Vave Personal Ultrasound

USER MANUAL

vave

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About This Manual

This document is licensed as part of the purchase of the Vave Personal Ultrasound System and is intended to meet FDA regulatory requirements. Install, operate, and maintain the Vave Personal Ultrasound according to the safety and operating procedures in this manual, and only for its intended purpose. Always use the information in this document with sound clinical judgment and best clinical procedures. Information in this Manual is subject to change. To obtain the latest version, go to www.vavehealth.com. You can also obtain a printed copy of this manual at no additional cost, go to www.vavehealth.com and contact Vave Health.

This document contains:
Product Information: Description, technical specifications, and intended use
Product Quick Start: Begin scanning
Product Usage: Features, system set up and performance
Product Care: Cleaning and disinfection
Product Safety: Critical safety standards, principles, and policies
References: Regulatory requirements, terms and conditions, glossary of terms, and acoustic output data

Target Audience

This document is written for trained healthcare professionals.

Document Conventions

Touch Gestures

Drag
Press and move in any direction

Swipe
Press and quickly move finger left or right

Tap
Press and release press quickly

Pinch
Press with two fingers and bring them together

Press and Hold
Press and hold press

Zoom
Press with two fingers and spread them out

Icons

! **Caution**	Possible risks beyond the reasonable control of Vave
X **Avoid**	Actions to avoid
» **Note**	Information/Suggestions

1 About the Vave Personal Ultrasound

The Vave Personal Ultrasound is subject to the laws in the jurisdiction in which it is used. Install, use, and operate the product only in ways that adhere to applicable laws or regulations.

- Keep product packaging with medical device. Do not dispose.
- Using the product incorrectly, or for purposes other than intended and expressly stated in this manual may release Vave or its agents from some or all responsibility for resultant noncompliance, damage, or injury.
- In compliance with part 15 of the FCC rules, operation of this device 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.
- Install and operate medical equipment according to electromagnetic compatibility (EMC) guidelines. This product has demonstrated EMC compliance under conditions that include the use of compliant peripheral devices. Using portable and mobile radio-frequency (RF) communications equipment can affect the operation of medical equipment.
- Do not operate the system in the presence of flammable gases or anesthetics.
- Users are responsible for image quality and diagnosis.

1.1 System Description

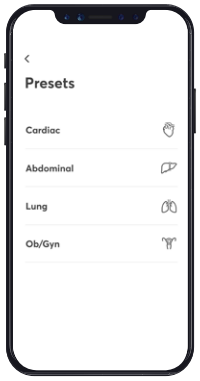
The Vave Personal Ultrasound is a wireless, pocket-sized diagnostic ultrasound device consisting of both hardware and a mobile application ("Vave App"). The purpose of the system is to provide a low-cost, easy to use and high-quality ultrasound platform for teaching and clinical applications.

The ultrasound probe ("Vave Phased") uses a state-of-the-art piezoelectric transducer, houses a removeable lithium ion battery and components required for ultrasound imaging and Wi-Fi connectivity.

The Vave Phased can wirelessly transmit data to a mobile application ("Vave App"), which displays the ultrasound images and allows certain image parameter modifications through its user interface. The mobile application runs on non-proprietary commercial display devices capable of supporting wireless connections (iOS or Android based tablets or phones) so users can view images and control the Vave Probe on a mobile device. Ultrasound scans can be saved in an examination file on the device and exported for storage or printing.

Vave Probe

Vave App
(display device not included)



The Vave Phased contains a removable lithium ion battery. The battery is charged through the provided charger.

Battery Specifications:

Battery manufacturer	Vave
Battery type/chemistry	Lithium ion
Battery model number	VBT
Battery management	Fuel gauge with protection circuitry and temperature monitoring
Battery life	500 cycles
Charger	Input: 100-240 VAC, 50/60 Hz, 1.0-0.6 A Output: 12 VDC, 2.5 A
Battery	3.7 V/4800 mAh
Charge time	< 12 hours from an empty battery to full charge

1.2 System Dimensions

Vave Probe	**Dimensions** 169x54x38 mm (including battery) **Weight** 205 g (without battery) **Frequency range** 1.5 MHz to 3.5 MHz
Vave Battery	**Dimensions** 83.4x54x21.8 mm **Weight** 115 g
Vave Charger	**Dimensions** 104x59.9x44.9 mm **Weight** 130 g

1.3 Product Usage

1.3.1 Intended Use

The Vave Personal Ultrasound is intended for diagnostic ultrasound imaging in B-Mode. It is indicated for diagnostic ultrasound imaging in the following applications: Fetal/Obstetrics, Abdominal (includes Gynecology, Renal, and Urology), Pediatric, Thoracic/Pleural, Cardiac Adult, Cardiac Pediatric, Peropheral Vessel, and procedural guidance of needles into the body.

The Vave ultrasound system is a transportable system that is intended for use in environments where healthcare is provided by trained healthcare professionals.

Diagnostic Ultrasound Indications for Use
System: Vave Phased Array
Transducer: Phased Array Transducer
Intended Use: Diagnostic ultrasound imaging of the human body as in the chart on the following page.

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N						
	Abdominal	N						
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N						
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal							
	(Conventional)							
	Musculo-skeletal							
	(Superficial)							
	Intravascular							
	Other (Thoracic/ Pleural)	N						
Cardiac	Cardiac Adult	N						
	Cardiac Pediatric	N						
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
	Peripheral vessel	N						
	Other (Nonvascular)	N						

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Includes imaging to assist in a) needle and catheter placements in vascular or other anatomical structures and b) guidance for nerve block procedures.

- Abdominal includes gynecology, renal and urology
- Thoracic/pleural detection of fluid and pleural motion/sliding
- Peripheral vessel includes arteries and veins
- Non-vascular is image guidance for freehand needle/catheter placement

For Use in Surgical Environments
Before you use the Vave Probe for intra-operative procedures, follow the instructions for high-level disinfection (for instructions see page 32), then cover the Vave Probe with a sterile sheath:
- Use only CIVCO REF 610-1212.
- Download the usage instructions from http://civco.com and read all the information before use.

When you have finished using the Vave Probe, immediately clean it (for instructions, see the "Cleaning and Disinfecting" section of this User Manual), followed by another high-level disinfection.

If the sheath breaks during the intra-operative procedure, dispose the sheath and follow the same cleaning and high-level disinfection process as above, then cover the Vave Probe with a new sheath before continuing use.

Additional Usage Notes:
- Circumstances in the patient's environment may negatively impact the scanner and the exam. For example: (1) Chemicals and gases in the operating room. (2) Altitudes below -382 m or above 4000 m.
- Vulnerable patients, such as children and pregnant/nursing women, may be more prone to negative effects from prolonged exposure to acoustic energy during scanner use.
- Biological incompatibility may exist between scanner materials and the biological tissues, cells, and body fluids of the patient/user.
- Using the scanner in the patient environment may be unsafe in conditions of extremes in humidity (RH<15% and RH>90%) or temperature (<40°C / 104°F or >0°C / 32°F).
- Users should be trained healthcare professionals (e.g., doctors, nurses, technicians) with previous training in ultrasound. Federal law restricts device sale to or on the order of a physician. Unqualified/untrained personnel purchasing and using the Vave Scanner may be unable to attain quality images.

Symbols Glossary
These symbols are included in our product literature and industrial design in compliance with ISO and IEC regulatory standards. Please consult the table below for each symbol and its meaning.

Standard Icon Glossary

	IEC 60417 - 5172 Class II equipment
	IEC 60417 - 5333 Type BF applied part
	ISO 7010 - M002 Refer to instruction manual/booklet
	ISO 7000 - 1641 Operator's manual; operating instructions
	ISO 7010 - W001 General warning sign
	Additional symbols: Caution

1.3.2 Contraindications
The Vave Personal Ultrasound is not intended for use in the following situations:
- Introducing the Vave Probe within a body cavity or organ (= endocavitary use, e.g. rectum, vagina or esophagus)

1.4 Hardware

1.4.1 Warranty

Your Vave Probe includes a one-year warranty. To purchase an extended warranty, go to www.vavehealth.com.

1.4.2 Disposal

Vave Probe equipment and accessories are designed and manufactured in alignment with environmental protection standards. Disposal should follow the same standards. Vave Probe materials required for quality treatment and functionality can be environmentally hazardous if improperly disposed. Please follow all local, state, and federal regulations or return materials to Vave.

1.5 Security

1.5.1 Information Security

Protecting the privacy and security of patient health information is an important responsibility of the healthcare provider and medical device manufacturer. The Vave App and Vave Personal Ultrasound platform are designed to safeguard the confidentiality, integrity, and availability of electronic patient information and reduce the risk of security breaches. It is the users' responsibility to use the Vave Personal Ultrasound in accordance with this guide, security guidance, the policies of your institution, and regulatory requirements.

Vave Health's Role in Product Security

Vave Health conducts ongoing security assessments and testing to identify potential security weaknesses in the Vave Health platform. The Vave Health product engineering team monitors for vulnerabilities in our software, third-party software, and mobile operating systems. With that information, the Vave engineering team revises its software and systems, implements security controls, and releases software patches to minimize security threats.

Users' Role in Product Security

Warning: Unauthorized modifications to your mobile device ("rooting" or "jailbreaking") can cause the ultrasound system to malfunction, lead to data theft, or potential misdiagnosis. The Vave App is designed to detect unauthorized modifications to your device and will not run if the device has been modified.

Warning: To minimize the risk to patient data security, Vave Health recommends you install applications only from trusted sources and limit their installation and use to healthcare and business needs.

Secure Device Use

It is your responsibility to use the Vave Personal Ultrasound System as described in the "Using the Vave Phased Array Probe" and "Security Guidelines" sections in this manual. Consult your Healthcare Information Technology Security team to ensure your mobile device is configured in accordance with your specific site requirements and data export/sharing policies.

Security Updates
The Vave Platform restricts device firmware updates to authorized software distributed through the Vave Health Mobile App. It is your responsibility to upgrade the Vave Probe and Firmware as described in the "Updating the Vave Probe" section of this manual. In addition, it is your responsibility to upgrade and apply operating system and security updates to your mobile device.

iOS Operating System Updates
1. Connect your device to both a power source and trusted Wi-Fi
2. Tap Settings > General > Software Update
3. Tap Download and Install.

Android Operating System Updates
1. Connect your device to power and trusted Wi-Fi
2. Open Settings
3. Select About Device or About Phone
4. Tap Check for Updates
5. Install (Install Now, Reboot and Install, or Install System Software) as prompted.

1.5.2 Network Security
Warning: Connecting to an untrusted wireless access point or network may allow malicious parties to see your Wi-Fi signals, perform harmful actions, and view communications from your mobile device.

Your mobile device connects to the Vave Phased Array Probe using a private Wi-Fi network that supports WPA2 encryption (Wi-Fi Protected Access). The Wi-Fi password is unique to your Vave Phased Array Probe.

The Wi-Fi SSID and serial number of the Vave Phased Array Probe are listed on the label affixed to the Vave Phased Array Probe. The serial number will be your Wi-Fi WPA2 passcode. For instructions, see the "Connecting Your Mobile device to a Vave Probe" section of this guide.

You are able to connect your Mobile device to your local institution network and the Internet using Wi-Fi or cellular device connection. When connecting to Wi-Fi, we recommend that you only connect to networks that are secured with WPA2 using a password or certificate.

For information on connecting your Mobile device to your institution's Wi-Fi network, follow the instructions of your Information Technology team and refer to your network equipment documentation.

Credential Security
Warning: Change your Vave Health account password if you suspect it may have been revealed, discovered, or otherwise compromised.

It is your responsibility to protect your security credentials (i.e. your UserID/Email and password) used to sign-in to the Vave App. We recommend to use strong passwords that are at least 10 characters and include special characters or a long passphrase.

We recommend you use a unique, dedicated password for your Vave App. Never reveal your password to anyone and change your password if you suspect compromise. The Vave Health platform uses a one-time PIN sent to your mobile device via Short Message Service (SMS) to confirm your identity at (i) first-time sign-on, (ii) when you reset your password, or (iii) when you login from an unrecognized device.

Device Access
To prevent unauthorized access to the Vave App, ensure your mobile device requires a passcode, PIN, pattern or biometric identification for access. We recommend configuring your mobile device to lock after a maximum of 15 minutes of inactivity.

Encryption
The Vave App automatically encrypts information and images contained within the Vave App. For additional protection, we recommend enabling device encryption to help ensure all data stored on the system is protected and increase the strength of your access-control, rendering data unrecoverable by unauthorized users.

Physical Device Control
You and your healthcare organization should control and limit physical access to the Vave Phased Array Probe to prevent accidental, casual, or deliberate contact by unauthorized individuals.

Report any loss of theft of your Vave Ultrasound Probe or Mobile device to your security and/or privacy officer.

Visual Access Control
Minimize unauthorized visual access to protected patient information by maintaining awareness of where the device is being used, positioning the device to prevent viewing from over-the-shoulder, through doorways, hallways, and other traffic areas.

Image Export, Transmission, and Upload
Normal operation of the device operates over the secure/encrypted dedicated Wi-Fi network between the mobile device and Vave Phased Array Probe and Vave App encrypted data store.

Exported data will be saved to the local "camera roll" of the device and is no longer protected by Vave App credentials. Exported data is de-identified to minimize the risk of data breach.

Exported images may also be shared or emailed via your local institution Wi-Fi network, cellular network, text/SMS, or other public Wi-Fi network. Follow your institution's policy on the proper and approved use of institution email, personal email services and text/SMS when attempting to export or share data from the Vave Ultrasound Device.

Warning: Personal email services, text/SMS, and untrusted Wi-Fi networks may not be secure and could compromise patient privacy.

! Caution: Any individual with biometric, password, or PIN access to your Mobile device will be able to view and access de-identified images in your camera roll.

1.5.3 Confidentiality
Patient Information in the Vave App is encrypted in storage — and in transmit between the probe and app — using industry standard AES encryption to reduce the risk of data breach if the device is lost or stolen.

Credential information (passwords) for the Vave App is stored using a one-way cryptographic function in a secure key enclave on the mobile device.

Images shared or exported to a saved scan folder or to the camera roll are de-identified and do not contain Protected Health Information (PHI). We recommend ultrasound images are reasonably secured and access to image data be restricted when possible. We recommend deleting images in the local camera roll when no-longer needed.

1.5.4 Integrity
Integrity of the data transmitted between the Vave Phased Array Probe and the Vave App is assured as follows:
- Authentication and encryption reduce the risk of a malicious user interception, viewing, or modifying data.
- Integrity checks ensure the completion and validity of image data received
  - TCP channels are used to ensure that image information is delivered correctly
  - UDP channels are used for image transmission with checksums
  - If data for an image is incomplete or invalid, the entire image frame is discarded

1.5.5 Availability

Images and cines are maintained in the Vave Health App until they are deleted by the user. After a large number of images are stored, the device storage may become full, requiring image deletions before storing additional images.

The Vave App requires an internet connection to register a new user and/or Vave Phased Array Probe. The Internet is required when logging in to the Vave App after logging out, Vave App update, or after a period of 30 days. Unless logged out, users can stay logged into the Vave App for 30 days without an internet connection.

Images are maintained locally on the mobile device. Device Failure, accidental deletion, or device reset will erase all images on the mobile device. To maintain long term availability of images, the mobile device should be backed up — or images exported and saved on an external system.

1.5.6 Accountability

If you suspect that your password has been compromised, suspect that your device may be infected with malware, or the behavior of the device is not as expected, you should immediately notify the privacy and/or security personnel at your institution. Additionally; you should Contact Vave Health customer Support as specified in the "Help" section of this manual.

1.6 System Requirements

Using the Vave Personal Ultrasound with a smart device that does not meet the minimum requirements may result in low-quality images, unexpected results and possible misdiagnoses. Small devices may not have the necessary resolution for viewing small structures.

Minimum Device Specifications:

iOS Devices Requirements

- Operating System: iOS 9+
- Processor: CPU: A10+
- Technical Features: GPU: PowerVR Series 7+ or Apple GPU. RAM: 2 GB+
- Devices: iPhone 7, iPhone 8, iPhone X, iPad Pro (2nd and 3rd generation), etc.

Android Devices Requirements

- Operating System: 6.0 Marshmallow+ (API level 23)
- Processor: CPU: Octa-core 1.6 GHz
- Technical Features: GPU: Dedicated GPU. RAM: 3 GB+
- Devices: Samsung Galaxy Tab S3, Google Pixel C, etc.

2 Quick Tour

2.1 Interface and Screens Overview

2.1.1 Icons

Icons are used throughout the app to visually guide users. There are three types of icons:

- Menu Icons: Navigational icons to move you to new app screens
- Tool Icons: Functional icons that perform an action
- Status Icons: Indicate the status of a parameter

Vave Interface Icons:

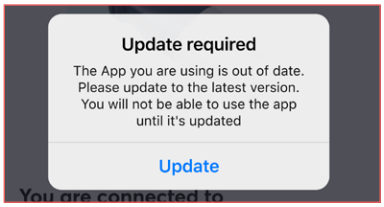
	Abdominal		Lung
	Cardiac		OB/GYN
	Scan		Saved Exams
	Organizations		Settings
	Wi-Fi Signal — strong signal strength	Disconnect	Disconnected
Shared	Shared Indicator		Back
	Search		Play
	Battery empty		Discard
	Battery 30%		Close
	Battery 60%		Delete file/folder
	Battery full		Save file to camera roll
A	Admin Indicator		Export file

2.1.2 Alerts and Notifications

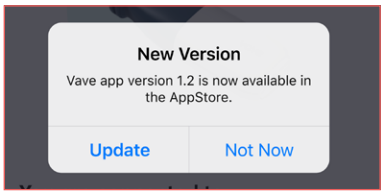
Use the table below to identify and understand alerts displayed in the Vave interface.

Vave Interface Alerts

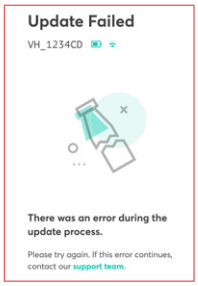
Password Password is required.	**Password is Required** If user does not enter the password, a password required validation will appear under the password input.
Email nhb Wrong email format.	**Wrong Email Format** If input entry does not support email format, a wrong email format validation will appear under the password input.
Login failed. Invalid email or password	**Sign in Failure** A sign in failed validation will appear if submitted password doesn't match email address or if no account has been created with the entered email address.
I agree to the Terms of Service Field is required	**Terms of Service** Checkbox alert shows up if the field is required to be checked to proceed.
Verification code Please enter valid verification code	**Verification Code** Verification Code alert shows up if you provide an invalid code.
Probe's battery is low (5%) Please connect it to the charger Dismiss	**Low Battery** If your probe is running out of battery, a low battery alert will appear on top of the screen.
Probe is too hot. It will shut down in 30 seconds.	**Temperature Alert** If the probe gets too hot, it will automatically shut down 30 sec after displaying this warning.
You are not connected to the Internet. To register a probe please connect to the Internet wifi or use Mobile Data. Go to Wi-Fi Settings	**No Wi-Fi** This alert shows up if you are not connected to the Internet when trying to register new probe.
You are connected to VH_1234CD Disconnect You need to register this probe to be able to use it and Start The Exam.	**Probe Registration** Probe registration alert will appear when you connect to a probe that is not yet registered.



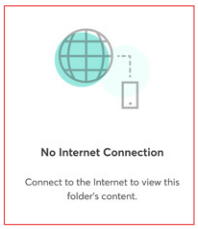
Required Update
If there is a required update for the probe available, you will see a required update alert.



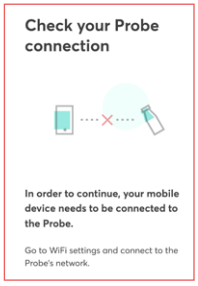
Optional Update
If there is an optional update for the probe available, you will see an optional update alert.



Update Failed
Update Failed alert shows up if the update process of the probe has not ended successfully.



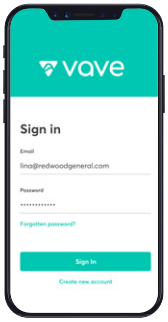
No Internet Connection
No Internet Connection alert shows up if you try to view a folder that is not available offline and you have no Internet connection at that time.



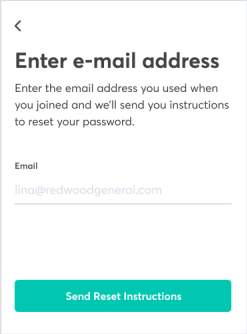
Check Your Probe Connection
Check Your Probe Connection alert shows up when connecting to the probe process fails.

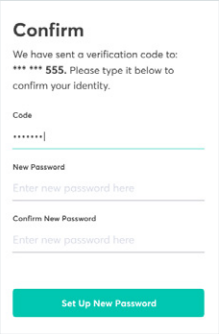
2.1.3 Sign-in Page

When you open the Vave App, it displays a sign-in screen for your user ID/Email and password.



Forgot Password: Enter your email to receive a verification code to be entered on your phone so you can reset your password.



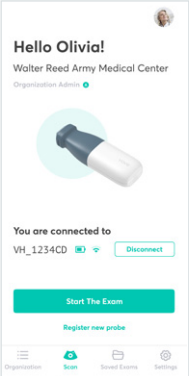


2.1.4 Menu Options

The following menu options are available:

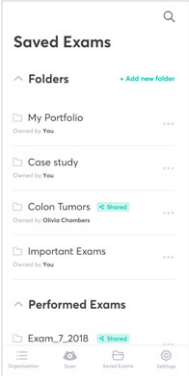
- Organizations
- Scan
- Saved Exams
- Settings

Note: Profile settings are accessible from Organization Selection Screen



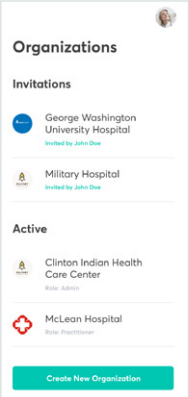
Scan
Displays the following sections:

- Probe Connection
- Start The Exam
- Register New Probe

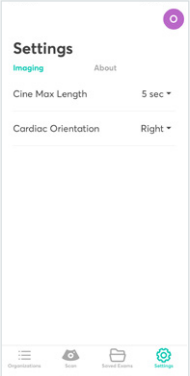


Saved Exams
This page displays a collection of exams that you have completed.

- Folders: allows you to organize/group your scans.
- Exams: list of saved exams.



Organization
This page displays a list of organizations to which the user belongs or to which he or she has been invited.



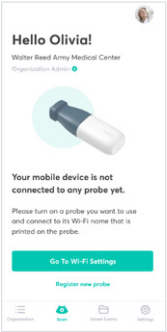
Settings
Displays the following sections:

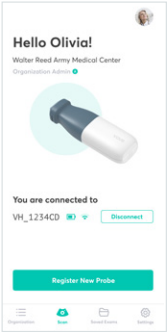
- Imaging
- About

2.1.5 Beginning Scanning

Once you are signed in, you will see the following options:

- **Go to Wi-Fi settings:** redirects you to your mobile Wi-Fi settings in order to connect to the Vave Probe's wireless network
- **Register New Probe:** allows you to register a new probe in the system



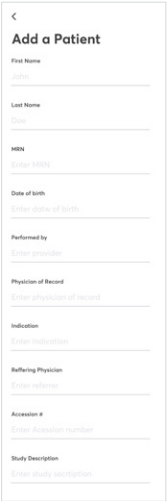


Once your mobile device is connected to a Vave Probe, you'll see the following options:

- **Start The Exam:** allows you to start a new exam
- **Disconnect:** lets you disconnect a connected probe
- **Register New Probe:** walks you through registration of a new probe

2.1.6 Patient Demographics

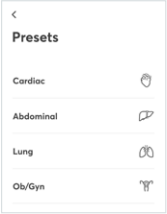
On this screen you'll be able to enter Patient information ("Add a patient").



2.1.7 Presets

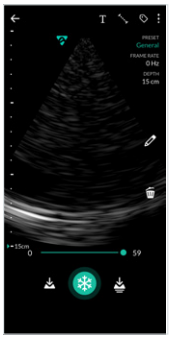
This screen allows you to choose from the following preset options:

- Cardiac
- Abdominal
- Lung
- OB/GYN



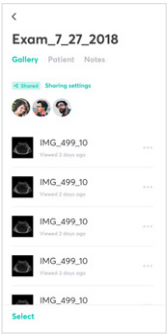
2.1.8 Imaging Page

This screen displays the image and allows the user to manipulate the visualization of the anatomy (depth, gain) — and freeze or save images/movie clips.



2.1.9 Review Page/Gallery

When you have finished imaging, you can evaluate and edit images and cines that were acquired during the exam.



3 Using The Vave Probe

This chapter explains how to install and use your Vave Probe safely and effectively. Refer to to the safety section of this manual before handling the Vave Probe.

- ! Ensure your mobile device requires a passcode, PIN, pattern or biometric identification for access. We recommend configuring the device to lock after a maximum of 15 minutes of inactivity.
- ! Ensure your mobile device follows your institution's security policy.

3.1 Downloading the Vave App

3.1.1 iOS

Compatible devices: iPhone 7, iPhone 8, iPhone X, iPad Pro (2nd and 3rd generation)

Before downloading the Vave App, you need to have an iTunes account. If you can't find the App, your device might not meet the minimum requirements or the App might not be available in your country.

- Go to the app store and search for the Vave App
- To download, tap the Install button and follow the on-screen instructions
- To launch, tap the Open button

3.1.2 Android

Compatible devices: Samsung Galaxy Tab S3, Google Pixel C

Before downloading the Vave App, you need to have an Google Play Store account. If you can't find the App, your device might not meet the minimum requirements or the App might not be available in your country.

- Go to the app store and search for the Vave App
- To download, tap the Install button and follow the on-screen instructions
- To launch, tap the Open button

3.2 Updating the Vave Probe

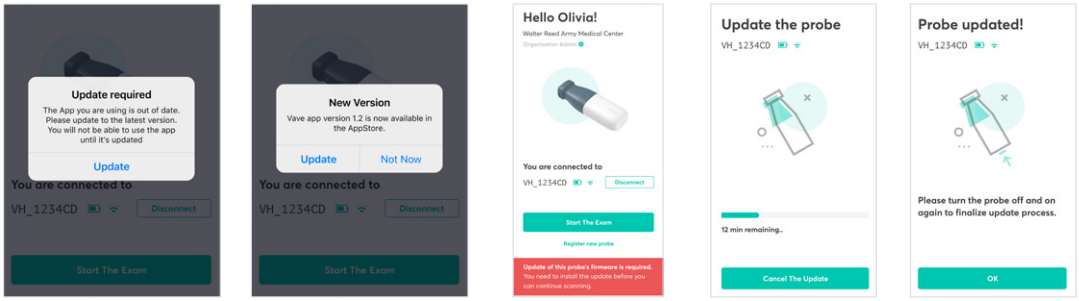
3.2.1 Software Updates

Update notifications will appear in the Vave App as well as in the iTunes app store or Google Play Store when they become available. If the update is mandatory, you will not be able to use the Vave App until you have downloaded the update.

3.2.2 Firmware Updates

After you connect to the probe's Wi-Fi, a red "New Firmware Available" notification will appear on the bottom of the screen if a firmware update is needed.

To install the update, tap on the "Update Probe" prompt. A loading page will indicate how many minutes the update will take to load. When the update is complete, click OK to finish the installation.



3.3 Inserting & Removing Battery

For more information regarding battery maintenance please refer to hardware maintenance section of this manual.

3.3.1 Inserting the Battery

To insert the battery into the Vave Probe:

1. Make sure that the battery contacts are facing downward and that the battery label is facing the Vave Probe.
2. Slide the battery into the Vave Probe until it locks into place.

3.3.2 Removing the Battery

To remove the battery from the Vave Probe:

1. Pull the battery away from the Vave Probe.
2. Slide the battery out of the Vave Probe.

3.3.3 Charging the Battery

- Connect the line cord of the AC power adapter to an indoor electrical outlet.
- Connect the AC power adapter to the receptacle on the battery charger.
- Remove the battery from the Vave Probe by following the instructions on Removing the Battery above.
- Insert the battery into a slot on the battery charger.

3.4 Turning the System On & Off

Before you begin using the Vave Personal Ultrasound, make sure you have the Vave Probe, and also your smart device with the Vave App installed.

3.4.1 Turning On the Vave Probe & Starting the Vave App

- To turn on the Vave Probe, press the power button on the probe for 1 second. The blue light indicates that the probe is on.
- To open the Vave App, tap the Vave App icon on your smart device's home screen.

3.4.2 Exiting the Vave App & Turning Off the Vave Probe

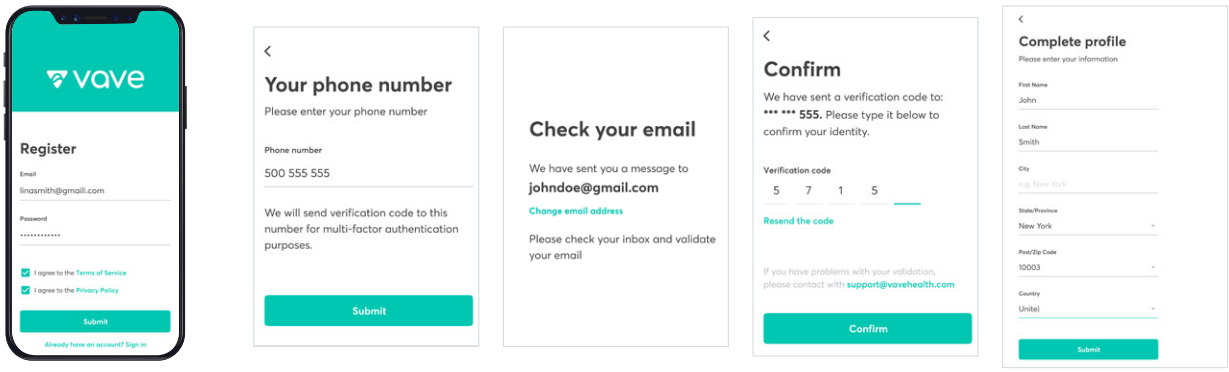
- To close the App: Exit the Vave App and disconnect from Wi-Fi. Note: If you close the Vave App without ending the current exam session, the exam will be saved and closed.
- To turn off the system: Press the power button on the probe. Light: Blue.

3.5 Account Creation, Signing In & Out

3.5.1 Creating Account

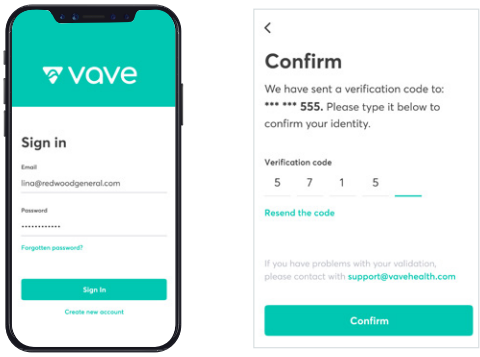
Upon opening the Vave App you'll see the Registration screen.

1. Enter an Email address and password. These will be used for each sign in.
2. Read and agree to the Terms of Service and Privacy Policy.
3. Enter a phone number (with country code). This will be used to send verification codes for two-factor authentication.
4. Open your email account and follow the link sent by Vave to validate your email.
5. Return to the Vave App. Vave will send a verification code to the provided phone number. Enter the code and tap confirm.
6. Now you can complete your profile. All fields are required.



3.5.2 Signing In — Two-Factor Authentication

When you open the Vave App, a sign-in screen will be displayed. Enter your email and password. After you tap "Sign In," you will receive verification code via text message that you can enter in the following confirmation screen.

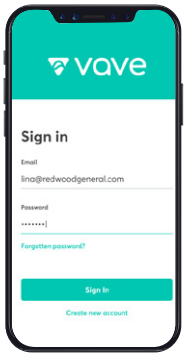


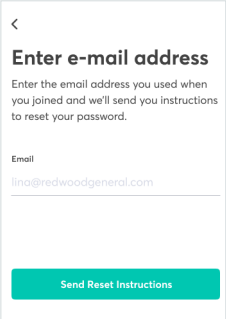
3.5.3 Signing Out

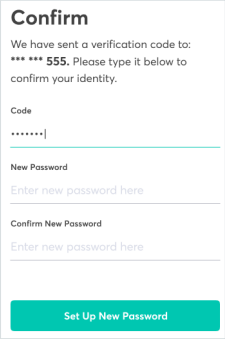
Your can log out of your account at any time from your profile settings page. Note: You will be automatically signed out after 30 days.

3.5.4 Forgot Password

To reset your password, open the "Forgotten password?" option on the sign-in screen. Enter the email address you used to sign up. A verification code will be sent to your phone via text message. You will then be able to enter a new password.







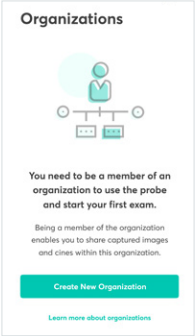
3.6 Organizations

In order to perform exams you have to be a member or admin of an organization. At first, the Organization Screen will appear empty. This is where invitations and active organizations will appear. You can also decide to create your own organization and invite members to join.

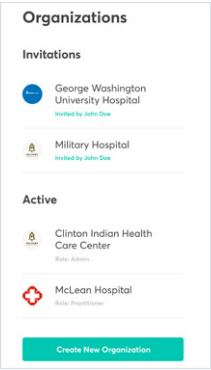
The following options are available:

- Create New Organization: starts organization creation process
- Learn More About Organizations: displays detailed information about organizations
- Profile Settings (user avatar): lets you modify your profile

The following screen will appear if you have no organizations set up:

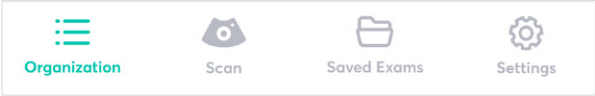


Invitations to join organizations and active organizations will appear as shown below. You can select an Invitation to accept it or select an active organization to open the main Vave App dashboard.



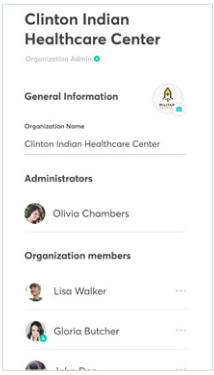
3.6.1 Organization Settings

To manage organization settings/view organization information you must tap on three dots that appear next to the organization name.



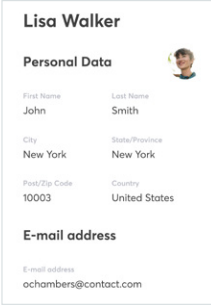
The following screen will appear with the following options:

- Change organization name (only if you are the admin)
- View details of Admins and Members by tapping on their name
- Invite new members to organization



After tapping on a selected member's name a Member Details Page will appear. As an organization member, you will only have access to view these details. As an admin, you will also have the following options:

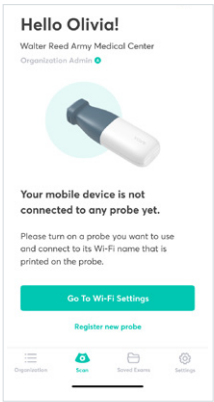
- Set as an Admin: sets selected member as an admin of active organization
- Remove from Organization: removes selected member from active organization



3.6.2 Profile Settings

From the Organization List and Scan screens you can tap on the user avatar in the upper-right corner to open profile settings. You can change your profile, log out of your account or reset password.

The email address is tied to an account and cannot be changed by the user. To use a new email, you will need to create a new account.



3.6.3 General Settings

You can access the General settings by clicking on the Settings icon in the bottom bar. In the Imaging section, you can adjust the Cine Length and the Cardiac Probe Marker Orientation:

Cine Max Length: the dropdown menu gives you the option to adjust the time a forward recorded cine will be recorded to either 2 sec, 5 sec or 10 sec.

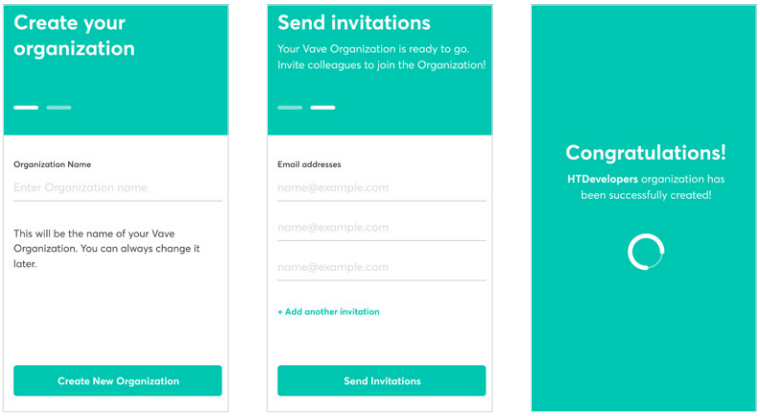
Cardiac Orientation: By default the probe marker on the ultrasound image for the cardiac preset is on the right side. Here you can change the probe marker to the left side.

In the About Section, you can view your App version, and — if connected to your Vave Probe — also the Firmware version and registration date of your probe.

These settings are reset to default when the app is closed, i.e., they are retained only as long as the app is running.

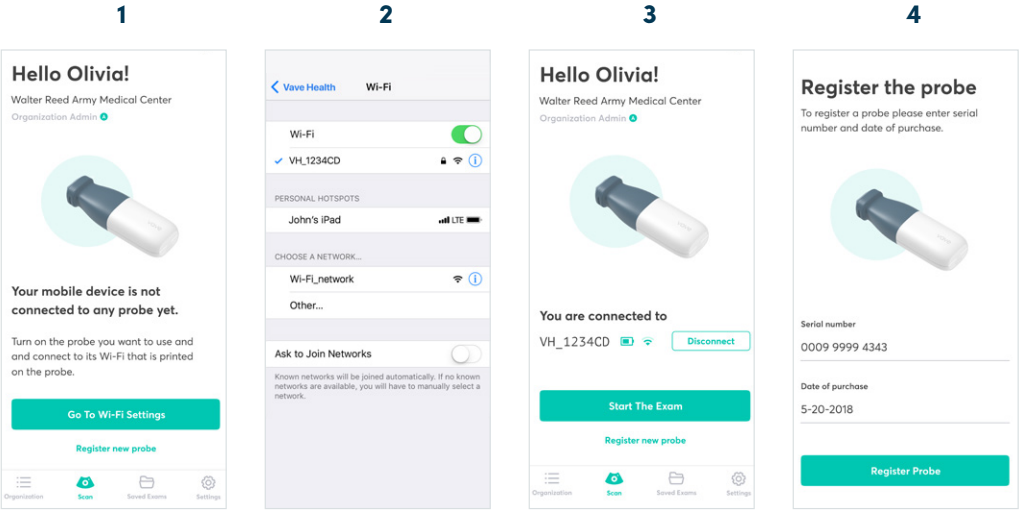
3.6.4 Creating a New Organization

Select "Create New Organization" and provide an organization name (which can be changed later).
Send invitations to add organization members or skip this step and invite them later.



3.7 Register the Vave Probe

Before the first use, you have to register a new Vave Probe. On the Scan Page, choose "Register New Probe" and follow the step-by-step instructions to set up your probe.

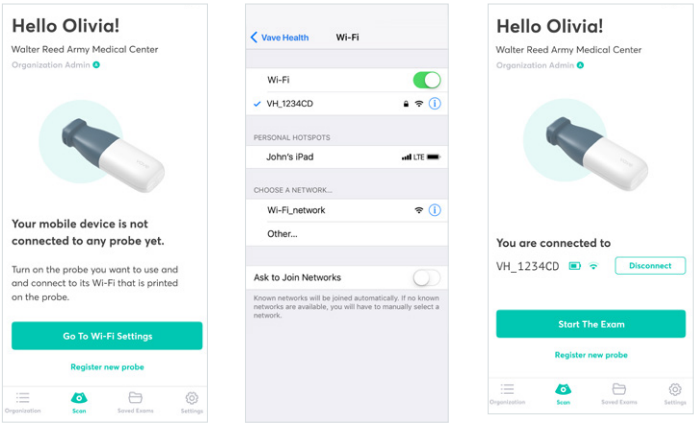


3.8 Connecting Your Smart Device to a Vave Probe

You can manually connect your scanner before entering the App by going to your Wi-Fi settings and selecting the Wi-Fi network beginning with "VAVE-VP3".

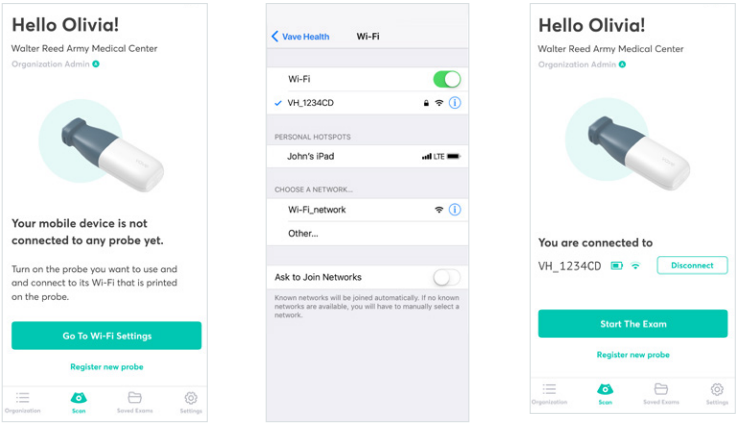
3.8.1 Connecting Android Device to Vave Probe

1. Open the App
2. In the "Scan" page, choose "Shortcuts to Wi-Fi settings" under Connect Probe
3. This will direct you to a list of available Wi-Fi networks. Select the Wi-Fi network beginning with "VAVE-VP3" and return to the App



3.8.2 Connecting iOS Device to Vave Probe

1. Open the App
2. In the "Scan" page, choose "Go to Wi-Fi Settings"
3. This will direct you to the list of your available Wi-Fi networks. Select the Wi-Fi network beginning with "VAVE-VP3". Once connected, you can go back to the App.



3.9 Managing Exams

Notifications and alerts from third-party applications may interrupt you or the Vave App, thereby interfering with the exam.

- ! If the vibration range is too high, this may cause the scanner to malfunction during an exam.
- ! Using an improper gel type or combining gel types may pose patient risks and produce poor-quality images. For proper transmission of the acoustic beam, use only Aquasonic 100, prior to its expiration date. Download and read Aquasonic 100 usage instructions from www.parkerlabs.com before operating the device.

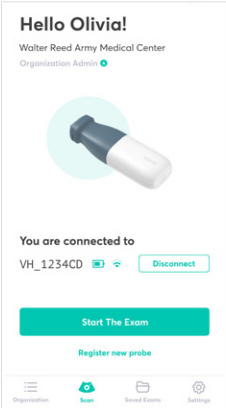
Do not use:

- ✖ Lotion-based products or gels containing mineral oil
- ✖ Hand-sanitizing gels
- ✖ Scanners left soaking in gel

3.9.1 Starting New Exams

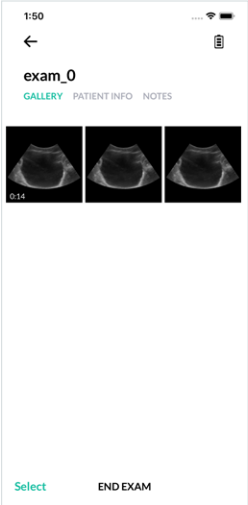
Once the probe is connected

- Go to the Scan tab
- Choose "Start New Exam"
- Select "Pick a Scan Preset"
  - After the "Connecting to Probe" screen establishes a connection, use the imaging screen to start an exam.



3.9.2 Ending an Exam

To end an exam, choose "End Exam" on the Gallery screen or close the App.



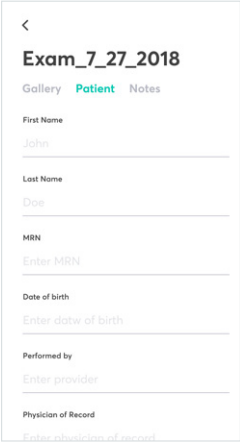
3.10 Managing Patient Information

3.10.1 Entering Patient Information

Make sure the probe is connected to your mobile device.

On the scan tab, choose "Start New Exam" and enter detailed patient information manually. Information is saved once you move to the next page.

- On the saved exam page, go to the "Patient info" section to enter or change patient information.



! Please make sure that you entered the correct patient information. Always be sure to follow your institution's policies regarding Patient Health Information!

3.11 Imaging

Typical use of the Vave Probe is five continuous scanning minutes followed by 10 minutes in standby mode (or turned off).

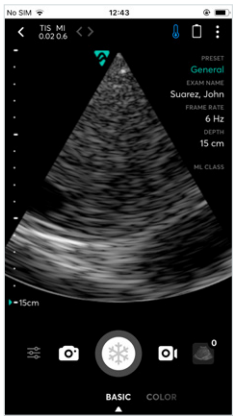
3.11.1 Imaging Mode: B-Mode

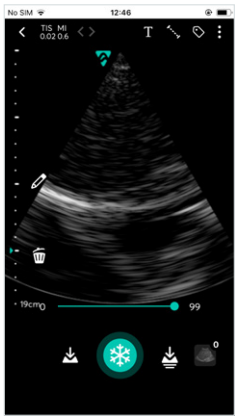
When you start an exam, the Vave Probe defaults to B-Mode (brightness mode). Sometimes referred to as 2D Mode, this two-dimensional imaging mode displays in grayscale.

3.11.2 Imaging Display Overview

The imaging display screen includes an ultrasound image in the center of the screen, exam information (patient name, MI and TI values), image information (preset, frame rate), gallery icon, capture bar, and mode bar.

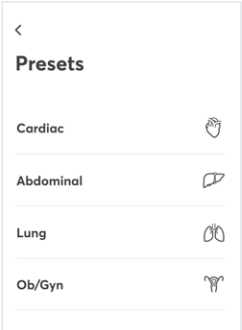
These display features are labeled in the following figures:





3.11.3 Preset

From the imaging screen, change presets by tapping the preset setting in the right corner or going back to the preset screen.



3.11.4 Capture Bar

The capture bar contains additional settings, snap, freeze, and record cine and the gallery icon.

Depth

- To adjust **depth**, swipe up or down over the ruler on the left side of the screen.

Gain

- To manually adjust the **gain**, swipe left-to-right (increase) or right-to-left (decrease) on the ultrasound image.

Focal Depth

- To adjust the **focal depth** press and hold on the ultrasound image. The teal triangle to the left of the ruler indicates the current focal depth.

Snap, Freeze/Unfreeze, Save Image and Cines

- To directly save an image to the gallery, press the camera icon.
- To **freeze/unfreeze** during live imaging, press the snowflake icon. Once frozen, you can adjust the frame by horizontally sliding the frame slider. To **save a frozen image**, press the save image icon to the left of the freeze button. To save the frozen cine, press the save cine icon to the right of the freeze button.
- To **record a cine**, tap the record icon during live imaging. To stop the recording, tap the record icon again. After recording, tap the trash icon to discard the cine or tap the save icon to save the cine.

Zoom in/out

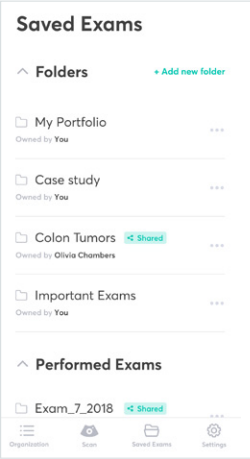
- To zoom in (expand) an area of the image, use the zoom gesture referenced in the touch gesture overview.
- To zoom out (reduce) an area of the image, pinch the image.

3.12 Review Findings

When you have finished imaging, you can evaluate and edit the exam images and cines.

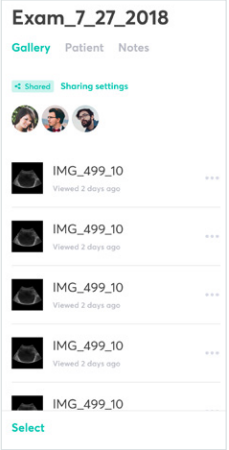
Saved exams

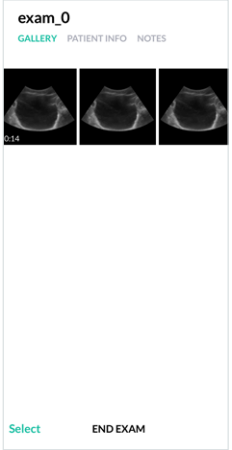
- To view your saved exams, tap the saved exams icon. You will see two sections: “Performed Exams” and “Folders”. Each section can have several folders. Tap a folder name to open it.
- The Folders section contains a folder named “My Portfolio”. In this folder you can collect ultrasound images. To add a new folder, tap “+ Add new folder” and name the folder.



3.12.1 Reviewing Images & Cines

Go to the gallery page by tapping the gallery icon on the imaging screen. In the gallery you can review (locally) saved images/cines and end the exam. Tap on image to open a detailed image view.





3.12.2 Manage Images & Cines

To select several images/cines: tap the select option and tap the images/cines you want to select.

To delete images/cines: select the image(s)/cine(s) and tap the trash icon.

To add images/cines to a saved scan folder:

1. Select the image(s)/cine(s)
2. Tap the briefcase icon for a popup list of existing folders
3. Select the folder where you would like to store the documents
4. A de-identified copy of the image will be added to your chosen folder

To export images/cines:

5. Select the image(s)/cine(s) and tap the share icon
6. Export Options will appear:
    - Email (Internet connection needed)
    - Save to Camera Roll
7. Choose the export option you want, follow the instructions, and a deidentified copy of the image will be exported

! Exported Images will be de-identified/not contain any Patient Health Information (PHI)!

! Please make sure you follow hospital procedures regarding PHI!

3.14 Maintenance

The only maintenance required is to clean and disinfect the Vave Probe and battery according to the instructions in the Cleaning & Disinfecting section of this manual. Perform maintenance regularly and as needed. The system must be serviced by trained personnel only. Failing to regularly maintain or verify the Vave Probe may lead to undetected performance errors.

3.14.1 Hardware Maintenance and Storage

Recharging Batteries

When you receive your Vave Probe, charge the battery to 100% before use.

- Because the Vave Probe is battery-operated, you must recharge the battery when necessary. An empty battery takes approximately 4 hours to fully charge. Once fully charged, a battery has approximately 2 hours of typical scanning time.
- Charge the battery using only the specified charger. Connecting the battery charger to a power supply not manufactured by Vave may expose the battery to the incorrect voltage/current, which could damage the battery charger.
- Do not charge the battery while on board an aircraft. Charging the battery in a rotary-wing airborne ambulance may cause the battery charger's power supply to interfere with the aircraft's electrical system.
- The battery power level of the Vave Probe is displayed in the Vave App when the Vave Probe is connected to your smart device. When the battery reaches a charge level equal to less than 10 minutes of residual scanning time, a visual warning is presented to the user.

Storing Scanners

To protect your Vave Probe:

» Dry thoroughly before storage.

» Avoid storing in extreme temperatures.

» Avoid placing under direct sunlight for prolonged periods of time. This will not impact the Vave Probe's safety and performance but may discolor the housing's finish.

» Store separately from other equipment. More details can be found in the System Specifications part of this manual under "Environmental Operating, Transient and Storage Conditions."

3.14.2 System Maintenance

You can access the audit logs in profile settings. Tap on the user avatar on the upper-right corner to open profile settings. You can change or view the audit log by tapping the "View Your Activity" button.

3.15 Help

3.15.1 Need Help?

If you require additional assistance please contact Vave Health at www.vavehealth.com

4 Cleaning & Disinfecting

It is your responsibility to appropriately clean and disinfect your compatible smart device in accordance with the device manufacturer's instructions and with your institution's policies for cleaning and disinfecting of medical devices. This chapter will guide you through the cleaning and disinfection process for the Vave Probe.

When cleaning and disinfecting the Vave Probe:

- Follow the procedures in the order they are listed in this guide, without skipping any steps.
- Use only cleaning solutions approved by Vave Health, as other solutions may be incompatible and damaging. For a list of compatible disinfectants, see the "Cleaners & Disinfectants" section of this User Manual.
- Check expiration dates, recommended product concentration, duration of disinfection and solution efficacy.
- Wear appropriate personal protective equipment (PPE), such as eyewear and gloves, as recommended by the chemical manufacturer.

! The transducer may not withstand the repetitive cleaning or disinfecting processes specified in this manual and this may damage or deteriorate its safety provisions.

! Cleaning or disinfecting the transducer while the battery is installed, may cause the battery to short-circuit and overheat, causing an electric shock or burn.

! During an emergency, when the transducer may be used to examine multiple patients in a short period of time, the lack of proper cleaning and disinfection between patients may spread infections to other patients and users.

4.1 Cleaning

Before cleaning, visually inspect the probe for any unacceptable deterioration, such as corrosion, discoloration, pitting, or cracked seals. If any damage is evident, discontinue use and contact Vave Health.

If the device does not have visual damage, prepare the cleaning solution and follow the procedure below.

1. Turn off the probe.
2. Remove the battery from the probe.
3. Use a compatible premoistened disinfectant wipe (CaviWipes™) to wipe the entire exterior of the transducer and battery until thoroughly cleaned.
4. If necessary, repeat step 3 with new cleaning material until all gel, particulate matter and bodily fluids have been removed.
5. After cleaning the probe, wipe the exterior surface with a clean, non-abrasive, dry cloth.

4.2 Disinfecting

Make sure you have cleaned the Vave Probe before beginning disinfection (see previous section, "Cleaning").

Before you begin, determine the level of disinfection by referring to Spaulding Classification section of this manual.

- Different levels of disinfection require different steps, not just different solutions.
- The Vave Probe is not designed for sterilization and cannot be sterilized before or between uses.

Intermediate-Level Disinfection

After cleaning, choose low- or intermediate-level disinfectants compatible with your Vave Probe. Follow the label instructions for preparation, temperature, solution strength, and duration of contact. Make sure you have removed the battery and cleaned the Vave Probe before beginning disinfection (see previous section, "Cleaning").

1. Use a compatible premoistened disinfectant wipe (CaviWipes™) to wipe the probe and battery for 1 minute.
2. Air-dry the probe and battery or towel-dry with a clean, non-linting cloth.
3. Examine the probe for any damage, such as cracks or splitting where fluid can enter. If any damage is evident, discontinue use and contact Vave Health.

High-Level Disinfection

If the Vave Probe has come into contact with broken skin, mucosal membranes or blood, you must perform high-level disinfection. Make sure you have removed the battery and cleaned the Vave Probe before beginning disinfection (see previous section, "Cleaning").

1. Check the expiration date and prepare the disinfectant solution following the label instructions for solution strength and disinfection duration .
2. Using the disinfectant CIDEX® OPA, at a temperature of 23°C (73°F), immerse the probe and the battery in the undiluted disinfectant solution for the required duration.
3. Rinse the probe and battery using the instructions on the disinfectant label.
4. Air-dry the probe and battery or towel-dry with a clean, non-linting cloth.
5. Examine the probe for any damage, such as cracks or splitting where fluid can enter. If damage is evident, discontinue use of the probe and contact Vave Health.

4.3 Spaulding Classification

The level of cleaning and disinfection required for your Vave Probe is based on the Spaulding classification system. Following the correct classification will help reduce cross-contamination and the spread of infection.

Each Spaulding classification mandates a specific level of cleaning and disinfection of equipment, before it can be used for the next exam. Determine the Spaulding classification based on Use.

Class	Use	Method
Non-Critical Class	Touches intact skin	Cleaning followed by intermediate disinfection
Semi-Critical Class	Touches mucous membranes and non-intact skin	Cleaning followed by high-level disinfection (HLD)

5 Safety

This chapter provides instructions on safe usage of the Vave Probe and includes additional safety guidelines. There are two types of safety information in this section:

- Warnings: indicate information critical to safe operation
- Cautions: highlight potential damage that may void your warranty or service contract, or destroy patient data.

5.1 About Diagnostic Ultrasound

Diagnostic ultrasound is a non-invasive technique used to generate images inside the body. Ultrasound probes, or transducers, produce sound waves at a high frequency (above 20KHz) and then detect ultrasound echoes that are sent back. When echoes reach the transducer, the resulting electrical signals are recorded on an ultrasound scanner. The return echoes calculate the distance between the transducer and the tissue's boundary. These recorded distances create a two-dimensional image of body tissues.

During an exam, ultrasound gel is applied to the skin to prevent pockets of air from forming between the transducer and the skin. Air pockets can inhibit ultrasound waves entering the body.

Some of the clinical uses for ultrasound include imaging of the heart, lungs, blood vessels, fetus, thyroid, breast, brain, abdominal organs, pelvic organs, skin and muscles. Ultrasound can also be used to help guide movements in minimally invasive surgeries or guide the insertion of a catheter into a blood vessel.

5.1.1 Interactions with Matter

The transducer generates high frequency sound waves that pulsate along a narrow beam in one direction. It also acts as a microphone, receiving echoes generated by tissue the beam encounters. These returning ultrasound waves generate an electrical signal that is transferred and displayed on the screen in real-time as an image.

5.1.2 Studies

Unlike many medical radiation tools, ultrasound uses non-ionizing radiation, which means it does not come with many of the same risks associated with other radiation imaging techniques. Numerous epidemiological ultrasound studies have indicated there is no causal relationship between any known negative effects and exposure to diagnostic ultrasounds of this type (Ziskin & Petitti, 1988; Barnett et al., 2000).

5.1.3 Biological Risks

Ultrasound imaging is considered safe, but ultrasound energy does have the potential to produce biological effects. During an ultrasound exam, the ultrasound waves may warm tissues in the body. In some cases, this warming may even produce pockets of gas in bodily fluids or tissues. The long-term consequences of these biological effects is not yet known. For these reasons, many organizations have advocated for carefully regulated use of ultrasounds during pregnancy. Any use of ultrasound imaging for non-medical purposes is strongly discouraged.

5.2 Safety Topics

This section covers general safety information. Safety information applicable to specific tasks or functions is noted throughout the manual.

The Vave Personal Ultrasound is intended for use by trained healthcare professionals. Do not use the Vave Personal Ultrasound unless you have read and understand the instructions in this manual and all of the information in this section. Operating the system without proper safety awareness could lead to fatal or serious personal injury.

"Diagnostic ultrasound is recognized as a safe, effective, and highly flexible imaging modality capable of providing clinically relevant information about most parts of the body in a rapid and cost-effective fashion." (World Health Organization)

5.2.1 Product Safety

Vave Health is responsible for the safety of the Vave Probe. The safety of connected mobile devices is the user's responsibility. Always read and follow the safety guidelines for your smart device.

Product Warnings

The following actions may cause serious or fatal injury:

- Operating the Vave Probe without proper training on use and safety.
- Attempting to remove, modify or override any element of the system, especially safety features.
- Using the system with any product not specifically recognized as compatible with the Vave Probe.
- Continuing use after the first sign or suspicion of system malfunction or defect. If suspected, contact Vave immediately.
- Using the system for anything beyond its intended function.

Product Compatibility

The Vave Probe comes with a battery, battery charger and a power supply for the charger. Do not use your Vave Probe or Vave Battery Charger in combination with other products or components not made by Vave, unless Vave expressly recognizes those other products or components as compatible.

Any modifications to the Vave system can be made only by Vave or by third parties expressly authorized by Vave to do so. Modifications must comply with all applicable country and regional laws and regulations. Modifications made without the appropriate training, or by using unapproved parts, may damage the system or cause personal injury. The system limit for patient contact temperature is 43°C (109°F) and acoustic output values follow U.S. Food and Drug Administration limits. If the power monitor protection circuit senses an over-current condition, the probe will shut off to prevent overheating and limit acoustic output.

5.2.2 Battery Safety

If the battery emits an odor or heat, is deformed or discolored, or in any way appears abnormal during use, recharging or storage, immediately remove it and contact Vave. If the battery fails to charge fully, replace it. Do not discard the battery by fire.

The following actions may damage the battery:

- Using or charging the battery near a heat source
- Touching battery contacts
- Opening, crushing, puncturing or short-circuiting contacts
- Connecting the positive and negative terminals directly to metal objects
- Using the battery in temperatures below -20°C (-4°F) or above 60°C (140°F)
- Charging the battery in temperatures below 10°C (50°F) or above 45°C (113°F)
- Forcing the battery into the system. The polarity of the battery terminals is fixed and cannot be reversed
- Connecting the battery to an electrical power outlet
- Charging the battery using non-Vave equipment
- Leaving the battery in direct sunlight

5.2.3 Cleaning Safety

It is important to clean and maintain the Vave Ultrasound System. Thorough cleaning is particularly important for pieces of peripheral equipment, because they contain electromechanical parts. It is your responsibility to clean and disinfect your Vave Probe in accordance with the cleaning and disinfecting instructions in this manual. For instructions on cleaning and disinfecting, refer to Cleaning and Disinfecting sections section of this manual.

Cleaners & Disinfectants

- Use only cleaners and disinfectants recommended by Vave Health and carefully follow all manufacturer instructions.
- Disinfectants are recommended based on their chemical compatibility (not their biological effectiveness) with product materials. For the biological effectiveness of a disinfectant, see the guidelines and recommendations of the disinfectant manufacturer, the U.S. Food and Drug Administration, and the U.S. Centers for Disease Control.

Minimizing the Effects of Residual Disinfectant

When using an OPA-based disinfectant, residual solution may remain on your probe if you do not carefully follow the manufacturer's instructions. Vave also recommends limiting probe soaking to the minimum time recommended by the disinfectant manufacturer.

Factors Affecting Disinfectant Efficacy

The following factors will affect the efficacy of a disinfectant solution:

- Number and location of microorganisms
- Resistance level of microorganisms
- Concentration and potency of disinfectant
- Other physical and chemical factors
- Organic and inorganic matter
- Duration of disinfectant exposure
- Biofilms

5.2.4 Clinical Safety

Syringe Safety

If the needle is not visible, do not perform the needle procedure.

- Thin needles can bend when entering tissue. Verify the needle's position by identifying the echoes from the needle.
- Make sure you are not using a false needle image to locate the needle. False needle images can result from reverberations or other tissue artifacts.

Defibrillator Safety

If you are using the Vave Personal Ultrasound and defibrillation is required, use defibrillators that do not have grounded patient circuits. To determine whether a defibrillator patient circuit is grounded, see the defibrillator service guide, or consult a biomedical engineer.

Before defibrillation, remove any part of the system that is in contact with the patient.

5.2.5 Biological Safety

Latex

The Vave Ultrasound System does not contain any natural rubber latex.

The following are FDA recommendations on latex awareness:

- When taking general histories of patients, include questions about latex sensitivity. For surgical and radiology patients, spina bifida patients and health care workers, this recommendation is especially important. Questions about itching, rashes, or wheezing after wearing latex gloves or inflating a toy balloon may be useful. For patients with positive histories, flag their charts.
- If latex sensitivity is suspected, consider wearing a non-latex glove over the latex glove if the patient is sensitive. If both the health professional and the patient are sensitive, a latex middle glove could be used. (Latex gloves labeled "Hypoallergenic" may not always prevent adverse reactions.)
- Whenever latex comes in contact with mucous membranes, be alert to the possibility of an allergic reaction.
- If an allergic reaction does occur and latex is suspected, advise the patient of a possible latex sensitivity and consider an immunologic evaluation.
- Advise the patient to tell health professionals and emergency personnel about any known latex sensitivity before undergoing medical procedures.

Bioeffects

Thermal

Thermal bioeffects refers to the heat created by ultrasound energy. Tissue absorbs ultrasound energy to varying degrees depending on the tissue's absorption characteristics. The absorption coefficient dictates how body tissue will absorb the ultrasound energy:

- **Fluids:** The absorption coefficient of fluids is very low. Fluids such as amniotic fluid, blood, and urine absorb little ultrasonic energy. That means the ultrasound goes through the fluid easily with very little energy decrease or temperature elevation.
- **Bone:** Bone has a high absorbtion coefficient. Dense bone absorbs energy very quickly, which causes the temperature to rise. Adult bone absorbs nearly all acoustic energy from the ultrasound. However, fetal bone absorption coefficients can vary.
- **Soft tissue:** Soft tissue absorbtion varies by organ. The tissue density within a particular organ is also not always the same. However, we will assume that attenuation remains the same throughout the organ. Attenuation is caused by **absorbtion** or beam **scattering**.

Mechanical (Non-Thermal)

Mechanical bioeffects, such as cavitation, occur when output exceeds a certain level. This threshold varies depending on tissue type. Cavitation occurs when the ultrasound interacts with gas bubbles, causing sudden changes in bubble size at nucleation sites. The change in bubble size can increase temperature and pressure, which causes stress on surrounding tissues and can produce free radicals. Gas-containing structures, such as lungs, are most susceptible to cavitation; still, cavitation is unlikely to occur as higher frequency ultrasounds do not allow enough time for bubble growth.

Scientific evidence suggests that cavitation can only occur when the output threshold is reached. Therefore exposure to pressure levels below the threshold will never produce cavitation, regardless of exposure length.

There are two categories of cavitation:

- **Stable:** Stable cavitation includes gas bodies that vibrate or pulsate continuously around their equilibrium sizes. As the oscillations create a rhythm, the gas body develops into a liquid-like medium that begins to flow; This is called microstreaming. Microstreaming can cause stress that disrupts cell membranes.
- **Inertial:** During inertial (transient) cavitation, bubbles or cavitation nuclei expand due to rarefactional pressure and then implode. In some cases the implosion may damage cell tissue, ultimately causing cell death. Implosion can also create highly reactive chemical species.

Exposure of the lung to small implosions can produce small hemorrhages under some circumstances. Generally these lesions heal quickly with no longterm effects,.

5.2.6 ALARA Principle

ALARA Principle

ALARA guides the safe use of diagnostic ultrasound. There is no predetermined set of rules to help select the correct exposure for each situation. Sonographers and other qualified ultrasound users determine the amount of exposure that is "as low as reasonably achievable." The ALARA principle helps keep exposure low and reduces bio effects.

The default preset is set prior to the examination for each new patiet. The scanning technique of the qualified ultrasound user and the patient's body determine the system settings. Additonal variables that affect how the ALARA principle is implemented include: patient body size, location of bones relative to the focal point, attenuation, and exposure time.

Applying ALARA: The appropriate system setting is determined by the specific diagnostic information needed.

According to ALARA, ultrasound usage should be limited to the lowest acoustic output for the shortest duration of time. The ultrasound user should consider the type of patient, exam type, patient history, difficulty in retrieving the required information, and the potential of localized heating due to transducer surface temperatures. The user may adjust image quality and limit ultrasound energy output in one of three ways: direct controls, indirect controls, and receiver controls.

Using System Controls to Implement ALARA

Direct controls: The Vave Personal Ultrasound system does not contain any controls that directly affect output. Therefore, the person performing the scan must control exposure time and scanning technique to implement the ALARA principle. To ensure that acoustic and thermal limits are not exceeded for all imaging modes, the Vave Personal Ultrasound is designed to automatically adjust output. The system does not exceed a spatial peak temporal average intensity (ISPTA) of 44.9 mW/cm2 for all settings. The mechanical index (MI) and thermal index (TI) may exceed values greater than 1.0 for some settings.

Indirect controls: Controls affecting imaging mode, freeze, and depth indirectly affect output. Because freeze stops all ultrasound output but keeps the last image displayed on screen, you can use it to limit exposure time while studying an image and maintaining probe position during a scan. Some controls, such as depth, show a rough correspondence with output, and may be used as a general means for indirectly reducing MI or TI.

Controls indirectly affecting intensity:

- Focusing depth: Setting the scanner focus at the proper depth improves the resolution of that structure, without the need to increase intensity to see it better.

Receiver controls: The receiver controls are the gain controls. Receiver controls do not affect acoustic output. They should be used, if possible, to improve image quality before using controls that directly or indirectly affect output. (American Institute of Ultrasound In Medicine)

User responsibility: The various output levels mean significant responsibility is placed on the user to ensure the correct settings are used. Changing the mode of operation or manipulating controls has the potential to cause major changes in output and exposure. Patient safety is the responsibility of the user.

To obtain good diagnostic information, a high return signal amplitude is needed. This can be attained either by higher output, similar to talking louder, or by higher receiver gain, similar to a hearing aid with a volume control. You must attain the best diagnostic information with minimal exposure to the patient. The threshold at which ultrasound energy causes bioeffects for each individual patient is unknown. Therefore, it is important to collect diagnostic information at the lowest possible output level by adjusting the output intensity of the equipment.

As a general guideline:

- Select the correct scanner application.
- Optimize the image by using focus, receiver gain, and other imaging controls.

Additional considerations:

- Minimize scan time by performing only medically required ultrasound scans.
- Use diagnostic ultrasounds efficiently and effectively.
- Compromising the exam's quality by rushing the exam could result in a poor exam, which could require follow-up exams and additional exposure time.
- Note that output is affected by focus.

Output Display

The output display provides the user with an indication of the potential for bioeffects that might be caused by the ultrasound energy being emitted. With this information, users can better control the diagnostic ultrasound equipment and examination to ensure that diagnostic information is obtained with minimal risk to the patient.

- **Display Standards (TI Display/MI Display)**
  The system output display consists of the following exposure indices to indicate the potential thermal and mechanical effects:
  - TI: This is continuously displayed over the range of 0.0 to maximum output, based on the application, in increments of 0.1, and consists of the following indices:
    - thermal index for soft tissue (TIS)
    - thermal index for bone (TIB)

    Keep output display indices to a minimum. Select a TI based on:
    - Approximate index for the application: TIS is used for imaging soft tissue, TIB for a focus at or near bone.
    - Factors that might create artificially high or low TI readings: Location of fluid or bone, or blood flow. For example, is there a highly attenuating tissue path so that the actual potential for local zone heating is less than the TI displays?
    - For B-mode scanning, heating tends to be near the surface.
  - MI: This is continuously displayed over the range of 0.0 to 1.9, in increments of 0.1.

  TI Display
  The TI indicates any conditions that may lead to a temperature increase on the surface of the body, within the body tissue, or at the point of focus of the ultrasound beam on bone. TI does this by estimating temperature increases in those body tissues with specific properties. The actual temperature increase is influenced by factors such as tissue type, vascularity, and mode of operation. Use the TI as a guide for implementing the ALARA principle.

  You can choose to display one of the following types of TI indices:
  - TIS: Indicates potential for heating within soft homogeneous tissue.
  - TIB: Indicates potential for heating at or near the focus after the ultrasound beam has passed through soft tissue or fluid. For example, at or near second- or third-trimester fetal bone.

  MI Display
  The higher the MI value, the greater the likelihood of mechanical bioeffects occurring. The potential for mechanical bioeffects varies by peak rarefactional pressure and ultrasound frequency. The MI accounts for these two factors. Use the MI as a guide for implementing the ALARA principle.

  When interpreting the MI, remember that it is intended to estimate the potential for mechanical bioeffects; there is no specific MI value that indicates the occurrence of a mechanical effect. The higher the index reading, the greater the potential. However, neither MI = 1 nor any other level indicates that a bioeffect is actually occurring.

- **Display Accuracy**
  The MI and TI have a precision of 0.1 unit on the system.

  Estimates of the MI and TI display accuracies are shown in the Acoustic Output Tables. The following factors are considered when estimating the accuracy of the displayed values:
  - Hardware variations
    - Variability among scanners and systems is a result of piezoelectric crystal efficiencies, process-related impedance differences, and sensitive lens-focusing parameter variations.
  - Estimation algorithm accuracy
    - Differences in system pulser voltage control and efficiencies also contribute to variability. There are inherent uncertainties in the algorithms used to estimate acoustic output values over the range of possible system operating conditions and pulser voltages.
  - Measurement variability
    - Inaccuracies in laboratory measurements can be caused by hydrophone calibration and performance, positioning, alignment, digitization tolerances and variability among test operators.

- **Controls Affecting Display Indices**
  Use system controls to change the TI and MI values.

  B-Mode Controls
  - **Focus:** When the focal depth is near the natural focus of the scanner, the MI may be higher.
  - **Zoom:** Increasing the zoom magnification by spreading the display may increase frame rate, thereby increasing the TI. The number of focal zones may also increase automatically to improve resolution.
    This action may change the MI, because the peak MI can occur at a different depth.

  Other Control Effects
  - B-Mode Depth: An increase in two-dimensional depth will automatically decrease the B-Mode frame rate, thereby decreasing the TI. The system may also automatically choose a deeper two-dimensional focal depth. A change of focal depth may change the MI.
  - Application: Acoustic output defaults are set when you select an application. Factory defaults vary by application. Default settings have been chosen below the FDA limits for intended use.
  - Imaging Mode Controls: When a new imaging mode is selected, both the TI and MI may change to default settings. Each mode has a corresponding pulse repetition frequency and maximum intensity point. In combined or simultaneous modes, the TI is the sum of the contribution from the modes enabled, and the displayed MI is the largest of the MI values associated with each mode and focal zone enabled. The system will return to the previously selected settings if a mode is turned off and then reselected.
  - Scanner: Each scanner type has unique specifications for contact area, beam shape, and center frequency. Selecting a scanner initializes its default settings, which varies by scanner, application, and selected mode. These defaults are set below the FDA limits for intended use.

  Step-by-step example of reducing output:
  When preparing to do a liver scan, the first step is to select the appropriate preset. Then adjust the focus to the area of interest and increase the receiver gain to produce a uniform representation of the tissue.

Acoustics

The system limits patient contact temperature to 43°C (109°F), and acoustic output values to their respective U.S. Food and Drug Administration limits. A power-protection circuit protects against over-current conditions. If the power monitor protection circuit senses an over-current condition, then the drive voltage to the scanner is shut off immediately, preventing overheating of the scanner surface and limiting acoustic output. Validation of the power protection circuit is done under normal system operation.

A temperature elevation of less than 1.5°C (2.7°F) is considered harmless to human tissue (including embryo or fetus). Temperatures in excess of this may cause harm, depending on the length of time maintained. A temperature elevation of 4°C (7.2°F), maintained for five minutes or more, is considered to be potentially hazardous to a fetus or embryo.

- **Acoustic Output & Measurement**
  The acoustic output for this system has been measured and calculated in accordance with the IEC 60601-2-37, "Medical electrical equipment — Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment," Edition 2.1, 2015-06; the NEMA Standard Publication UD-2, "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment," Revision 3, 2004; the IEC 62359, "Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields," Edition 2.0, 2017-09; and the FDA guidance document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Scanners," September 2008.

- **In situ, derated, & water value intensities**
  All intensity parameters are measured in water. Because water absorbs very little acoustic energy, these water measurements represent a worst-case value. Biological tissue does absorb acoustic energy. The true value of the intensity at any point depends on the amount and type of tissue and the frequency of the ultrasound that passes through the tissue. The intensity value in the tissue, in situ, has been estimated by using the following formula:
  In situ = Water [e-(0.23alf)] Where:

Variable	Value
In Situ	In situ intensity value
Water	Water value intensity
e	27183
a	Attenuation factor
Tissue	a9dB/cm-MHz)
Amniotic Fluid	0.006
Brain	0.53
Heart	0.66
Kidney	0.79
Liver	0.43
Muscle	0.55
l	Skin line to measurement depth (cm)
f	Center Frequency of the sxanner/systme/mode combination (MHz)

Because the ultrasonic path during an examination is likely to pass through varying lengths and types of tissue, it is difficult to estimate the true in situ intensity. An attenuation factor of 0.3 is used for general reporting purposes. Therefore, the in situ value which is commonly reported uses the formula:
In situ derated = Water [e-(0.069lf)]

Because this value is not the true in situ intensity, the term “derated” is used.

Mathematical derating of water based measurements using the 0.3 dB/cm MHz coefficient may yield lower acoustic exposure values than would be measured in a homogenous 0.3dB/cm MHz tissue. This is true because nonlinearly propagating acoustic energy waveforms experience more distortion, saturation, and absorption in water than in tissue, where attenuation present along the tissue path will dampen the buildup of nonlinear effects.

The maximum derated value and the maximum water value do not always occur at the same operating conditions. Therefore, the reported maximum water and derated values may not be related by the in situ (derated) formula. For example: A multi-zone array scanner that has maximum water value intensities in its deepest zone may have its largest derated intensity in one of its most shallow focal zones.

- **Conclusions regarding tissue models & equipment survey**

  Tissue models are necessary to estimate attenuation and acoustic exposure levels in situ from measurements of acoustic output made in water. Model accuracy may be limited due to varied tissue paths during diagnostic ultrasound exposures and soft tissue irregularities. No single tissue model can predict exposures in all situations.

  A homogeneous tissue model with an attenuation coefficient of 0.3 dB/cm MHz throughout the beam path is commonly used when estimating exposure levels. This model tends to overestimate the in situ acoustic exposure when the beam path is composed entirely of soft tissue, because the attenuation coefficient of soft tissue is generally higher than 0.3dB/cm MHz. When the path contains significant amounts of fluid, as in many first- and second-trimester pregnancies scanned transabdominally, this model may underestimate the in situ acoustical exposure. For example, when the beam path is longer than 3cm and moves predominantly through fluid, a value of 0.1dB/ cm MHz is more accurate for the derating term. Fixed-path tissue models, in which soft tissue thickness is held constant, can also provide an estimate for in situ acoustical exposures when the beam path is longer than 3cm and consists largely of fluid. When this model is used to estimate maximum exposure to the fetus during transabdominal scans, a value of 1dB/cm MHz may be used during all trimesters.

  Fixed-path tissue models, in which soft tissue thickness is held constant, sometimes are used to estimate in situ acoustical exposures when the beam path is longer than 3cm and consists largely of fluid. When this model is used to estimate maximum exposure to the fetus during transabdominal scans, a value of 1dB/cm MHz may be used during all trimesters.

  The maximum acoustic output levels of diagnostic ultrasound scanners vary widely:
  - Maximum MI values of approximately 2 are known to occur for currently available equipment. The Maximum MI values are similar for real-time B-Mode.
  - Computed estimates of the upper limits for temperature elevations during transabdominal scans were obtained in a survey of 1988 and 1990 Doppler equipment. The vast majority of models yielded upper limits less than 1°C and 4°C (1.8°F and 7.2°F) for exposures of first-trimester fetal tissue and second-trimester fetal bone, respectively. The largest values obtained were approximately 1.5°C (2.7°F) for first-trimester fetal tissue and 7°C (12.6°F) for second-trimester fetal bone. These estimated maximum temperature elevations are for a "fixed-path" tissue model and scanners with Ispta (derated) values greater than 500 mW/cm2. The temperature elevations for fetal bone and tissue were computed based on calculation procedures given in Sections 4.3.2.1 through 4.3.2.6 in "Bioeffects and Safety of Diagnostic Ultrasound" (AIUM Report, January 28,1993).

- **Acoustic Measurement Precision & Uncertainty**

  All table entries have been obtained at the same operating conditions that result in the maximum index value in the first column of the tables. Values for measurement precision and uncertainty are listed in the following tables for power, pressure, intensity, and center frequency. Measurement precision on the following quantities is determined by making repeated measurements and stating the standard deviation as a percentage.

Precision	
Pr	<1%
Wo	7.6%
fc	<1%
PII.3	2.8%

Uncertainty (Percentage, 95% Confidence Value)	
Pr	±8.4%
Wo	±16.8%
fc	<±1%
PII.3	±16.2%

5.2.7 Fire & Electrical Safety

Fire Safety
Always have fire extinguishers available for both electrical and non-electrical fires. In the event of an electrical or chemical fire, use only extinguishers that are specifically labeled for such purposes. Using water or other liquids may cause fatal or other serious personal injury.

To help prevent electrical fires, only use electrical products in an environment for which they were designed. Apply, observe, and enforce appropriate fire regulations for the type of medical area being used.

Electrical Safety
- To reduce electrical shock hazards, inspect the scanner face and housing before use. Discontinue use if the housing is damaged, or if the face is cracked, chipped, or torn.
- All patient-contact scanners not specifically indicated as defibrillation-proof must be removed from the patient before applying high-voltage defibrillation pulse.
- High-frequency electrical signals from an ultrasound can interfere with pacemaker operation. Be alert to this potential hazard and stop using the system if you notice it is interfering with a pacemaker.
- Connecting accessories that have not been approved by Vave could result in electrical shock.
- Electrosurgical units (ESUs) and other scanners intentionally introduce RF electromagnetic fields (currents) into patients. Because imaging ultrasound frequencies are within the RF range, ultrasound scanner circuits are susceptible to RF interference.
- A burn hazard may result from a surgical equipment with a defect in the high-frequency surgical neutral electrode connection. Do not use scanners with high-frequency surgical equipment.
- Using accessories other than those specified for use with the Vave Probe may result in increased emissions.

5.2.8 Electromagnetic Safety
The Vave Personal Ultrasound uses wireless technology to communicate with your smart device. Wireless communication can be affected by severe weather conditions and radio frequency interference. Such environments will not cause the safety of the Vave Personal Ultrasound to deteriorate, but the captured image may show signs of unwanted noise and/or artifacts. The technology used in the Vave Personal Ultrasound is designed to minimize these affects but may not eliminate them entirely.

Electromagnetic Compatibility
The Vave Probe has been manufactured with existing electromagnetic compatibility requirements and complies with electromagnetic compatibility standards to provide reasonable protection against harmful interference in a typical medical installation.

Use of this system in the presence of an electromagnetic field can cause degraded image quality. If this occurs frequently, review the environment surrounding the system and identify possible sources of radiated emissions.

Electrostatic Discharge Precautions
Electrostatic discharge (ESD), or static shock, results from the flow of an electrical charge from a person or object of a higher charge to that of a lower charge. ESD is most prevalent in low-humidity environments, often caused by heating or air-conditioning.

To reduce ESD:
- Use anti-static spray on carpets, linoleum, and mats. Or use a ground wire connection between the system and the patient table or bed.
- Do not touch the connector pins on the battery.

Electromagnetic Emissions
Ensure that the Vave Personal Ultrasound is used only in those operating environments indicated in the following table. Operating the system in an environment that does not meet these conditions may degrade system performance.

Electromagnetic Interference

The way an electromagnetic interference (EMI) from other equipment affects the Vave Personal Ultrasound depends on the system's operation mode, image control settings, and the type and level of electromagnetic phenomena. Electromagnetic phenomena may be intermittent, making it difficult to identify the source.
If you experience EMI, use caution if you continue using the system, or consider relocating your system.

The following table describes typical interferences seen in imaging systems. It is impossible to describe all manifestations of interference, because it depends on many parameters of the transmitting equipment.
Some factors include the type of modulation used by the signal carrier, the source type, and the transmitted level.
It is also possible for the interference to degrade the imaging system's performance and become invisible on the image. If the diagnostic results are suspicious, confirm the diagnosis using other methods.

Imaging Mode	ESD1	RF2	Power Line3
B-mode	Change of operating mode, system settings or system reset. Brief flashes in the displayed or recorded image.	For sector imaging scanners, white radial bands or flashes in the center lines of the image. For linear imaging scanners, white vertical bands, sometimes more pronounced on the sides of the image.	White dots, dashes or diagonal lines ner the center of the image.

Possible causes of electrostatic interference:
- ESD caused by charge buildup on insulated surfaces or persons.
- RF energy from portable phones, hand-held radios, smart devices, commercial radio and TV stations.
- Conducted interference on power lines, switching power supplies, electrical controls and lightning.

Separation Distance

Recommended Separation Distance

The following table shows recommended separation distances between the system and any RF-transmitting equipment. To reduce the risk of interference, when using portable and mobile RF communications equipment, follow the recommended separation distance (calculated from the equation applicable to the frequency of the transmitter). Ensure that field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, are less than the compliance level in each frequency range as noted in the table.

Field strength is difficult to predict with accuracy if it comes 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. To assess the electromagnetic environment from fixed RF transmitters, consider conducting an electromagnetic site survey. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level in the table, observe the system to verify normal operation. If abnormal performance is observed, apply additional measures, such as reorienting or relocating the system.

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

The recommended separation distance guidelines in the following table may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

The table here provides guidance on conducted and radiated interference from portable and fixed RF transmitting equipment.

Recommended Separation Distances by Transmitter Frequency

Rated Maximum Output Power of Transmitter (Watts)	150kHz to 80 MHz	80 to 800 MHz	800 MHz to 2.5 GHz
0.01	0.35 m (13.8 in)	0.12 m (4.7 in)	0.23 m (9.1 in)
0.1	1.1 m (3.6 ft)	0.38 m (15 in)	0.73 m (28.7 in)
1	3.5 m (11.5 ft)	1.2 m (3.9 ft)	2.3 m (7.5 ft)
10	11 m (36.1 ft)	3.8 m (12.5 ft)	7.3 m (24 ft)
100	35 m (114.8 ft)	12 m (39.4 ft)	23 m (75.5 ft)

For example, if a portable transmitter has a maximum radiated power of 1W and an operating frequency of 156 MHz, it can be operated at distances greater than 1.2 m (3.9 ft) from the system.

Avoiding Electromagnetic Interference

An ultrasound system is designed to receive signals at radio frequencies, making them susceptible to interference generated by RF energy sources. Other examples of interference are medical equipment, information technology products, and radio and television transmission towers.

To help locate the source of the interference, consider the following questions:

- Is the interference intermittent or constant?
- Does the interference show up only with one scanner or with several scanners?
- Do two different scanners operating at the same frequency have the same problem?
- Is the interference present if the system is moved to a different location in the facility?
- Can the EMC coupling path be attenuated? For example, placement of a scanner or printer close to an ECG cable can increase electromagnetic interference. Moving the cable or other medical equipment away from the location of the scanner or printer can result in reduced electromagnetic interference.

Once you find the interference's source, contact Vave.

Regulation of Low-Power Motor for Radio Wave Range

NCC Warning:

Article 12: Without permission, any company, distributor, or user must not modify the certified low-power radio frequency motor, by changing the frequency, power, or the original design features or functions.

Article 14: The use of low power radio frequency motor must not affect airplane safety or legal telecommunications. If you discover any danger to airplane safety or interference to legal telecommunications, stop use immediately until the safety is improved or the interference is eliminated. The legal telecommunication refers to wireless telecommunication under regulations. The low power radio frequency motor must bear the disturbance from legal telecommunication or industrial, scientific, or medical radio wave device. (1) Avoidance of operations affecting nearby radar systems. (2) High-gain directivity antennas must be applied only to fixed point-to-point systems.

6 References

6.1 Compliance Statement

The Vave Personal Ultrasound system complies with national standards and laws. Users are responsible for ensuring that the chosen mobile device and probe are compliant with the law in the jurisdiction where the product is used. Vave Health meets all regulatory standards listed in this chapter.

6.2 The Vave Probe Personal Ultrasound System

6.2.1 Product Classification

- Device with scanners (internally powered ME equipment):
  - US FDA: Class II
- Scanners: Type BF applied parts, IP67
- Battery: IP67
- Ordinary Equipment/Continuous Operation
- Non-AP/APG

6.2.2 Product Model Number

The model reference for the Vave Personal Ultrasound system, components, or accessories will consist of a 3-character alphanumeric:

Product	Model Reference
Vave Personal Ultrasound	VUS
Vave App	VUA
Vave Phased	VP3
Vave Battery Charger	VCG
Vave Battery	VLN
Probe Cap	VCP

Each scanner has a unique serial number assigned, which is used to track quality control. The following format of the serial number will be used:
<3-character model reference>-<2-digit numerical revision>-<2-digit year and 2-digit month>-<4-digit running number>

Example: VUS-01-1809-0001

6.2.3 System Specifications

Conforms the following specifications:
• Gray shades: (256) in B-Mode

Environmental operating, transient and storage conditions
These are the environmental conditions that are acceptable for transport and storage of the Vave Probe between uses:

	Operating Limits	Transient Operating Limits	Storage Limits
Pressure	620 hPa to 1 060 hPa	—	—
Humidity	15% to 90% non-condensing	15% to 90% non-condensing	-40 °C (-40°F) to + 5°C (+41°F) without relative humidity control; +5°C (+41°F) to +35°C (+95°F) at a relative humidity up to 90% non-condensing; > 35°C (+95°F) to 70°C (+158°F) at a water vapour pressure up to 50 hPa
Temperature	0°C (+32°F) to +40°C (+104°F)	-20°C (-4°F) to + 50°C (+122°F)	

If stored or transported in conditions outside what's stated above, the scanner may degrade in performance or become unusable.

If the probe has been in an environment above 40°C (104°F), allow to cool to operating temperature before turning on or operating — approximately 25 minutes depending on length of temperature exposure. Do not allow the transducer to contact the patient if the temperature of the transducer is higher than 43°C (109°F).

The Vave Probe automatically shuts down if the probe surfaces other than the patient contact area reach a temperature of 48°C. The patient contact area will not exceed 43°C during operation. If the scanner reaches its maximum surface temperature, it automatically shuts down.

The temperature icon:
• Blue: indicates that the scanner is cool.
• Orange: indicates that the scanner is heating up
• Red: it indicates that the scanner is too warm.

If the probe has been in an environment below 0°C (32°F), allow to reach operating temperature before turning on or operating — approximately 20 minutes depending on length of temperature exposure. Condensation inside the devices could cause damage.

6.3 Standards

6.3.1 Biocompatibility

ANSI/ISO 10993-1:2009 — Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process.

6.3.2 Electrical Safety

The Vave Personal Ultrasound System has been evaluated, tested, and found to meet the applicable requirements of the following international safety standards:

IEC 62133 2012 Secondary cells and batteries containing alkaline or other non-acid electrolyte — Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications

IEC 60601-1 2012, Medical Electrical Equipment — Part 1: General requirements for basic safety and essential performance.

IEC 60601-1-2 2012, Medical Electrical Equipment — Parts 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility - Requirements and tests

IEC 60601-2-37 2007, Medical Electrical Equipment — Parts 2-37: Particular Requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

6.3.3 Federal

The Vave Personal Ultrasound Phased complies with part 15 of the FCC Rules.

6.3.4 Labeling

ISO 60417:2014 — Graphical symbols for use on equipment. See Symbols Glossary section of this User Manual.

6.3.5 Quality

Performance

IEC 60601-1-2 2012, Medical Electrical Equipment — Parts 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests

IEC 60601-2-37 2007, Medical Electrical Equipment — Parts 2-37: Particular Requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

ANSI/AAMI/IEC 62366-1 2015, Medical Devices — Part 1: Application of Usability Engineering to Medical Devices

IEC 60601-1-11 2015, Medical Electrical Equipment — Parts 1-11: General Requirements for Basic Safety and Essential Performance — Collateral Standard: Requirements for Medical Electrical Equipment And Medical Electrical Systems Used in The Home Healthcare Environment
IEC 60601-1-12 2014, Medical Electrical Equipment — Parts 1-12: General Requirements for Basic Safety and Essential Performance — Collateral Standard: Requirements for Medical Electrical Equipment And Medical Electrical Systems Intended For Use In The Emergency Medical Services Environment

Risk, Product Specification, Design Review, & Verification/Validation
21 CFR 11 2014 Electronic Records and Electronic Signatures

21 CFR 801 2014 Labeling

21 CFR 820 2014 Quality System Regulation

21 CFR 821 Medical Device Tracking Requirements

21 CFR 822 Post Market Surveillance

21 CFR 830 Unique Device Identifier

IEC 62304 Medical Device software — software lifecycle processes

IEC 62366 Medical Devices-Application of usability engineering to medical devices

ISO 10993-1 2009 Biological evaluation of medical devices — Part 1: Evaluation and testing withing a risk management process

ISO 14971 2007 Medical Devices — Application of Risk Management to Medical Devices

6.3.6 Security & Privacy
ANSI/AAMI/ISO 14971:2007 Medical devices — Application of risk management to medical devices

NIST Framework for Improving Critical Infrastructure Cybersecurity

U.S. Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191

AAMI TIR57:2016 Principles for medical device security — Risk management

ANSI/AAMI/IEC TIR80001:2014: Application of risk management for IT-networks incorporating medical devices

NIST Special Publication 800-53 Security and Privacy Controls for Federal Information Systems and Organizations

NIST Special Publication 800-30 Revision 1 — Guide for Conducting Risk Assessments

Content of Premarket Submissions for Management of Cyber Security in Medical Devices — Guidance for Industry and Food and Drug Administration Staff

Postmarket Management of Cybersecurity in Medical Devices — Guidance for Industry and Food and Drug Administration Staff

6.3.7 Wireless
U.S. • FCC15.247

6.4 Wireless Compliance with FCC and ISEDC

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. However, there is no guarantee that interference will not occur in a particular installation.
If this equipment does cause harmful interference to radio or television reception, 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 receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

The FCC requires the user to be notified that any changes or modifications made to this device that are not expressly approved by Vave Health, Inc. may void the user's authority to operate the equipment. per 47 CFR §15.19 This device complies with part 15 of the FCC Rules. 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.

This device complies with Innovation, Science and Economic Development Canada's licence-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 of the device.

Cet appareil est conforme aux flux RSS exemptés de licence d'Innovation, Science et Développement économique Canada. L'opération est soumise aux deux conditions suivantes:
(1) Cet appareil ne doit pas provoquer d'interférence; et
(2) Cet appareil doit accepter toute interférence, y compris les interférences susceptibles de provoquer un fonctionnement indésirable de l'appareil.

ISEDC Radiation Exposure Statement
Radiation Exposure Statement: This equipment complies with the IC RSS-102 radiation exposure limits set forth for an uncontrolled environment.

Énoncé d'exposition aux rayonnements: Cet équipement est conforme aux limites d'exposition aux rayonnements ioniques RSS-102 Pour un environnement incontrôlé.

6.5 Acoustic Output Tables

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-Scan	
					Apart<1cm²	Apart>1cm²		
Maximum Index value			1.39	0.978	-	-	-	(a)
Associated acoustic parameter	Pr3 (MPa)		2.30					
	W_0 (mW)			185	-		-	(a)
	min of [W .3 $(Z_1)_1$ I_{TA}, $_3(Z_1)$] (mW)					-		
	Z1 (CM)					-		
	Zsp					-		
	Zsp		4.53				-	
	deq(Zsp)						-	
	fc (MHz)		2.76	2.03	-	-	-	(a)
	Dim of Aprt	x (cm)		1.8	-	-	-	(a)
		Y (cm)		1.2	-	-	-	(a)*
Other Information	PD		0.830					
	PRF		2000					
	pr @ PII_{max}		3.55					
	deq @ PII_{max}						-	
	Focal Length	FLx (cm)		10.0	-	-		
		Fly (cm)		7.0	-	-		
	I_{PA3} @ MImax (W/cm²)		318					
Operating Control Conditions	2.8 MHz, 50 mm, V4 2.0 MHz, 100 mm, V5		√					
				√				

*Intended use does not include cephalic so TIC is not computed.

6.6 Control Effects Guidance Documents

For more information about ultrasonic bioeffects and related topics, see the following:

- "Bioeffects and Safety of Diagnostic Ultrasound." AIUM Report, January 28, 1993.
- "American Institute of Ultrasound in Medicine Bioeffects Consensus Report." Journal of Ultrasound in Medicine, Volume 27, Issue 4, April 2008.
- Third Edition of the AIUM Medical Ultrasound Safety brochure, 2014.
- Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Scanners. FDA, September 2008.
- WFUMB. "Symposium on Safety of Ultrasound in Medicine: Conclusions and Recommendations on Thermal and Non-Thermal Mechanisms for Biological Effects of Ultrasound." Ultrasound in Medicine and Biology, 1998: Volume 24, Supplement 1.
- Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Scanners, FDA, 2008.
- Medical Ultrasound Safety, American Institute of Ultrasound in Medicine (AIUM), 2014.
- Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment, American Institute of Ultrasound in Medicine, 1993.

6.7 Cleaners & Disinfectants

The following table lists the cleaners and disinfectants compatible with your Vave Personal Ultrasound scanner and accessories. The products listed in the following table are chemically compatible and have been tested for efficacy.

Level of Disinfection	Solution	Active Ingredients	Usage
Low Level	CaviWipes™	Alcohol, Quarternary Ammonia	Wipe – Follow manufacturer's instructions
High Level	Cidex® OPA	Ortho-phthalaldehyde	Soak – Follow manufacturer's instructions

You may also use products not specifically listed in the compatibility table but with similar active ingredients and marketed for medical use. Because of the large number of available cleaners and disinfectants, it is impossible to have an all-inclusive list. If you are unsure of the suitability of a particular product, contact Vave Health for more information.

6.8 Glossary Of Terms

6.8.1 Acoustic Outputs

For ultrasound terms not included in this glossary, refer to Recommended Ultrasound Terminology, Third Edition, published by AIUM.

- **Aaprt** Area of the active aperture measured in cm2.
- **deq(z)** Equivalent beam diameter as a function of axial distance z, and is equal to [(4/ϖ)(Wo/ITA(z))]0.5, where ITA(z) is the temporal-average intensity as a function of z in centimeters.
- **deq@PIImax** Equivalent beam diameter at the point where the free-field, spatial-peak pulse intensity integral is a maximum in centimeters.
- **depth** Refers to the depth of the display. A constant speed of sound of 1538.5meters/second is assumed in the calculation of echo position in the image.
- **Dim. of Aaprt** Active aperture dimensions for the azimuthal (x) and elevational (y) planes in centimeters.
- **fc** The center frequency (MHz). For MI, fc is the center frequency associated with the transmit pattern giving rise to the global maximum reported value of MI. For TI, when using combined modes involving transmit patterns of unequal center frequency, fc is defined as the overall range of center frequencies of the respective transmit patterns.
- **in situ** In the natural or original position.
- **FL** Focal length, or azimuthal (x) and elevational (y) lengths if different, measured in centimeters.
- **Ipa.3@MImax** Derated pulse average intensity at the maximum MI in units of W/cm2.
- **ISPTA.3** Derated spatial peak, temporal average intensity in units of milliwatts/cm2.
- **ISPTA.3z1** Derated spatial-peak temporal-average intensity at axial distance z1 in units of milliwatts/cm2.
- **ITA.3(z1)** The derated spatial-peak temporal-average intensity at axial distance in units of milliwatts/cm2.
- **MI (mechanical index)** An indication of the likelihood of mechanical bioeffects occurring. The higher the MI, the greater the likelihood of mechanical bioeffects.
- PD Pulse duration (microseconds) associated with the transmit pattern giving rise to the reported value of MI.
- **Pr.3** Derated peak rarefactional pressure associated with the transmit pattern giving rise to the value reported under MI in units of megapascals.
- **pr@PIImax** Peak rarefactional pressure at the point where the free-field, spatial-peak pulse intensity integral is a maximum in units of megapascals.
- **PRF** Pulse repetition frequency associated with the transmit pattern giving rise to the reported value of MI in Hertz.
- **TI (thermal index)** The ratio of total acoustic power to the acoustic power required to raise tissue temperature by 1°C (1.8°F) under defined assumptions.
- **TI type** Applicable thermal index for the scanner, imaging mode, and exam type.
- **TI value** Thermal index value for the scanner, imaging mode, and exam type.
- **TIB (bone thermal index)** A thermal index for applications in which the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone.
- **TIBnon-scan** The bone thermal index in the non-autoscanning mode.
- **TIC (cranial bone thermal index)** A thermal index for applications in which the ultrasound beam passes through bone near the beam entrance into the body.
- **TIS (soft tissue thermal index)** A thermal index related to soft tissues.
- **TISscan** The soft tissue thermal index in an auto-scanning mode.
- **TISnon-scan** The soft tissue thermal index in the non-autoscanning mode.
- **W3(z1)** Derated ultrasonic power at axial distance z1 in units of milliwatts.
- **Wo** Ultrasonic power, except for TISscan, in which case it is the ultrasonic power passing through a one-centimeter window in units of milliwatts.
- **z1** Axial distance corresponding to the location of maximum [min(W3(z), ITA.3(z) x 1 cm2)], where z ≥ _zbp in centimeters.
- **Zbp** 1.69 (Aaprt) in centimeters.
- **Zsp** For MI, the axial distance at which pr.3 is measured. For TIB, the axial distance at which TIB is a global maximum (for example, zsp = zb.3) in centimeters.
- **z@PII.3max** The axial distance corresponding to the maximum of the derated spatial-peak pulse intensity integral (megapascals).

6.8.2 Acoustic Artifacts

Image artifacts are common in clinical sonography (ultrasound) and may be a source of confusion. Some artifacts may be avoidable, caused by improper scanning techniques. Other artifacts are generated by physical limitations. Ultrasound artifacts can be understood by considering the physical properties of the ultrasound beam, the propagation of sound in matter, and assumptions of image processing.

Recognition of these artifacts is important because they may indicate tissue composition and inform a diagnosis. The ability to recognize and remedy ultrasound artifacts is critical for producing quality images and providing optimal patient care (M.K. Feldman MD et al, 2009).

Acoustic Shadowing is characterized by a signal void behind structures that strongly absorb or reflect ultrasound waves.

Acoustic Enhancement also called posterior enhancement or enhanced through transmission. Refers to the increased echoes deep to structures that transmit sound exceptionally well, such as a fluid filled cyst.

Beam Width Artifact occurs when a reflective object located beyond the widened ultrasound beam, after the focal zone, creates false detectable echoes that are displayed as overlapping the structure of interest. It is possible to avoid this artifact by adjusting the focal zone to the depth level of interest and by placing the transducer at the center of the object being studied.

Comet-Tail Artifact is a grey-scale ultrasound finding seen when small calcific/crystalline/highly reflective objects are interrogated and is believed to be a special form of reverberation artifact.

Mirror Image Artifact is a type of beam path artifact when the interrogating ultrasound beam hits an angled, highly reflective surface, such as soft tissue/gas interface. It is reflected off into surrounding soft tissue (angle of incidence = angle of reflection).

Reverberation Artifact occurs when an ultrasound beam encounters two, strong parallel reflectors. When the ultrasound beam reflects back and forth between the reflectors ("reverberates"), the ultrasound transducer interprets the sound waves returning from the reverberation as deeper structures, since it took longer for the wave to return to the transducer. Reverberation artifacts can be improved by changing the angle of insonation so that reverberation between strong parallel reflectors cannot occur.

Ring Down Artifact is a special type of resonance artifact. Its appearance is similar to the ladder-like reverberation of comet-tail artifacts, but it is produced by a completely different mechanism (gas bubbles).

Refraction Artifact can occur when a transmitted ultrasound pulse strikes an interface at a non-perpendicular angle. The difference in propagation speeds between the two tissues can cause refraction to occur. Should the refracted incident sound wave strike a reflector and cause an echo to return to the transducer, this may be displayed at an incorrect location as the transducer assumes all echoes have traveled along a direct path. Refraction artifact should resolve if the transducer is moved such that the incident pulse if perpendicular to the interface.

Speckle Artifact is caused by the scattering of waves from the surface of small structures within a certain tissue and produces a textured appearance.

Speed Displacement Artifact is a gray scale ultrasound finding that can be identified as an area of focal discontinuity and displacement of an echo deeper than its actual position in an imaged structure. The artifact is due to the image processor's assumption that the velocity of the ultrasound beam within the imaged anatomy is uniform and that distance of the structure from the transducer is the sole factor determining that structure's location. A commonly encountered scenario is a speed displacement artifact due to slowing of the ultrasound beam by local fat.

Side Lobe Artifacts occur where side lobes reflect sound from a strong reflector that is outside of the central beam. The echoes display as if they originated from within the central beam. Side lobe artifacts are echogenic, linear or curvilinear artifacts. Strong reflectors include bowel gas adjacent to the gallbladder or urinary bladder.

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