required for ultrasound image formation and wireless transmission. The Vave Wireless Ultrasound System is available with a Phased probe and a Universal probe, which together support the clinical applications listed in this chapter.

The Vave Probe communicates wirelessly with the Vave Health App, which displays ultrasound images, provides image control and measurement functions, and enables storage, review, and export of exam data. Exam data may be stored on the mobile device and, where configured, synchronized to VaveCloud™ or exported to a configured PACS. Images synchronized to VaveCloud™ can also be reviewed using the Vave Web Portal.

1.2 Intended Use

The Vave Wireless Ultrasound System is intended for diagnostic ultrasound imaging and fluid flow analysis of the human body.

1.3 Indications for Use

The Vave Wireless Ultrasound System is indicated for diagnostic ultrasound imaging and fluid flow analysis of the human body in the following clinical applications: Fetal/Obstetrics; Abdominal (including Gynecology, Renal, and Urology); Pediatric; Musculoskeletal (Conventional); Musculoskeletal (Superficial); Small Organ (including Breast, Thyroid, and Scrotum); Thoracic/Pleural; Cardiac Adult; Cardiac Pediatric; Peripheral Vessel; and procedural guidance of needles into the body.

Supported modes of operation include B-Mode, M-Mode, Color Doppler, and combined modes (B+M, B+C).

The specific clinical applications and modes of operation supported by Vave Wireless Ultrasound System and each probe are detailed in the tables below.

Table 1. Vave Wireless Ultrasound System — Clinical Applications and Modes of Operation

GENERAL CATEGORY	SPECIFIC APPLICATION	B-MODE	M-MODE	COLOR DOPPLER	COMBINED
Fetal Imaging and Other	Fetal / Obstetrics	X	X	X	B+M, B+C
	Abdominal (including Gynecology, Renal, Urology)	X	X	X	B+M, B+C
	Pediatric	X	X	X	B+M, B+C
	Small Organ (Breast, Thyroid, Scrotum)	X	X	X	B+M, B+C
	Musculoskeletal (Conventional)	X	X	X	B+M, B+C
	Musculoskeletal (Superficial)	X	X	X	B+M, B+C
	Other (Thoracic/Pleural)	X	X	X	B+M, B+C
Cardiac	Cardiac Adult	X	X	X	B+M, B+C
	Cardiac Pediatric	X	X	X	B+M, B+C
Peripheral Vascular	Peripheral Vessel (arteries, veins)	X	X	X	B+M, B+C
	Other (non-vascular image guidance for needle/catheter placement)	X	X	X	B+M, B+C

Table 2. Vave Universal Probe — Clinical Applications and Modes of Operation

GENERAL CATEGORY	SPECIFIC APPLICATION	B-MODE	M-MODE	COLOR DOPPLER	COMBINED
Fetal Imaging and Other	Fetal / Obstetrics	X	X	X	B+M, B+C
	Abdominal (including Gynecology, Renal, Urology)	X	X	X	B+M, B+C
	Pediatric	X	X	X	B+M, B+C
	Small Organ (Breast, Thyroid, Scrotum)	X	X	X	B+M, B+C
	Musculoskeletal (Conventional)	X	X	X	B+M, B+C
	Musculoskeletal (Superficial)	X	X	X	B+M, B+C
	Other (Thoracic/Pleural)	X	X	X	B+M, B+C
Cardiac	Cardiac Adult	X	X	X	B+M, B+C
	Cardiac Pediatric	X	X	X	B+M, B+C
Peripheral Vascular	Peripheral Vessel (arteries, veins)	X	X	X	B+M, B+C
	Other (non-vascular image guidance for needle/catheter placement)	X	X	X	B+M, B+C

Table 3. Vave Phased Probe — Clinical Applications and Modes of Operation

GENERAL CATEGORY	SPECIFIC APPLICATION	B-MODE	M-MODE	COLOR DOPPLER	COMBINED
Fetal Imaging and Other	Fetal / Obstetrics	X	X	X	B+M, B+C
	Abdominal (including Gynecology, Renal, Urology)	X	X	X	B+M, B+C
	Pediatric	X	X	X	B+M, B+C
	Small Organ (Breast, Thyroid, Scrotum)				
	Musculoskeletal (Conventional)				
	Musculoskeletal (Superficial)				
	Other (Thoracic/Pleural)	X	X	X	B+M, B+C
Cardiac	Cardiac Adult	X	X	X	B+M, B+C
	Cardiac Pediatric	X	X	X	B+M, B+C
Peripheral Vascular	Peripheral Vessel (arteries, veins)				
	Other (non-vascular image guidance for needle/catheter placement)				

1.4 Intended Users

The Vave Wireless Ultrasound System is intended to be used by qualified and trained healthcare professionals who are legally authorized or licensed to practice in the jurisdiction in which they operate. Users may or may not be operating under the supervision of a physician. Users may also include medical students operating under the supervision of a physician as part of their training.

CAUTION

United States federal law restricts this device to sale by or on the order of a physician (Rx Only).

1.5 Intended Patient Population

The Vave Wireless Ultrasound System is intended for use on human patients of all ages, including adult, pediatric, and neonatal populations, consistent with the indications for use listed above.

1.6 Intended Use Environment

The Vave Wireless Ultrasound System is a transportable system intended for use in professional healthcare facilities (including hospitals, clinics, and medical offices), home-

healthcare environments, road and air ambulance environments, and other settings where healthcare is delivered. The Vave Battery Charger is intended for stationary use.

1.7 Contraindications

The Vave Wireless Ultrasound System is not intended for endocavitary use (for example, rectum, vagina, or esophagus). The probe is designed for external application only. Insertion into body cavities may result in infection or tissue injury. This risk is mitigated because the probe's physical design is not suitable for endocavitary use.

The Vave Wireless Ultrasound System is not intended for ophthalmic use or any use that causes the acoustic beam to pass through the eye.

1.8 Essential Performance

The essential performance of the Vave Wireless Ultrasound System comprises:

- Generation and transmission of ultrasonic energy within the specified acoustic output limits.
- Reception and processing of echo signals to produce diagnostic-quality ultrasound images.
- Wireless transmission of image data to the mobile display device.
- Display of acoustic output indices (TI, MI) in accordance with applicable standards.

1.9 Operator Position and Visibility

The system is intended to be used with the operator holding the probe and viewing the mobile device display within the normal field of vision during scanning, at a typical viewing distance of up to 45 cm. The operator is expected to observe the display continuously during image acquisition and to remain within reach of the patient.

The patient may be positioned as appropriate for the clinical application (for example, lying down, seated, or standing). The examination may be conducted in the presence of other individuals provided they do not interfere with the operation of the system or with the conduct of the examination.

1.10 Use in Surgical Environments

The Vave Probe may be used in surgical intra-operative environments with a single-use sterile probe sheath. When used in a surgical environment:

1. Perform high-level disinfection of the probe in accordance with the instructions in Chapter 4.
2. Apply a single-use sterile sheath. Use only CIVCO REF 610-1212. Download and follow the sheath manufacturer's instructions for use from [CIVCO website](#).

3. After use, remove and dispose of the sheath, then perform high-level disinfection again before reuse.

CAUTION

Sheath damage may occur during instrument manipulation. Inspect the sheath carefully before and after use. If the sheath is damaged during a procedure, discontinue use, remove and dispose of the sheath, and reprocess the probe in accordance with the cleaning and high-level disinfection instructions in Chapter 4. A new sterile sheath must be applied before continuing use.

1.11 Cybersecurity

The Vave Wireless Ultrasound System incorporates cybersecurity controls to protect patient data and system integrity. End-user and customer-IT responsibilities are summarized below. Customers are responsible for implementing these controls in accordance with their own IT and security policies.

1.11.1 User Responsibilities

- Use strong passwords and protect login credentials.
- Enable device-level authentication (passcode, PIN, or biometric) on the mobile display device and configure it to lock automatically after no more than 15 minutes of inactivity.
- Keep the mobile device operating system up to date with the latest security patches.
- Install the latest version of the Vave Health App as updates become available.
- Connect only to trusted, encrypted wireless networks.
- When decommissioning a mobile device, uninstall the Vave Health App to remove associated data from the device.
- Report any suspected security incident or suspicious behavior to support@vavehealth.com.

1.11.2 Recommended Customer Controls

CONTROL	RECOMMENDATION
Anti-malware	Install reputable anti-malware software on mobile devices used with the Vave Wireless Ultrasound System in accordance with your IT policy. Keep definitions current and run regular scans.
Firewall	Enable a firewall consistent with your IT security policy to monitor and control network traffic.
Password policy	Enforce strong password requirements, do not reuse passwords across accounts, and enable multi-factor authentication where supported.
Software updates	Apply operating system and application updates promptly.

CONTROL	RECOMMENDATION
Encryption	Enable encryption for your mobile devices and backups.
Network security	Use WPA2 or WPA3 encryption on Wi-Fi networks. Change default router credentials and keep router firmware current.
Access control	Apply role-based access control and limit administrative privileges to authorized personnel.

1.11.3 System Cybersecurity Characteristics

- The Vave Health App communicates with Vave backend services using HTTPS.
- Image and patient data transmitted to a customer-configured PACS server are encrypted in transit using TLS/SSL.
- Data stored on the mobile device are encrypted at rest using AES-256.
- The Vave Probe and Vave Health App perform mutual authentication. Connections to unauthorized probes or counterfeit applications are refused.
- The Vave Health App requires periodic internet connectivity to maintain security updates. If the application does not connect to the internet for more than 60 days, the Vave App will limit functionality until the user reconnects to the internet.
- Customer PACS servers and associated network infrastructure are the responsibility of the customer.

1.11.4 Software Bill of Materials

A machine-readable Software Bill of Materials (SBOM) in JSON format is available on request by contacting support@vavehealth.com.

1.11.5 Incident Response

To report a suspected security vulnerability or incident, contact Vave Health at [Vave Health Customer Support](#). Vave Health will evaluate reported issues and, where appropriate, issue software updates through the applicable application store.

2 Safety

This chapter describes the safety information applicable to the Vave Wireless Ultrasound System. Additional safety information relevant to specific tasks is provided in other chapters. Read this chapter in full before operating the system.

2.1 Diagnostic Ultrasound Benefits and Risks

Diagnostic ultrasound is widely used in clinical practice because it provides significant diagnostic benefits and has a well-established safety record when used as intended.

2.1.1 Clinical Benefits

Real-time ultrasound imaging supports diagnostic assessment and clinical decision-making by enabling direct visualization of anatomical structures at the point of care. As a portable, radiation-free modality, ultrasound is suitable for use across a broad range of clinical environments, including bedside, outpatient, and emergency settings, and may complement or replace other imaging modalities when clinically appropriate.

2.1.2 Biological Risks

Ultrasound energy can produce thermal and mechanical bioeffects in tissue; users must apply the ALARA (As Low As Reasonably Achievable) principle to minimize exposure, particularly when scanning the embryo or fetus, neonates, and other sensitive patient populations. See Section 2.7, Biological Safety, for details.

Any serious incident that has occurred in relation to the Vave Wireless Ultrasound System should be reported to Vave Health at [Vave Health Customer Support](#) and to the competent authority of the country in which the user and/or patient is established.

2.2 Training and Responsibility

The Vave Wireless Ultrasound System is intended for use by trained healthcare professionals. Do not operate the system unless you have read and understood this manual in its entirety and have received training appropriate to the clinical application. Image quality, interpretation, and clinical diagnosis are the responsibility of the trained healthcare professional performing the examination.

2.3 Patient, Personnel, and Product Safety

The safety of any connected mobile display device is the responsibility of the user. Always follow the safety guidelines provided by the manufacturer of the mobile device.

2.3.1 General Warnings

WARNING

- Do not operate the Vave Wireless Ultrasound System without proper training in its use and safety.
- Do not attempt to remove, modify, or override any safety feature of the system.
- Do not use the system with any product or accessory not specifically identified by Vave Health as compatible.
- Discontinue use immediately at the first sign or suspicion of system malfunction or defect and contact Vave Health Customer Support.
- Do not use the system for any purpose other than its intended use.
- The Vave Probe does not contain natural rubber latex; however, probe covers, gloves, or other accessories used with it may. Check package labeling before use, as contact with latex may cause severe allergic reactions.

2.3.2 Product Compatibility

CAUTION

- The Vave Wireless Ultrasound System includes the Vave Probe, the Vave Battery, and the Vave Battery Charger. Do not use these components with products or components from another manufacturer unless specifically approved by Vave Health.
- Modifications to the Vave Wireless Ultrasound System may be performed only by Vave Health or by third parties authorized by Vave Health. Any modification must comply with applicable regulations.
- Modifications made using unapproved parts, or made without appropriate authorization, may cause personal injury or damage the system and will void the warranty.

2.3.3 Hazardous Environments

WARNING

- Do not operate the Vave Wireless Ultrasound System in the presence of flammable gases, anesthetics, vapors, or liquids.
- Do not operate the system in oxygen-rich environments.
- Do not operate the system at altitudes below -382 m or above 4,000 m above sea level.
- Do not operate the system outside the environmental conditions specified in Chapter 3.

2.3.4 Acoustic Coupling Gel

CAUTION

- Use only ultrasound gels approved for diagnostic ultrasound imaging, applied prior to their expiration date.
- Do not use lotion-based products, gels containing mineral oil, hand-sanitizing gels, or combinations of different gel types. Improper coupling media may pose patient risk and produce poor-quality images.
- Do not leave the probe soaking in gel.

2.3.5 Third-Party Application Interruptions

CAUTION

Notifications, alerts, and vibrations from third-party applications on the mobile display device may interrupt the Vave Health App or the user and interfere with the examination. Configure the mobile device to minimize non-essential interruptions during clinical use.

2.3.6 Probe Temperature

CAUTION

The Vave Probe will automatically shut down if its surface temperature reaches 45°C (113°F). A warning message is displayed approximately 30 seconds before automatic shutdown. The patient-contact area will not exceed 43°C (109°F) during normal operation.

2.3.7 Defibrillation

WARNING

Do not use the Vave Wireless Ultrasound System during defibrillation. Before defibrillation, remove all components of the system from contact with the patient. Defibrillation current may travel through conductive pathways, creating a risk of burns or injury to the patient or operator, and may interfere with proper defibrillator pad contact.

2.3.8 Needle Guidance and Biopsy

CAUTION

- The needle must be visible at all times when performing needle-guided procedures.
- Verify the needle's position. Needles can bend upon insertion.
- Be aware that reverberation or other tissue artifacts may produce a false needle image.

2.4 Battery Safety

WARNING

- If the battery shows any abnormal behavior such as unusual odor, heat, discoloration, or deformation during use, charging, or storage, stop use immediately and contact Vave Health Customer Support.
- Do not open the battery enclosure. Battery leaks may expose users or patients to hazardous chemicals.
- Dispose of the battery in accordance with local regulations. Do not incinerate.

CAUTION

- Do not charge the battery with any equipment other than the Vave Battery Charger.
- Do not connect the battery directly to a mains power outlet.
- Do not use the battery below -20°C (-4°F) or above 60°C (140°F).
- Do not charge the battery below 10°C (50°F) or above 45°C (113°F).
- Do not use or charge the battery near heat sources.
- Do not leave the battery in direct sunlight.
- Do not touch the battery contacts.
- Do not open, crush, puncture, or short-circuit the battery.
- Do not allow the battery terminals to contact metal objects.
- Do not force the battery into the probe.

2.5 Electrical Safety

WARNING

- Inspect the probe visually before and after each use, and before and after cleaning or disinfection. If the probe face or housing is damaged, cracked, chipped, or torn, discontinue use and contact Vave Health Customer Support.
- Remove the probe from the patient before applying high-voltage defibrillation.
- Do not use the Vave Probe with patients who have implanted pacemakers. High-frequency signals may interfere with pacemaker operation.
- Do not connect accessories that are not approved by Vave Health. Unapproved accessories may result in electrical shock or increased electromagnetic emissions.
- Do not use the Vave Probe with high-frequency surgical equipment. A burn hazard may result as the probe is not shielded against defects in high-frequency surgical neutral electrode connections.

2.6 Electromagnetic Compatibility

The Vave Wireless Ultrasound System complies with applicable electromagnetic compatibility (EMC) standards. EMC compliance provides reasonable protection against

harmful interference in a typical medical installation. Full EMC compliance data are provided in Chapter 6.

2.6.1 Wireless Communication

The Vave Wireless Ultrasound System uses wireless technology to communicate with the mobile display device. Wireless communication may be subject to disruption from severe weather, radio-frequency interference, or other sources. The system is designed to minimize the impact of such disruption on image quality but cannot eliminate it entirely.

2.6.2 Electromagnetic Interference

CAUTION

Electromagnetic interference (EMI) may degrade image quality. Interference may appear as noise, artifacts, flickering, or distortion, potentially reducing diagnostic accuracy. If interference is observed, relocate the system or the source of interference as necessary.

Possible sources of electromagnetic interference include:

- Electrostatic discharge (ESD) from charge build-up on insulated surfaces or persons.
- Radio-frequency energy from mobile phones, two-way radios, smart devices, and commercial radio or television transmitters.

Review the environment where the Vave Wireless Ultrasound System is used on a regular basis to confirm that electromagnetic fields are not causing image-quality degradation.

2.6.3 Use Adjacent to Other Equipment

CAUTION

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, observe both this equipment and the other equipment to verify normal operation.

2.7 Biological Safety

Diagnostic ultrasound is widely used in clinical practice and has a well-established safety profile. When applied according to its intended use, diagnostic ultrasound has not been shown to produce long-term adverse effects. However, ultrasound energy can produce biological effects, and users must apply the ALARA principle to minimize patient exposure.

2.7.1 Thermal Effects

Thermal bioeffects refer to tissue heating caused by absorbed ultrasound energy. The degree of heating depends on tissue absorption characteristics. Fluids (such as amniotic fluid, blood, and urine) have low absorption, while bone has high absorption. Soft-tissue absorption is

intermediate. The Thermal Index (TI) displayed during imaging provides an estimate of the potential for tissue heating.

2.7.2 Mechanical (Non-Thermal) Effects

Mechanical bioeffects, such as cavitation, may occur when ultrasound pressure exceeds certain thresholds in tissues containing gas. Tissues such as the lungs are more susceptible. The Mechanical Index (MI) displayed during imaging provides an estimate of the potential for mechanical effects. Cavitation does not occur below threshold pressures regardless of exposure duration.

2.7.3 ALARA Principle

Under the ALARA (As Low As Reasonably Achievable) principle, ultrasound exposure should be limited to the lowest acoustic output for the shortest duration that permits clinically adequate imaging. When applying ALARA, consider the patient population, the examination type, the patient history, the difficulty of obtaining the required information, and the potential for localized heating from probe-surface temperature.

To apply ALARA in practice:

- Minimize scan time. Perform only medically indicated examinations.
- Select the clinical preset appropriate to the examination.
- Use the lowest acoustic output consistent with diagnostic image quality.
- Monitor the displayed TI and MI values continuously during imaging.

2.7.4 Further Reading

The American Institute of Ultrasound in Medicine publishes the Medical Ultrasound Safety booklet, which covers the principles of ultrasound, potential biological effects, the derivation and significance of the acoustic output indices, and application of ALARA. This material is recognized by the FDA as an acceptable ALARA training resource.

Contact: AIUM, 14750 Sweitzer Lane, Suite 100, Laurel, MD 20707-5908, USA. Telephone: +1 800 638 5352.

2.8 Acoustic Output Display

The Vave Wireless Ultrasound System is a Track 3 device. Acoustic output parameters comply with IEC 60601-2-37 and other applicable standards. The Thermal Index (TI) and Mechanical Index (MI) are displayed continuously during imaging.

2.8.1 Thermal Index (TI)

The Thermal Index indicates conditions that may lead to a temperature increase at the body surface, within body tissue, or at the focus of the ultrasound beam on bone. The TI estimates temperature increase under defined assumptions. Three TI variants are used depending on the clinical context:

- TIS (Soft Tissue Thermal Index): indicates the potential for heating within homogeneous soft tissue.
- TIB (Bone Thermal Index): indicates the potential for heating when the ultrasound beam passes through soft tissue and the focal region is at or near bone.
- TIC (Cranial Bone Thermal Index): indicates the potential for heating when the beam passes through bone near the surface of the body.

2.8.2 Mechanical Index (MI)

The Mechanical Index indicates the estimated likelihood of mechanical bioeffects occurring, based on peak rarefactional pressure and ultrasound frequency. The maximum MI is limited in accordance with applicable regulatory requirements. A higher MI indicates a higher potential for mechanical effects; no specific MI value indicates that a mechanical effect will occur.

2.8.3 Display Precision

TI and MI are displayed in increments of 0.1 over the range from 0 to the maximum output, with a display precision of 0.1 unit.

2.8.4 Controls Affecting the Displayed Indices

Acoustic output defaults are set by the selected clinical preset. Selecting a new imaging mode may reset the TI and MI to the default values for that mode; returning to a previous mode will restore the previously selected values. Changing imaging parameters, such as focal depth or imaging depth, may change the displayed TI and MI values.

2.8.5 Acoustic Output Tables

NOTE

For complete definitions of the measurements used in the Acoustic Output Tables, see Table 201.101 in IEC 60601-2-37.

Table 4. B-Mode — Phased Probe

INDEX LABEL	MI	TIS AT SURFACE	TIS BELOW SURFACE	TIB AT SURFACE	TIB BELOW SURFACE	TIC
Maximum Index Value	1.01	0.43	0.43	0.43	0.43	n/a
Index Component Value	—	0.43	0.43	0.43	0.43	—
$p_{r,\alpha}$ at z_{MI} (MPa)	1.657	—	—	—	—	—
P (mW)	—	71.2	71.2	71.2	71.2	n/a
$P_{1\%}$ (mW)	—	33.1	33.1	33.1	33.1	—
z_s (cm)	—	—	n/a	—	—	—
z_b (cm)	—	—	—	—	n/a	—

INDEX LABEL	MI	TIS AT SURFACE	TIS BELOW SURFACE	TIB AT SURFACE	TIB BELOW SURFACE	TIC
z_{MI} (cm)	4.538	—	—	—	—	—
$z_{PII,\alpha}$ (cm)	4.538	—	—	—	—	—
f_{awf} (MHz)	2.719	2.719	2.719	2.719	2.719	n/a
p_{rr} (Hz)	1720	—	—	—	—	—
s_{rr} (Hz)	20	—	—	—	—	—
n_{pps}	1	—	—	—	—	—
$I_{p\alpha,\alpha}$ at $z_{PII,\alpha}$ (W/cm ²)	207.2	—	—	—	—	—
$I_{spta,\alpha}$ at z_{PII} (mW/cm ²)	11.04	—	—	—	—	—
I_{spta} at z_{PII} (mW/cm ²)	25.35	—	—	—	—	—
p_r at z_{PII} (MPa)	2.54	—	—	—	—	—
OPERATING CONDITION	MI	TIS AT SURFACE	TIS BELOW SURFACE	TIB AT SURFACE	TIB BELOW SURFACE	TIC
Preset	Lung	Lung	Lung	Lung	Lung	—
Focus (mm)	50	50	50	50	50	—

Table 5. Tissue Harmonic B-Mode — Phased Probe

INDEX LABEL	MI	TIS AT SURFACE	TIS BELOW SURFACE	TIB AT SURFACE	TIB BELOW SURFACE	TIC
Maximum Index Value	1.11	0.21	0.21	0.21	0.21	n/a
Index Component Value	—	0.21	0.21	0.21	0.21	—
$p_{r,\alpha}$ at z_{MI} (MPa)	1.451	—	—	—	—	—
P (mW)	—	73.8	73.8	73.8	73.8	n/a
$P_{1\times 1}$ (mW)	—	34.3	34.3	34.3	34.3	—
z_s (cm)	—	—	n/a	—	—	—
z_b (cm)	—	—	—	—	n/a	—
z_{MI} (cm)	5.15	—	—	—	—	—
$z_{PII,\alpha}$ (cm)	5.15	—	—	—	—	—
f_{awf} (MHz)	1.694	1.694	1.694	1.694	1.694	n/a
p_{rr} (Hz)	1320	—	—	—	—	—
s_{rr} (Hz)	30	—	—	—	—	—
n_{pps}	1	—	—	—	—	—
$I_{p\alpha,\alpha}$ at $z_{PII,\alpha}$ (W/cm ²)	134.9	—	—	—	—	—

INDEX LABEL	MI	TIS AT SURFACE	TIS BELOW SURFACE	TIB AT SURFACE	TIB BELOW SURFACE	TIC
$I_{\text{spta},\alpha}$ at z_{PII} (mW/cm ²)	16.27	—	—	—	—	—
I_{spta} at z_{PII} (mW/cm ²)	29.13	—	—	—	—	—
p_r at z_{PII} (MPa)	1.96	—	—	—	—	—
OPERATING CONDITION	MI	TIS AT SURFACE	TIS BELOW SURFACE	TIB AT SURFACE	TIB BELOW SURFACE	TIC
Preset	Cardiac	Cardiac	Cardiac	Cardiac	Cardiac	—
Focus (mm)	75	75	75	75	75	—

Table 6. M-Mode — Phased Probe

INDEX LABEL	MI	TIS AT SURFACE	TIS BELOW SURFACE	TIB AT SURFACE	TIB BELOW SURFACE	TIC
Maximum Index Value	1.11	0.08	0.08	0.08	0.08	n/a
Index Component Value	—	0.08	0.07	0.08	0.08	—
$p_{r,\alpha}$ at z_{MI} (MPa)	1.451	—	—	—	—	—
P (mW)	—	73.8	73.8	73.8	73.8	n/a
$P_{1\times 1}$ (mW)	—	34.3	34.3	34.3	34.3	—
z_s (cm)	—	—	2.504	—	—	—
z_b (cm)	—	—	—	—	4.856	—
z_{MI} (cm)	5.30	—	—	—	—	—
$z_{\text{PII},\alpha}$ (cm)	5.30	—	—	—	—	—
f_{awt} (MHz)	1.694	1.694	1.694	1.694	1.694	n/a
p_{rr} (Hz)	480	—	—	—	—	—
s_{rr} (Hz)	7.5	—	—	—	—	—
n_{pps}	n/a	—	—	—	—	—
$I_{\text{pa},\alpha}$ at $z_{\text{PII},\alpha}$ (W/cm ²)	134.9	—	—	—	—	—
$I_{\text{spta},\alpha}$ at z_{PII} (mW/cm ²)	27.65	—	—	—	—	—
I_{spta} at z_{PII} (mW/cm ²)	51.28	—	—	—	—	—
p_r at z_{PII} (MPa)	1.96	—	—	—	—	—
OPERATING CONDITION	MI	TIS AT SURFACE	TIS BELOW SURFACE	TIB AT SURFACE	TIB BELOW SURFACE	TIC
Preset	Cardiac	Cardiac	Cardiac	Cardiac	Cardiac	—
Focus (mm)	75	75	75	75	75	—

Table 7. Color Doppler — Phased Probe

INDEX LABEL	MI	TIS AT SURFACE	TIS BELOW SURFACE	TIB AT SURFACE	TIB BELOW SURFACE	TIC
Maximum Index Value	0.96	1.26	1.26	1.26	1.26	n/a
Index Component Value	—	1.26	1.26	1.26	1.26	—
$p_{r,\alpha}$ at z_{MI} (MPa)	1.41	—	—	—	—	—
P (mW)	—	170.8	170.8	170.8	170.8	n/a
$P_{1 \times 1}$ (mW)	—	79.4	79.4	79.4	79.4	—
z_s (cm)	—	—	n/a	—	—	—
z_b (cm)	—	—	—	—	n/a	—
z_{MI} (cm)	4.74	—	—	—	—	—
$z_{PII,\alpha}$ (cm)	4.74	—	—	—	—	—
f_{awf} (MHz)	2.15	2.15	2.15	2.15	2.15	n/a
prr (Hz)	2077	—	—	—	—	—
srr (Hz)	23.6	—	—	—	—	—
n_{pps}	8	—	—	—	—	—
$I_{pa,\alpha}$ at $z_{PII,\alpha}$ (W/cm ²)	305.4	—	—	—	—	—
$I_{spta,\alpha}$ at z_{PII} (mW/cm ²)	180.83	—	—	—	—	—
I_{spta} at z_{PII} (mW/cm ²)	364.22	—	—	—	—	—
p_r at z_{PII} (MPa)	2.01	—	—	—	—	—
OPERATING CONDITION	MI	TIS AT SURFACE	TIS BELOW SURFACE	TIB AT SURFACE	TIB BELOW SURFACE	TIC
Preset	Cardiac	Cardiac	Cardiac	Cardiac	Cardiac	—
Focus (mm)	50	50	50	50	50	—
ROI Span (degrees)	18.8	56.2	56.2	56.2	56.2	—

Table 8. B-Mode — Universal Probe

INDEX LABEL	MI	TIS AT SURFACE	TIS BELOW SURFACE	TIB AT SURFACE	TIB BELOW SURFACE	TIC
Maximum Index Value	0.84	0.21	0.21	0.38	0.38	0.38
Index Component Value	—	0.21	0.21	0.38	0.38	—
$p_{r,\alpha}$ at z_{MI} (MPa)	1.29	—	—	—	—	—
P (mW)	—	22.77	22.77	22.77	22.77	22.77
$P_{1 \times 1}$ (mW)	—	16.03	16.03	16.03	16.03	—
z_s (cm)	—	—	4.83	—	—	—

INDEX LABEL	MI	TIS AT SURFACE	TIS BELOW SURFACE	TIB AT SURFACE	TIB BELOW SURFACE	TIC
z_b (cm)	—	—	—	—	4.83	—
z_{MI} (cm)	4.83	—	—	—	—	—
$z_{PII,\alpha}$ (cm)	4.83	—	—	—	—	—
f_{awf} (MHz)	2.75	2.75	2.75	2.75	2.75	2.75
p_{rr} (Hz)	1728	—	—	—	—	—
s_{rr} (Hz)	27	—	—	—	—	—
n_{pps}	1	—	—	—	—	—
$I_{pa,\alpha}$ at $z_{PII,\alpha}$ (W/cm ²)	1.14E+02	—	—	—	—	—
$I_{spta,\alpha}$ at z_{PII} (mW/cm ²)	15.10	—	—	—	—	—
I_{spta} at z_{PII} (mW/cm ²)	35.72	—	—	—	—	—
p_r at z_{PII} (MPa)	2.04	—	—	—	—	—
OPERATING CONDITION	MI	TIS AT SURFACE	TIS BELOW SURFACE	TIB AT SURFACE	TIB BELOW SURFACE	TIC
Preset	Cardiac	Cardiac	Cardiac	Cardiac	Cardiac	—
Focus (mm)	150	150	150	150	150	—

Table 9. B-Mode — Universal Probe — Vascular Preset

INDEX LABEL	MI	TIS AT SURFACE	TIS BELOW SURFACE	TIB AT SURFACE	TIB BELOW SURFACE	TIC
Maximum Index Value	0.29	0.15	0.15	0.07	0.07	0.07
Index Component Value	—	0.15	0.15	0.07	0.07	—
$p_{r,\alpha}$ at z_{MI} (MPa)	2.56	—	—	—	—	—
P (mW)	—	1.60	1.60	1.60	1.60	1.60
$P_{1\times1}$ (mW)	—	2.00	2.00	2.00	2.00	—
z_s (cm)	—	—	3.00	—	—	—
z_b (cm)	—	—	—	—	3.00	—
z_{MI} (cm)	3.00	—	—	—	—	—
$z_{PII,\alpha}$ (cm)	3.00	—	—	—	—	—
f_{awf} (MHz)	6.45	6.45	6.45	6.45	6.45	6.45
p_{rr} (Hz)	1280	—	—	—	—	—
s_{rr} (Hz)	20.0	—	—	—	—	—
n_{pps}	1.00	—	—	—	—	—

INDEX LABEL	MI	TIS AT SURFACE	TIS BELOW SURFACE	TIB AT SURFACE	TIB BELOW SURFACE	TIC
$I_{p\alpha,\alpha}$ at $z_{PII,\alpha}$ (W/cm ²)	22.67	—	—	—	—	—
$I_{spta,\alpha}$ at z_{PII} (mW/cm ²)	0.43	—	—	—	—	—
I_{spta} at z_{PII} (mW/cm ²)	1.62	—	—	—	—	—
p_r at z_{PII} (MPa)	5.00	—	—	—	—	—
OPERATING CONDITION	MI	TIS AT SURFACE	TIS BELOW SURFACE	TIB AT SURFACE	TIB BELOW SURFACE	TIC
Preset	Vascular	Vascular	Vascular	Vascular	Vascular	—
Focus (mm)	30	30	30	30	30	—

Table 10. M-Mode — Universal Probe

INDEX LABEL	MI	TIS AT SURFACE	TIS BELOW SURFACE	TIB AT SURFACE	TIB BELOW SURFACE	TIC
Maximum Index Value	0.77	4.62E-02	4.62E-02	0.08	0.69	0.08
Index Component Value	—	—	—	0.08	0.69	—
$p_{r,\alpha}$ at z_{MI} (MPa)	1.26	—	—	—	—	—
P (mW)	—	4.80	4.80	4.80	4.80	4.80
$P_{1\times 1}$ (mW)	—	3.47	3.47	3.47	3.47	—
z_s (cm)	—	—	N/A	—	—	—
z_b (cm)	—	—	—	—	N/A	—
z_{MI} (cm)	5.30	—	—	—	—	—
$z_{PII,\alpha}$ (cm)	5.30	—	—	—	—	—
f_{awf} (MHz)	2.80	2.80	2.80	2.80	2.80	2.80
p_{rr} (Hz)	200	—	—	—	—	—
s_{rr} (Hz)	N/A	—	—	—	—	—
n_{pps}	1	—	—	—	—	—
$I_{p\alpha,\alpha}$ at $z_{PII,\alpha}$ (W/cm ²)	4.60E+01	—	—	—	—	—
$I_{spta,\alpha}$ at z_{PII} (mW/cm ²)	5.61	—	—	—	—	—
I_{spta} at z_{PII} (mW/cm ²)	14.70	—	—	—	—	—
p_r at z_{PII} (MPa)	2.10	—	—	—	—	—
OPERATING CONDITION	MI	TIS AT SURFACE	TIS BELOW SURFACE	TIB AT SURFACE	TIB BELOW SURFACE	TIC
Preset	Cardiac	Cardiac	Cardiac	Cardiac	Cardiac	—
Focus (mm)	150	150	150	150	150	—

Table 11. M-Mode — Universal Probe — Vascular Preset

INDEX LABEL	MI	TIS AT SURFACE	TIS BELOW SURFACE	TIB AT SURFACE	TIB BELOW SURFACE	TIC
Maximum Index Value	0.29	0.15	0.15	0.07	0.07	0.07
Index Component Value	—	0.15	0.15	0.07	0.07	—
$p_{r,\alpha}$ at z_{MI} (MPa)	2.56	—	—	—	—	—
P (mW)	—	1.60	1.60	1.60	1.60	1.60
$P_{1 \times 1}$ (mW)	—	2.00	2.00	2.00	2.00	—
z_s (cm)	—	—	N/A	—	—	—
z_b (cm)	—	—	—	—	N/A	—
z_{MI} (cm)	1: 3.00	—	—	—	—	—
$z_{PII,\alpha}$ (cm)	1: 3.00	—	—	—	—	—
f_{awf} (MHz)	1: 6.45 2: 6.45	1: 6.45 2: 6.45	1: 6.45 2: 6.45	1: 6.45 2: 6.45	1: 6.45 2: 6.45	1: 6.45 2: 6.45
prr (Hz)	1: 384	—	—	—	—	—
srr (Hz)	1: 6.0	—	—	—	—	—
n_{pps}	1: 1.00	—	—	—	—	—
$I_{p\alpha,\alpha}$ at $z_{PII,\alpha}$ (W/cm ²)	1: 22.67	—	—	—	—	—
$I_{spta,\alpha}$ at z_{PII} (mW/cm ²)	1: 0.13	—	—	—	—	—
I_{spta} at z_{PII} (mW/cm ²)	1: 0.49	—	—	—	—	—
p_r at z_{PII} (MPa)	1: 5.00	—	—	—	—	—
OPERATING CONDITION	MI	TIS AT SURFACE	TIS BELOW SURFACE	TIB AT SURFACE	TIB BELOW SURFACE	TIC
Preset	Vascular	Vascular	Vascular	Vascular	Vascular	—
Focus (mm)	30	30	30	30	30	—

Values reported where different conditions apply are indicated as condition 1 / condition 2.

Table 12. Color Doppler — Universal Probe

INDEX LABEL	MI	TIS AT SURFACE	TIS BELOW SURFACE	TIB AT SURFACE	TIB BELOW SURFACE	TIC
Maximum Index Value	1.42	0.90	0.90	1.82	1.82	1.82
Index Component Value	—	0.90	0.90	1.82	1.82	—
$p_{r,\alpha}$ at z_{MI} (MPa)	2.23	—	—	—	—	—
P (mW)	—	108.93	108.93	108.93	108.93	108.93
$P_{1 \times 1}$ (mW)	—	79.13	79.13	79.13	79.13	—

INDEX LABEL	MI	TIS AT SURFACE	TIS BELOW SURFACE	TIB AT SURFACE	TIB BELOW SURFACE	TIC
z_s (cm)	—	—	N/A	—	—	—
z_b (cm)	—	—	—	—	N/A	—
z_{MI} (cm)	4.72	—	—	—	—	—
$z_{PII,\alpha}$ (cm)	4.72	—	—	—	—	—
f_{awt} (MHz)	2.40	2.40	2.40	2.40	2.40	2.40
p_{rr} (Hz)	2304	—	—	—	—	—
s_{rr} (Hz)	18	—	—	—	—	—
n_{pps}	1	—	—	—	—	—
$I_{p\alpha,\alpha}$ at $z_{PII,\alpha}$ (W/cm ²)	3.87	—	—	—	—	—
$I_{spta,\alpha}$ at z_{PII} (mW/cm ²)	0.07	—	—	—	—	—
I_{spta} at z_{PII} (mW/cm ²)	0.12	—	—	—	—	—
p_r at z_{PII} (MPa)	0.50	—	—	—	—	—
OPERATING CONDITION	MI	TIS AT SURFACE	TIS BELOW SURFACE	TIB AT SURFACE	TIB BELOW SURFACE	TIC
Preset	Cardiac	Cardiac	Cardiac	Cardiac	Cardiac	—
Focus (mm)	100	100	100	100	100	—

Table 13. Color Doppler — Universal Probe — Vascular Preset

INDEX LABEL	MI	TIS AT SURFACE	TIS BELOW SURFACE	TIB AT SURFACE	TIB BELOW SURFACE	TIC
Maximum Index Value	0.76	1.11	1.11	1.07	1.07	1.07
Index Component Value	—	1: 0.15 2: 0.96	1: 0.15 2: 0.96	1: 0.07 2: 1.0	1: 0.07 2: 1.0	—
$p_{r,\alpha}$ at z_{MI} (MPa)	3.70	—	—	—	—	—
P (mW)	—	1: 1.60 2: 38.50	1: 1.60 2: 38.50	1: 1.60 2: 38.50	1: 1.60 2: 38.50	1: 1.60 2: 38.50
$P_{1\times 1}$ (mW)	—	1: 2.00 2: 27.40	1: 2.00 2: 27.40	1: 2.00 2: 27.40	1: 2.00 2: 27.40	—
z_s (cm)	—	—	N/A	—	—	—
z_b (cm)	—	—	—	—	N/A	—
z_{MI} (cm)	3.00	—	—	—	—	—
$z_{PII,\alpha}$ (cm)	3.00	—	—	—	—	—
f_{awt} (MHz)	1: 6.45 2: 4.20	1: 6.45 2: 4.20	1: 6.45 2: 4.20	1: 6.45 2: 4.20	1: 6.45 2: 4.20	1: 6.45 2: 4.20

INDEX LABEL	MI	TIS AT SURFACE	TIS BELOW SURFACE	TIB AT SURFACE	TIB BELOW SURFACE	TIC
pr (Hz)	1: 2560.00	—	—	—	—	—
srr (Hz)	1: 20.0	—	—	—	—	—
n _{pps}	1: 1.00	—	—	—	—	—
I _{pα,α} at z _{Pll,α} (W/cm ²)	1: 132.13	—	—	—	—	—
I _{spta,α} at z _{Pll} (mW/cm ²)	1: 26.95	—	—	—	—	—
I _{spta} at z _{Pll} (mW/cm ²)	1: 64.2	—	—	—	—	—
p _r at z _{Pll} (MPa)	1: 5.00	—	—	—	—	—
OPERATING CONDITION	MI	TIS AT SURFACE	TIS BELOW SURFACE	TIB AT SURFACE	TIB BELOW SURFACE	TIC
Preset	Vascular	Vascular	Vascular	Vascular	Vascular	—
Focus (mm)	30	30	30	30	30	—

Values reported where different conditions apply are indicated as condition 1 / condition 2.

2.8.6 Measurement Precision and Uncertainty

Measurement precision is determined by making repeated measurements and reporting the standard deviation as a percentage.

PARAMETER	PRECISION	UNCERTAINTY (95 % CONFIDENCE)
p_r	<1 %	± 8.4 %
W_o	7.6 %	± 16.8 %
f_c	<1 %	< ± 1 %
Pll.3	2.8 %	± 16.2 %

3 Using the System

This chapter describes the procedures for setting up, powering, and operating the Vave Wireless Ultrasound System, including how to perform an examination and manage data.

NOTE

The Vave Health App and the Vave Web Portal are updated independently of this manual. Always install the latest available version of the Vave Health App. Release notes are available at [Vave Health Release Notes](#).

3.1 Environmental Conditions

PARAMETER	OPERATING	TRANSIENT OPERATING	STORAGE
Temperature	0°C to +35°C (+32°F to +95°F)	–20°C to +50°C (–4°F to +122°F)	–40°C to +70°C (–40°F to +158°F)
Humidity	15% to 90% non- condensing	15% to 90% non- condensing	5% to 90% non- condensing
Atmospheric pressure	620 hPa to 1060 hPa	Not applicable	Not applicable

If the probe is moved from a 20°C (68°F) environment into conditions within the transient operating range, normal operation is maintained for a minimum of 15 minutes.

CAUTION

- If the probe has been exposed to temperatures above 35°C (95°F), allow it to cool to operating temperature before turning on — approximately 25 minutes depending on the duration of exposure.
- If the probe has been exposed to temperatures below 0°C (32°F), allow it to warm to operating temperature before turning on — approximately 20 minutes depending on duration of exposure. Internal condensation may damage the device.
- Do not place the transducer in contact with the patient if the probe surface temperature is above 43°C (109°F).

3.2 System Setup

3.2.1 Mobile Device Requirements

The Vave Wireless Ultrasound System requires a compatible iOS or Android smart device to run the Vave Health App. Minimum and recommended mobile device specifications are provided in Chapter 6. A list of tested mobile devices is available at [Vave Health Customer Support](#).

CAUTION

Using the Vave Wireless Ultrasound System with a mobile device that does not meet the minimum specifications may result in degraded image quality, unexpected behavior, and potential misdiagnosis.

3.2.2 Installing the Vave Health App

Download the Vave Health App from the Apple App Store (iOS) or Google Play store (Android). A Vave account is required to operate the Vave Wireless Ultrasound System. Contact your organization's Vave administrator to obtain account access.

3.2.3 Mobile Device Security Configuration

CAUTION

Secure the mobile device with a passcode, PIN, pattern, or biometric authentication to prevent unauthorized access and potential data leakage. Configure the device to lock automatically after no more than 15 minutes of inactivity. Ensure the mobile device complies with your organization's applicable security policies.

3.3 Battery

The Vave Probe is powered by a removable, rechargeable lithium-ion battery. Before using the system for the first time, charge the battery fully using the Vave Battery Charger.

3.3.1 Removing the Battery

1. Pull the battery away from the nose of the probe.
2. Slide the battery off completely.

3.3.2 Inserting the Battery

1. Orient the battery so that the battery contacts face the probe contacts and the battery label faces the probe.
2. Slide the battery into the probe until it locks into place.

3.3.3 Charging the Battery

1. Connect the AC adapter to the Vave Battery Charger and plug the adapter into a mains outlet.
2. Confirm that the charger LED alternates between yellow and green, indicating that power has been applied.
3. Remove the battery from the Vave Probe.
4. Insert the battery into the charger.

5. The charger LED is solid yellow while the battery is charging. If the LED continues to alternate between yellow and green, remove the battery from the charger and reinsert it.
6. When the charger LED turns solid green, the battery is fully charged.

NOTE

A fully charged battery provides a minimum of 1 hour of typical B-Mode scanning time; actual time varies by preset. The battery requires approximately 90 minutes to charge from 20% to 80%.

Charge the battery only with the Vave Battery Charger. Using a non-Vave charger may damage the battery or create a safety hazard.

Do not charge the battery on board an aircraft, including in rotary-wing airborne ambulances.

3.3.4 Low-Battery Indication

When the battery level is low, the Vave Health App displays a low-battery warning. Recharge or replace the battery promptly. At very low battery levels, the probe cannot establish a connection with the mobile device until the battery is recharged.

3.4 Powering the System

3.4.1 Turning On the Probe

Press and hold the power button on the probe for approximately one second. The indicator LED illuminates blue and turns green when the probe is ready to connect.

3.4.2 Turning Off the Probe

Press the power button on the probe. The indicator LED turns off.

NOTE

To conserve battery life, the probe automatically shuts down after a defined period without a connection to the Vave Health App.

3.4.3 Connecting the Probe to the Mobile Device

The Vave Health App guides the user through the wireless connection process between the mobile device and the probe. Follow the on-screen instructions. When the connection is established, the imaging screen is displayed and scanning can begin.

NOTE

The Vave Probe communicates with the Vave Health App over its own built-in Wi-Fi. The mobile display device does not need to be connected to Wi-Fi to use the Vave Probe.

The mobile device's Wi-Fi and Bluetooth must be enabled for the probe and App to connect.

3.5 Software and Firmware Updates

The Vave Health App and Vave Probe firmware are updated over the air. Updates may be mandatory or optional.

3.5.1 Application Updates

Application updates are distributed through the Apple App Store and Google Play store. Update notifications are displayed within the App and in the respective App store. When an update is mandatory, the App must be updated before use can continue.

3.5.2 Probe Firmware Updates

Probe firmware updates are initiated automatically by the Vave Health App when a new firmware version is available. Do not power off or remove the battery from the probe during a firmware update. When the update is complete, the probe is ready for use.

CAUTION

If a firmware update does not complete successfully, follow the on-screen instructions to retry. If the update continues to fail, contact Vave Health Customer Support.

3.6 Performing an Examination

The Vave Health App supports the full imaging workflow, including selecting a clinical preset, entering patient information, acquiring images, taking measurements, adding annotations, and reviewing or exporting exams.

3.6.1 Pre-Examination Inspection

CAUTION

Inspect the probe visually before and after each use, and before and after cleaning or disinfection. Regular, thorough inspection helps prevent patient injury and supports diagnostic image quality.

3.6.2 Scanning Time and Thermal Management

Typical use of the Vave Probe is up to 5 minutes of continuous scanning followed by 10 minutes in powered off. Continuous scanning sessions longer than 15 minutes may result in perceptible heating of the probe. If the probe temperature approaches the thermal shutdown threshold, the system will display a warning approximately 30 seconds before automatic thermal shutdown.

The Vave Health App includes an Auto-Freeze function, which pauses imaging when no change is detected in the scan field. Normal operation can be resumed with a single tap. Auto-Freeze reduces power consumption and thermal build-up. The Auto-Freeze function is enabled by default and can be disabled in the Vave Health App settings.

3.6.3 Clinical Presets

The Vave Health App provides clinical presets that configure imaging parameters for specific applications (for example, Cardiac, Abdominal, Lung, OB/GYN, Vascular, MSK, Bladder, Soft Tissue). Select the preset appropriate to the clinical application before imaging. Available presets depend on the probe in use.

3.6.4 Imaging Modes

The Vave Wireless Ultrasound System supports B-Mode imaging (default), Color Doppler, and M-Mode. Availability of individual modes depends on the probe and preset.

3.6.5 Measurements and Calculations

The Vave Health App provides measurement and annotation tools (including linear and area measurements, text annotation, centerline, bladder volume calculation, and obstetric biometric calculations) to support clinical assessment. Availability of individual tools depends on the probe and preset

CAUTION

All measurements and calculations must be reviewed and verified by the clinician. Adjust calipers as needed before confirming a measurement.

3.6.6 Patient Information

Patient information may be entered manually during a scanning session or imported from a configured Modality Worklist. Always verify that the correct patient is associated with the examination before saving or exporting. Follow your organization's policies on Protected Health Information (PHI).

3.6.7 Ending an Examination

End the examination using the in-App control. Open examinations are saved automatically even if the App is closed before the examination is ended. Following each examination, proceed with cleaning and disinfection as described in Chapter 4.

3.7 Data Storage, Export, and Synchronization

Examination data may be stored locally on the mobile device and, where enabled, synchronized to VaveCloud™ or sent to a configured PACS. Images can also be exported to the mobile display device's photo gallery. Images exported to the device's photo gallery are de-identified to remove Protected Health Information. Export options and synchronization behavior are configured in the Vave Health App and in the Vave Web Portal.

Exported images are de-identified to remove Protected Health Information. Users must follow their institution's policies regarding PHI handling and sharing.

NOTE

When automatic cloud synchronization is disabled, features that rely on cloud data, such as exam sharing and exam discussion, are unavailable.

3.8 Session Security

- Accounts are locked temporarily after multiple consecutive failed login attempts.
- The Vave Health App requires internet connectivity at least once every 60 days. The App displays reminders as this interval approaches; if 60 days pass without connectivity, the App will limit functionality until the user reconnects to the internet.
- Users are responsible for logging out when the mobile device is shared or handed over.

3.9 If a Malfunction Occurs

In the event of a suspected malfunction or defect:

1. Discontinue use of the affected component immediately.
2. Remove the probe from contact with the patient.
3. Power off the probe and remove the battery if it is safe to do so.
4. Do not attempt to repair or modify any component.
5. Contact Vave Health at [Vave Health Customer Support](#).

WARNING

Continuing to use the Vave Wireless Ultrasound System after the first sign or suspicion of malfunction may cause serious or fatal injury.

4 Cleaning, Disinfection, and Maintenance

This chapter describes the required cleaning, disinfection, storage, and maintenance procedures for the Vave Wireless Ultrasound System. The user and/or the healthcare facility is responsible for performing these procedures correctly and on the required schedule. Failure to do so may result in device malfunction, cross-contamination, or infection.

CAUTION

- The Vave Wireless Ultrasound System (including the probe, battery, charger, and accessories) is supplied non-sterile and is not designed to be sterilized. Do not sterilize any component. Attempting to sterilize may damage the device and increase the risk of injury or infection.
- The Vave Wireless Ultrasound System is intended for reuse. Follow the validated cleaning and disinfection procedures in this chapter.
- Use only cleaning and disinfection solutions approved by Vave Health listed in this chapter. Other solutions may be incompatible and may damage the device.
- Wear appropriate personal protective equipment (such as eyewear and gloves) as recommended by the chemical manufacturer.

4.1 After Each Examination

After completing each examination, perform the following steps:

1. Inspect the probe for visible damage, deterioration, or contamination.
2. Clean and disinfect the probe and battery as described in Section 4.3.
3. Clean the mobile display device as described in Section 4.5.
4. Recharge the battery if necessary.
5. Store the system as described in Section 4.7.

4.2 Pre-Cleaning Inspection

Before cleaning, inspect the probe, battery, and charger visually for signs of damage or deterioration, including corrosion, discoloration, pitting, cracks, or broken seals. If any damage is evident, discontinue use and contact Vave Health Customer Support.

4.3 Cleaning and Disinfecting the Probe and Battery

4.3.1 Cleaning the Probe and Battery

WARNING

Do not clean or disinfect the probe while the battery is installed. Exposing the battery contacts to cleaning solutions may cause short-circuit and overheating, with a risk of electric shock or burns.

1. Turn off the probe.
2. Remove the battery from the probe.
3. Using a CaviWipes™ pre-moistened disinfectant wipe, wipe the entire exterior of the probe and the battery separately until thoroughly cleaned.
4. If necessary, repeat with a fresh wipe until all gel, particulate matter, and bodily fluids have been removed.
5. Wipe the exterior surfaces with a clean, non-abrasive, dry cloth.

4.3.2 Disinfecting the Probe and Battery

The required level of disinfection depends on the intended use of the probe. Apply the Spaulding classification to determine the appropriate level:

SPAULDING CLASS	USE	REQUIRED METHOD
Non-critical	Probe touches intact skin only.	Cleaning followed by intermediate-level disinfection.
Semi-critical	Probe touches mucous membranes or non-intact skin.	Cleaning followed by high-level disinfection.

The following cleaning and disinfection agents have been validated for compatibility with the Vave Probe and accessories:

LEVEL	SOLUTION	ACTIVE INGREDIENTS	METHOD
Intermediate-level disinfection	CaviWipes™	Isopropyl alcohol, quaternary ammonium compounds	Wipe. Follow manufacturer's instructions.
High-level disinfection	CIDEX® OPA	Ortho-phthalaldehyde	Immersion. Follow manufacturer's instructions.

Different levels of disinfection require different procedures, not merely different chemicals. Follow the procedure below that matches the required level.

Intermediate-Level Disinfection:

After cleaning (Section 4.3.1):

1. Using a CaviWipes™ pre-moistened disinfectant wipe, wipe the probe and the battery separately for a minimum of one minute.
2. Air-dry, or towel-dry with a clean, non-linting cloth.
3. Examine the probe and battery for any damage, such as cracks or splits where fluid could enter. If damage is evident, discontinue use and contact Vave Health Customer Support.

High-Level Disinfection:

When the probe has been in contact with broken skin, mucous membranes, or blood, high-level disinfection is required. After cleaning (Section 4.3.1):

1. Check the expiry date of the disinfectant solution and prepare it in accordance with the manufacturer's label for concentration and contact time.
2. Immerse the probe and the battery separately in undiluted CIDEX® OPA solution at 23°C (73°F) for the required contact time.
3. Rinse the probe and battery in accordance with the disinfectant label.
4. Air-dry, or towel-dry with a clean, non-linting cloth.
5. Examine the probe and battery for any damage, such as cracks or splits where fluid could enter. If damage is evident, discontinue use and contact Vave Health Customer Support.

4.4 Cleaning the Battery Charger

1. Unplug the charger cable from the mains outlet.
2. Disconnect the cable from the rear of the charger.
3. Using a pre-moistened disinfectant wipe, wipe all surfaces. Do not submerge the charger in any liquid.
4. Wipe with a clean, non-abrasive, dry cloth.

4.5 Cleaning the Mobile Display Device

Follow the mobile device manufacturer's cleaning instructions. As a general procedure:

1. Inspect the device for damage or deterioration. If damage is observed, discontinue use and replace the device with a compatible unit.
2. Power off the device.
3. Clean the external surfaces with a pre-moistened disinfectant wipe. Do not immerse the device in liquid.
4. Allow the device to dry as instructed by the disinfectant manufacturer.
5. Power on the device.

4.6 Drying and Final Inspection

After cleaning and disinfecting the probe, battery, and charger, allow the components to air-dry and then wipe the exterior surfaces with a clean, non-abrasive, dry cloth. Inspect for any residual damage before returning the system to service.

4.7 Storing the Device

To protect the Vave Wireless Ultrasound System when not in use:

- Dry components thoroughly before storage.
- Do not store the system in extreme temperatures. Observe the storage limits defined in Chapter 3.
- Avoid prolonged exposure to direct sunlight, which may discolor the housing finish.
- Store the probe separately from other equipment.
- Retain the original packaging for transport.

4.8 Maintenance and Service

The only user maintenance required for the Vave Wireless Ultrasound System is cleaning, disinfection, and battery care as described in this chapter.

CAUTION

The Vave Wireless Ultrasound System must be serviced only by personnel authorized by Vave Health. Failure to maintain or verify the probe on the required schedule may lead to undetected performance degradation. Do not attempt to open, repair, or modify any component.

4.9 Expected Service Life

The Vave Wireless Ultrasound System, including all accessories, is designed for an expected service life of 5 years under normal use conditions. Actual service life depends on frequency of use, environmental conditions, and adherence to the handling and maintenance instructions in this manual.

5 Troubleshooting

This chapter describes conditions that may arise during use of the Vave Wireless Ultrasound System and the appropriate user response, including when to contact Vave Health Customer Support.

WARNING

Discontinue use immediately at the first sign of system malfunction or defect and contact Vave Health Customer Support. Continued use following a malfunction may cause serious or fatal injury.

5.1 Probe and Battery Conditions

CONDITION	DESCRIPTION AND RESPONSE
Probe overheating warning	The Vave Health App displays a warning approximately 30 seconds before the probe reaches the thermal shutdown threshold. Complete the current examination promptly. The probe will automatically shut down at 45°C (113°F) to protect the user and patient. Allow the probe to cool before resuming use.
Automatic thermal shutdown	The probe has reached the maximum allowable surface temperature and has shut down. Remove the probe from contact with the patient. Allow the probe to cool to operating temperature before restarting. If thermal shutdowns occur repeatedly and the probe does not feel too warm, contact Vave Health Customer Support.
Low battery	The battery is running low. Complete the current examination and recharge or replace the battery as soon as practical.
Battery too low to connect	The battery charge is too low to establish a probe connection. Recharge the battery before attempting to connect.
Battery not charging	Confirm that the charger LED is solid yellow, indicating the battery is charging. If the LED is alternating between yellow and green, remove the battery from the charger and reinsert it. If the issue persists, contact Vave Health Customer Support.
Firmware update will not proceed	The probe battery must have sufficient charge before a firmware update will run. Charge the battery and retry.
Physical damage to the probe or battery	If the probe or battery shows cracks, broken seals, corrosion, discoloration, deformation, or unusual odor or heat, discontinue use immediately and contact Vave Health Customer Support.

5.2 Connection and Connectivity Conditions

CONDITION	DESCRIPTION AND RESPONSE
Probe will not connect	Confirm that the probe is powered on and the light is green, that the battery has sufficient charge, and that Wi-Fi and Bluetooth are enabled on the mobile device. If the probe still cannot connect after these checks, contact Vave Health Customer Support.
Automatic reconnection to probe fails	If the automatic reconnection attempt following a connection failure fails, restart the probe and the Vave Health App. If the issue persists, contact Vave Health Customer Support.
Unable to log into the App	An internet connection is required to log into the Vave Health App. Connect the mobile device to the internet and retry. If you are unable to log into the App when you have internet connectivity, contact Vave Health Customer Support.
Connectivity reminder	The Vave Health App requires internet connectivity at least once every 60 days. As this interval approaches, reminders are displayed in the App. After 60 days, the App will limit functionality until the user reconnects to the internet.
Account locked	After multiple consecutive failed login attempts, the account is temporarily locked to protect against unauthorized access. Wait for the lockout to expire or contact Vave Health Customer Support at support@vavehealth.com .

5.3 When to Contact Vave Health Customer Support

Contact Vave Health Customer Support at support@vavehealth.com if any of the following occur:

- Repeated thermal shutdowns during normal use.
- Visible damage, corrosion, or deformation of the probe, battery, or charger.
- The battery does not charge to full capacity, or shows abnormal heat, odor, or deformation.
- Repeated inability to connect the probe to the mobile device.
- Suspected cybersecurity incident or unusual application behavior.
- Any other suspected malfunction of the Vave Wireless Ultrasound System.

6 Specifications and References

This chapter provides the technical specifications, regulatory declarations, and disposal information for the Vave Wireless Ultrasound System.

6.1 Compliance Statement

The Vave Wireless Ultrasound System complies with the applicable national and regional standards and regulations for its intended markets. Users are responsible for ensuring that the selected mobile device and probe are compliant with the laws of the jurisdiction in which the system is used

6.2 Product Classification

CLASSIFICATION	DESIGNATION
Regulatory classification (United States)	FDA Class II
Regulatory classification (European Union)	EU MDR Class IIa
Electrical protection	Internally powered ME equipment
Applied part classification	Type BF
Ingress protection — Probe	IP67
Ingress protection — Battery	IP67
Ingress protection — Battery Charger	IP22
Mode of operation	Continuous operation
Anesthetic environment	Not AP / APG — not suitable for use in oxygen-rich or anesthetic environments

6.3 Product Model Numbers

PRODUCT NAME	MODEL NUMBER
Vave Universal Ultrasound	VA-0327
Vave Universal Probe	VA-0133
Vave Phased Personal Ultrasound	VA-0182
Vave Phased Probe	VA-0116
Vave Battery	VA-0175
Vave Battery Charger	VA-0252
Charger AC-DC Adapter	Mean Well GEM30112-P1J or NGE30112-P1J

6.4 System Specifications

COMPONENT	SPECIFICATION
Vave Universal Probe	Dimensions: 166 × 54 × 38 mm (with battery) Weight: 220 g (without battery) Frequency range: 2 MHz to 8 MHz Maximum imaging depth: adjustable 5 to 24 cm (sector); 2 to 8 cm (linear)
Vave Phased Probe	Dimensions: 169 × 54 × 38 mm (with battery) Weight: 215 g (without battery) Frequency range: 1 MHz to 5 MHz Maximum imaging depth: adjustable 5 to 24 cm
Vave Battery	Dimensions: 83.4 × 54 × 21.8 mm Weight: 130 g Chemistry: Lithium ion Voltage / Capacity: 3.6 V / 7,000 mAh
Vave Battery Charger	Dimensions: 104 × 59.9 × 44.9 mm Weight: 130 g Input: 12 VDC, 2.5 A Output: 4.35 VDC, 2.4 A
Charger AC Adapter	Input: 100 – 240 V AC, 50/60 Hz, 1.0 – 0.6 A Output: 12 VDC, 2.5 A
Scanning time	At least 1 hour of B-Mode operation on a full battery (worst-case; actual time varies by preset)
Battery charging time	Approximately 90min from 20% to 80%
Expected battery aging	1,000 charge cycles to 80% of original capacity

6.5 Mobile Display Device Requirements

CAUTION

Using the Vave Wireless Ultrasound System with a mobile device that does not meet the minimum specifications may result in degraded image quality, unexpected behavior, and potential misdiagnosis.

6.5.1 iOS Devices

REQUIREMENT	MINIMUM	RECOMMENDED
Operating system	One version prior to latest public release	Latest public release
Processor	A13	A16 or later
RAM	3 GB	6 GB or more

6.5.2 Android Devices

REQUIREMENT	MINIMUM	RECOMMENDED
Operating system	One version prior to latest public release	Latest public release
Processor	Quad-core	Octa-core or better
RAM	3 GB	6 GB or more

6.6 Hardware Warranty and Disposal

TOPIC	DESCRIPTION
Warranty	The Vave Probe includes a minimum one-year warranty. For current warranty terms, refer to Vave Health website .
Disposal	The Vave Probe, battery, and accessories may be environmentally hazardous if disposed of improperly. Follow all applicable local, regional, and national regulations for electronic medical device and lithium-ion battery disposal. Contact an authorized representative of Vave Health for information on decommissioning.
WEEE	Within the European Union, this device falls within the scope of Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE). Do not dispose of this device as unsorted municipal waste.

6.7 Wireless Transmission

The Vave Wireless Ultrasound System uses wireless communication between the probe and the mobile display device. Specifications of the wireless subsystem are summarized below.

FREQUENCY RANGE (MHZ)	MAX OUTPUT POWER (W)	MODULATION / TECHNOLOGY	MAXIMUM DATA RATE
2400 – 2483.5	0.0038	Bluetooth LE, GFSK	1 Mbit/s
	0.1659	OFDM / 802.11n (20 MHz)	72.2 Mbit/s
	0.1230	OFDM / 802.11n (40 MHz)	150 Mbit/s
5150 – 5350	0.0263	OFDM / 802.11a	54 Mbit/s
	0.0199	OFDM / 802.11n (20 MHz)	72.2 Mbit/s
	0.0123	OFDM / 802.11n (40 MHz)	54 Mbit/s
5470 – 5725	0.0257	OFDM / 802.11a	54 Mbit/s
	0.0195	OFDM / 802.11n (20 MHz)	72.2 Mbit/s
	0.0091	OFDM / 802.11n (40 MHz)	54 Mbit/s
5725 – 5850	0.1737	OFDM / 802.11a	54 Mbit/s
	0.1230	OFDM / 802.11n (20 MHz)	72.2 Mbit/s
	0.0851	OFDM / 802.11n (40 MHz)	150 Mbit/s

6.7.1 Wireless Compliance (FCC and ISED Canada)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio-frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. There is no guarantee that interference will not occur in a particular installation. If interference to radio or television reception is caused, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and the receiver.
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for assistance.

Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by Vave Health, Inc. may void the user's authority to operate the equipment.

This device complies with Innovation, Science and Economic Development Canada's license-exempt RSSs. Operation is subject to the following two conditions: (1) this device may not cause interference; and (2) this device must accept any interference, including interference that may cause undesired operation.

6.7.2 Radiation Exposure Statement

This equipment complies with the IC RSS-102 radiation exposure limits set forth for an uncontrolled environment.

6.8 Electromagnetic Compatibility

6.8.1 Electromagnetic Emissions

EMISSION TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT
RF emissions, CISPR 11	Group 1, Class B	The system uses RF energy for internal function and for wireless communication in the ISM bands. RF emissions outside the ISM bands are very low and are not likely to cause interference in nearby electronic equipment.
Magnetic effects, RTCA DO-160G §15.0	Equipment Category Z	—
Radiated RF emissions, RTCA DO-160G §21.5	Equipment Category M	—

EMISSION TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT
Harmonic emissions, EN/IEC 61000-3-2	Not applicable	The system is a portable, battery-powered device with no signal cables.
Voltage fluctuations / flicker, EN/IEC 61000-3-3	Not applicable	The system is a portable, battery-powered device with no signal cables.

6.8.2 Electromagnetic Immunity

IMMUNITY TEST	IEC 60601-1-2 TEST LEVEL	COMPLIANCE LEVEL
Electrostatic discharge (EN/IEC 61000-4-2)	±2 kV, ±4 kV, ±6 kV, ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±2 kV, ±4 kV, ±6 kV, ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF electromagnetic field (EN/IEC 61000-4-3)	10 V/m, 2 Hz modulation 10 V/m, 1 kHz modulation	10 V/m, 2 Hz modulation 10 V/m, 1 kHz modulation
Power-frequency magnetic field (EN/IEC 61000-4-8)	30 A/m, 50 Hz 30 A/m, 60 Hz	30 A/m, 50 Hz 30 A/m, 60 Hz

6.8.3 Immunity to Wireless RF Communication Equipment

Tested in accordance with EN/IEC 61000-4-3. The system complies with Performance Criterion A (equipment continues to operate as intended without operator intervention; no loss of function below the minimum performance level) at all the following test frequencies and field strengths:

TEST FREQUENCY (MHZ)	V/M	FRONT / REAR / LEFT / RIGHT — VERTICAL AND HORIZONTAL
380 – 390	27	Performance Criterion A
430 – 470	28	Performance Criterion A
704 – 787	9	Performance Criterion A
800 – 960	28	Performance Criterion A
1700 – 1990	28	Performance Criterion A
2400 – 2570	28	Performance Criterion A
5100 – 5800	9	Performance Criterion A

6.8.4 Recommended Separation Distances

The table below provides guidance on conducted and radiated interference from portable and fixed RF-transmitting equipment and the recommended separation distances between the system and such equipment. Follow the recommended distances to reduce the risk of interference.

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER (W)	80 MHZ TO 2700 MHZ	5.2 GHZ TO 5.8 GHZ
0.1	—	15.2 m (49.9 ft)

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER (W)	80 MHz TO 2700 MHz	5.2 GHz TO 5.8 GHz
2.2	3 m (9.8 ft)	—

Example: a portable transmitter with maximum radiated power of 2.2 W and operating frequency of 384 MHz can be used at distances greater than 3 m (9.8 ft) from the system.

Proximity magnetic field immunity per IEC 60601-1-2 §8.11 is not applicable; compliance is achieved via §8.11(b). A minimum separation distance of 0.15 m from magnetic-field-transmitting equipment is required during intended use, to ensure that magnetically sensitive circuitry is not exposed to Table 11 field strengths.

FREQUENCY RANGE	REQUIRED MINIMUM SEPARATION DISTANCE
9 kHz to 13.56 MHz	0.15 m