



Vave Wireless Ultrasound



USER MANUAL

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1 About the Vave Wireless Ultrasound

The Vave Wireless Ultrasound system is subject to local laws and regulations. Ensure that you follow applicable local laws and regulations when using the Vave Wireless Ultrasound system.

- Ensure you use the product as directed in this manual and according to its intended uses. Failure to do so could void the product's warranty and release Vave from any damage or injury resulting from this misuse.
- In compliance with part 15 of the FCC rules, operation of this device contains a general provision that devices may not cause interference and must accept any interference received.
- This ultrasound device may be used in all medical and domestic environments but may require special precautions regarding EMC. Follow the information provided in this manual regarding installation and use environments.



Caution: Do not operate the system in the presence of flammable gases or anesthetics.

- Image quality and diagnosis are the responsibility of the trained healthcare professionals performing exams.
- Keep product packaging with medical device. Do not dispose of the packaging.

System Description

The Vave Wireless Ultrasound is a wireless, pocket-sized diagnostic ultrasound device consisting of both hardware and a mobile application (“Vave Health 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 Probe”) uses a state-of-the-art piezoelectric transducer, and houses a removeable lithium ion battery and components required for ultrasound imaging and Wi-Fi connectivity.

The Vave Probe can wirelessly transmit data to a mobile application (“Vave Health 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 -- purchased separately) 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 Health App

(display device not included)



Product Usage

Indications for use and contraindications are noted below:

Intended Use

The Vave Probe is intended for diagnostic ultrasound imaging in B-Mode, M-Mode and Color Doppler Mode.

Indications for Use

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, Peripheral Vessel, and procedural guidance of needles into the body.

The Vave Probe 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 Probe

Transducer: Phased Array

Intended Use: Diagnostic ultrasound imaging of the human body as in the chart below.

Figure 1.1 Clinical Applications and Modes of Operation

Clinical Application		Mode of Operation			
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	Color Doppler	Combined (Specify)
Fetal Imaging & Other	Fetal	X	X	X	B+M, B+C
	Abdominal	X	X	X	B+M, B+C
	Pediatric	X	X	X	B+M, B+C
	Other (Thoracic/Pleural)	X	X	X	B+M, B+C
Cardiac	Cardiac Adult	X	X	X	B+M, B+C
	Cardiac Pediatric	X	X	X	B+M, B+C
Peripheral Vascular	Peripheral Vessel	X	X	X	B+M, B+C
	Other (Non-Vascular)	X	X	X	B+M, B+C
X = Indication					
Notes:					
1) Includes imaging to assist in:					
a) Needle and catheter placements in vascular or other anatomical structures, and					
b) Guidance for nerve block procedures.					
2) Abdominal includes gynecology, renal, and urology.					
3) Thoracic/pleural detection of fluid and pleural motion/sliding.					
4) Peripheral vessel includes arteries and veins.					
5) Non-Vascular is image guidance for freehand needle/catheter placement.					

Contraindications

The Vave Wireless 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)

For Use in Surgical Environments

Prior to using the Vave Probe in a surgical intra-operative environment, perform a high-level disinfection (for instructions see *High-Level Disinfection*), then apply a single-use sterile sheath to the Vave Probe:

- Use only CIVCO REF 610-1212.
 - Download and read the usage instructions from <http://civco.com>.
- After using the Vave Probe, clean perform another high-level disinfection.



Caution:

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:

- Chemicals and gases in a surgical environment and altitudes below -382m or above 4000m in the patient's environment may adversely impact the scanner and the exam.
- Always practice ALARA when scanning children and pregnant/nursing women, as they may be more susceptible to bioeffects from prolonged exposure to acoustic energy during scanner use.
- Extreme conditions in the patient environment may cause difficulty in scanning: humidity (RH<15% and RH>90%) or extreme temperature (<0°C / 32°F or >40°C / 104°F).
- Users can be trained healthcare professionals, healthcare students, and in-home users under a physician's care.



Caution:

Federal law restricts this device to sale by or on the order of a physician.

About This Manual

This user manual covers the use of the Vave Wireless Ultrasound System and meets FDA regulatory requirements. Install, operate, and maintain the Vave Wireless 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:

1. Product Overview: Description, intended use, indications for use, contraindications, and manual conventions
2. Performing an Exam: Performing a Patient's Exam
3. System Setup and Administrator's Guide: System set up and web interface
4. Product Safety: Critical safety standards, principles, and policies
5. References: Regulatory requirements, technical specifications, terms and conditions, glossary of terms, and acoustic output data

Target Audience

This document is written for trained healthcare professionals, healthcare students, and in-home users under a physician's care.

Manufacturer

Vave Health, Inc.
3031 Tisch Way #110
Plaza West, Suite
San Jose, CA 95128

Security

It's crucial to follow these security practices to safeguard sensitive patient data, protect personal information, and ensure the reliable and secure operation of the Vave System

- Use secure passwords.
- Keep your operating system up-to-date with the latest recommended security patches.
- Use secure wireless equipment and protocols.
- Lock your smart devices.
- Regularly update the Vave App.

Document Conventions

Figure 1.2 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

Figure 1.3 Informational Icons Used in the Manual



Level of Risk

Danger, Warning, Caution: Possible risks beyond the reasonable control of Vave Health.



Note

Information/Suggestions


Screen Icons

Figure 1.4 Screen Icons

	Abdominal		Battery Full		Scanning Button		Home
	Cardiac		Battery 60%		Mode Select		Edit (applied in Renaming Exam)
	Lung		Battery 30%		Record Cine		Patient Data
	OB/GYN		Battery Empty		Capture Image		Share
	Exam Folder		Export Destination		Save Single Frame		Menu
	Sync		Shared Indicator		Save Frames Range		Image Settings
	Sync Not Started Yet		Cine Indicator		Vave Assist		Scanning Activity
	Sync in Progress		Number of Cines in Exam Package		Join Session		Support
	Sync Done		Number of Files in Exam Package		Probe Settings		About
	File not Physically on the Device (but on the Cloud)		Password Shown		Probe Element Check		Send System Logs
	Downloading from Cloud in Progress		Password Hidden		Probe Temperature		More Icon

2 Performing an Exam

This chapter explains how to install and use your Vave Probe safely and effectively.

 **Note** Refer to the safety section of this manual before handling the Vave Probe.



Caution:

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.

Downloading the Vave Health App

The Vave Health App can be downloaded onto an iOS or Android device.

iOS

Operating system required: iOS 13+

To download the Vave Health App:

1. Go to the App store and search for the Vave Health App
2. To download, tap the Install button and follow the on-screen instructions
3. To launch, tap the Open button
4. If you can't find the App, your device might not meet the minimum requirement or the App might not be available in your country

Android

Operating system required: Android™ 9+

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

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

Updating the Vave Probe

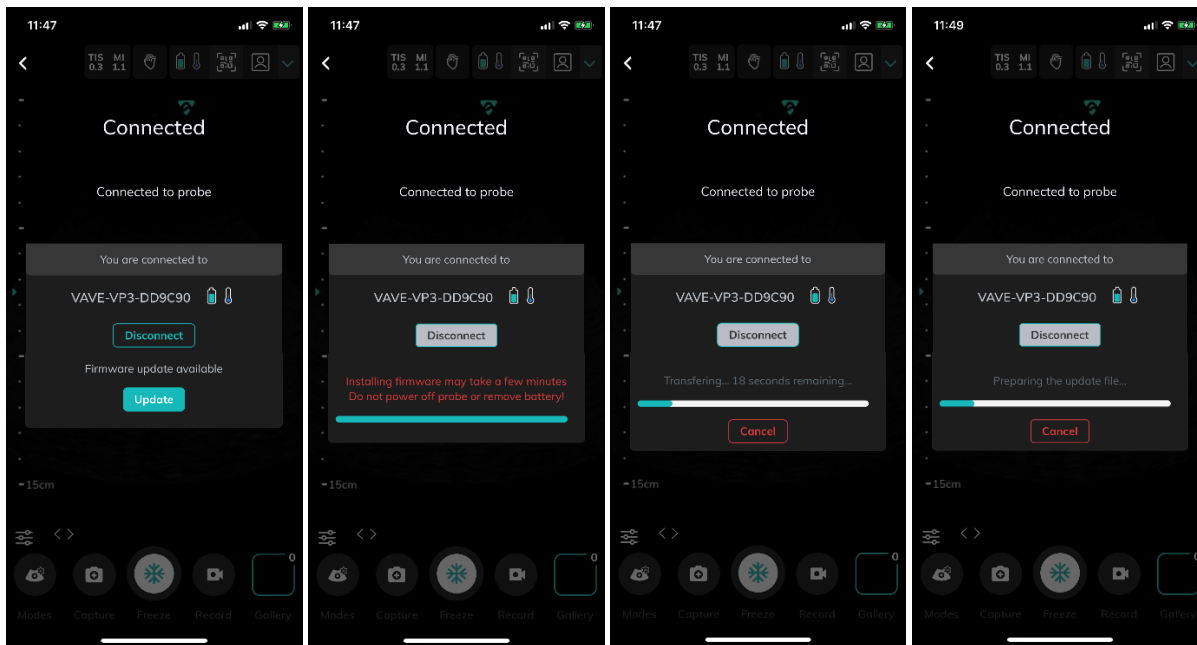
Ensure that the Vave Probe is kept up to date with the latest software and firmware levels.

Software Updates

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

Firmware Updates

After you connect to the probe's Wi-Fi, a red "Firmware Update Available" notification will appear if a firmware update is needed. Tap on the "Update" button to install, and a loading screen will show the update progress.



The Vave Probe Battery

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

Charging the Battery

1. Connect the line cord of the AC power adapter to an indoor electrical outlet
2. Connect the AC power adapter to the receptacle on the battery charger
3. Note that the charger LED toggles between yellow and green when power is applied
4. Remove the battery from the Vave Probe by following the instructions on Removing the Battery above
5. Insert the battery into a slot on the battery charger
6. The LED will stay yellow when the battery is charging
7. The LED will stay green when the battery is fully charged

Figure 2.1 Charging the Battery



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.

Figure 2.2 Inserting the Battery



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

Turning the Vave Probe On/Off

Make sure you have the Vave Probe, and also your smart device with the Vave Health App installed.

Turning On the Vave Probe and Starting the Vave Health App

1. To turn on the Vave Probe, press the power button on the probe for 1 second. The blue light on the probe base will turn on, changing to green when the probe is ready to be connected
2. Next, open the Vave Health App on your smart device's home screen to begin scanning.

Figure 2.3 Probe On/Off

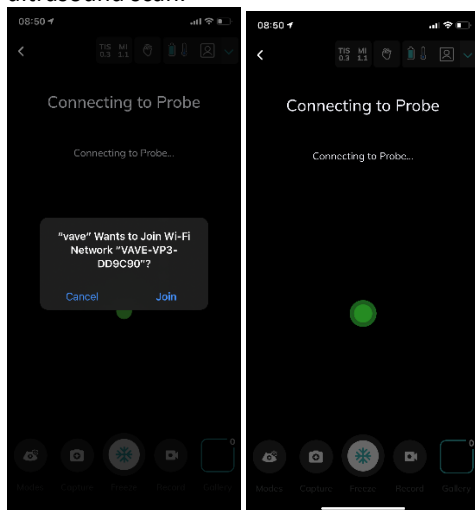


Exiting the Vave Health App and Turning Off the Vave Probe

1. To close the App, exit the Vave Health App — any open exam will be saved, even if you close the app without ending the current exam session
2. To turn off the probe, press the power button on the probe, and the light will turn off

Connecting the Vave Probe to the Smart Device

6. Open the Vave Health App and turn on your probe.
7. Tap the circular Scan button in the center of the bottom menu on the Home screen and wait for the light to turn from blue to green.
8. The App guides you through the connection process and when connected, the Imaging screen appears and you can start an ultrasound scan.



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

Exam Workflow Overview

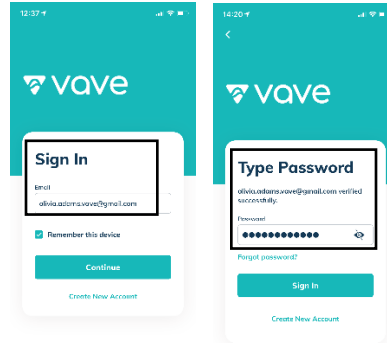


Caution:

Before use, carefully inspect the probe. Always inspect the probe before and after cleaning, disinfection, or use.

Sign-In Page

When you open the Vave Health App, it displays a sign-in screen for your user ID/Email and password. After tapping Continue, you can enter your password and tap Sign In to submit the password and log in.



Menu Options

Selections:

***Navigate the Device to Your Organization, Recent Exams, or Settings**

***Select Scanning Tools**

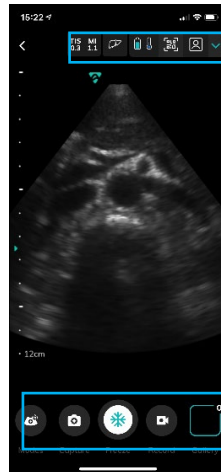
***Review Exams:**

My Exams (Exams you have performed),

My Portfolio (Exams organized into folders)

My Shared (Shared Exams)

Scanning Tools



1 2 3 4 5 6



1 Acoustic Power, TIS/MI

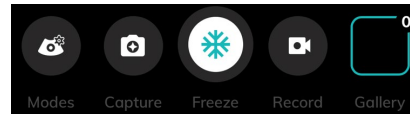
2 Application Preset

3 and 4 Battery and Temperature

5 VaveCast QR Code

6 Patient Information

8 9 10 9 11



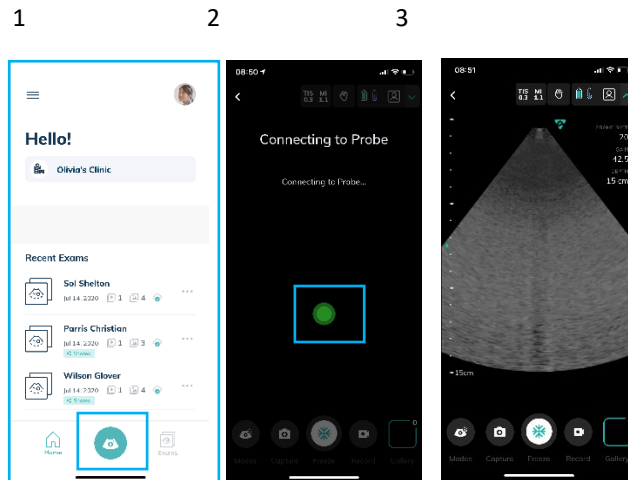
8 Imaging Mode

9 Image Capture

10 and 11 Freeze and Image Gallery

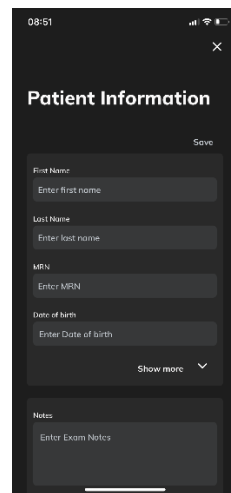
How to Begin Scanning

- 1 Once you're signed in, you will see the Home screen. Turn on the probe. Tap the circular Scan button in the center of the bottom menu to start scanning.
- 2 The app guides you through the connection process.
- 3 Once you're connected to the probe, you can start the ultrasound scan.



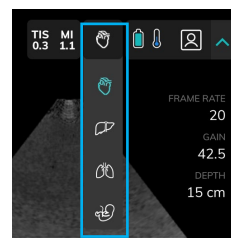
Enter Patient Information

Enter Patient information by tapping on the patient icon in the top menu on the right.



Select Application Preset

Choose the exam's application preset.



- Cardiac
- Abdominal
- Lung
- OB/GYN

Imaging Screen

Here you can:

- 1 Manipulate the visualization of the image (depth, gain).
- 2 Freeze or save images/movie clips.

1



2

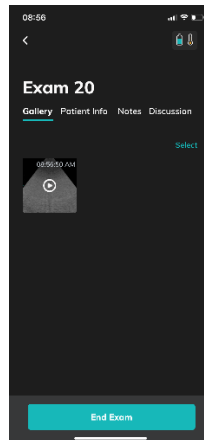


Gallery

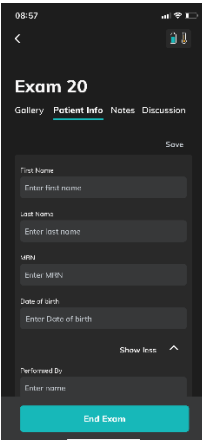
During imaging sessions, you can:

- 1 Evaluate and edit images and cines acquired during the exam.
- 2 Access Patient Data, Exam Notes and Discussions.

1



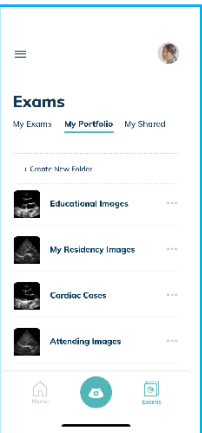
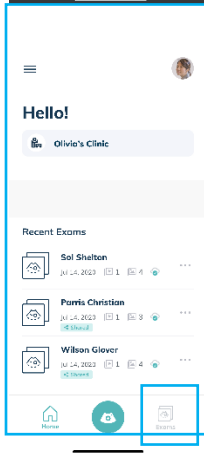
2



When finished, tap the End Exam button at the bottom of the screen.

Exams Screen

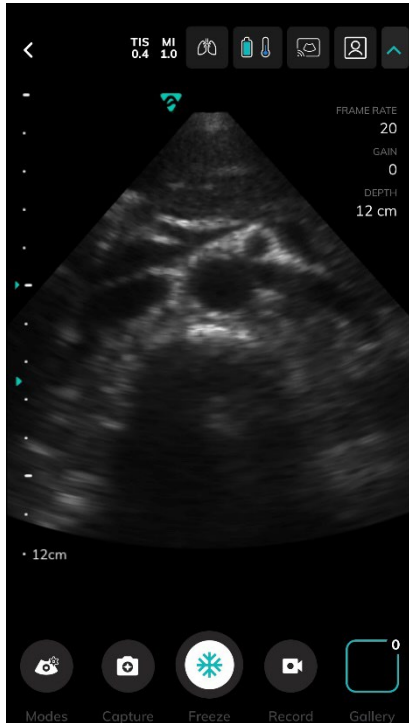
Tap the Exams icon in the bottom-right corner of your Home screen to review all of your Exams and access My Portfolio and My Shared tabs.



Performing a Patient Exam

Typical use of the Vave Probe is 5 minutes of continuous scanning, followed by 10 minutes in standby mode or powered off.

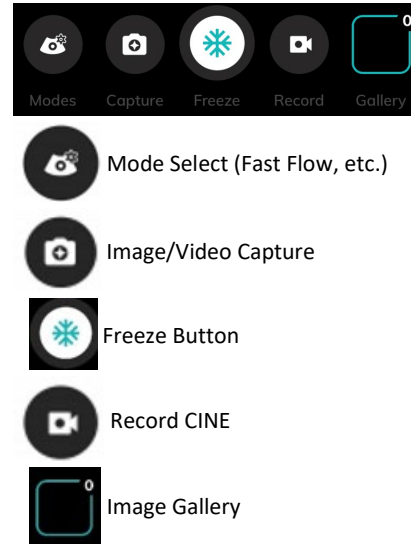
Imaging Display Overview



The imaging display screen includes:

- Exam Information (MI and TI values)
- Image Information (Preset, Frame Rate, etc.)
- An ultrasound image in the center of the screen

Modes, Capture tools Gallery Icons:

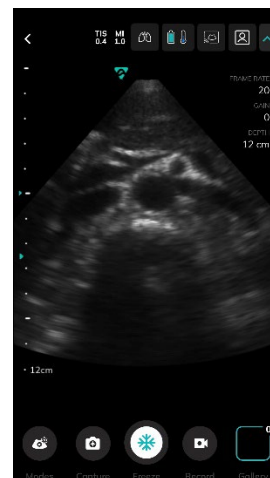


Selecting the Mode and Application Preset

Tapping the Modes icon in the bottom left corner opens a Mode bar with a choice of three modes: Fast Flow, Slow Flow, and M-Mode. To exit a mode, tap the red “end” button in the Mode bar at the bottom of the screen.

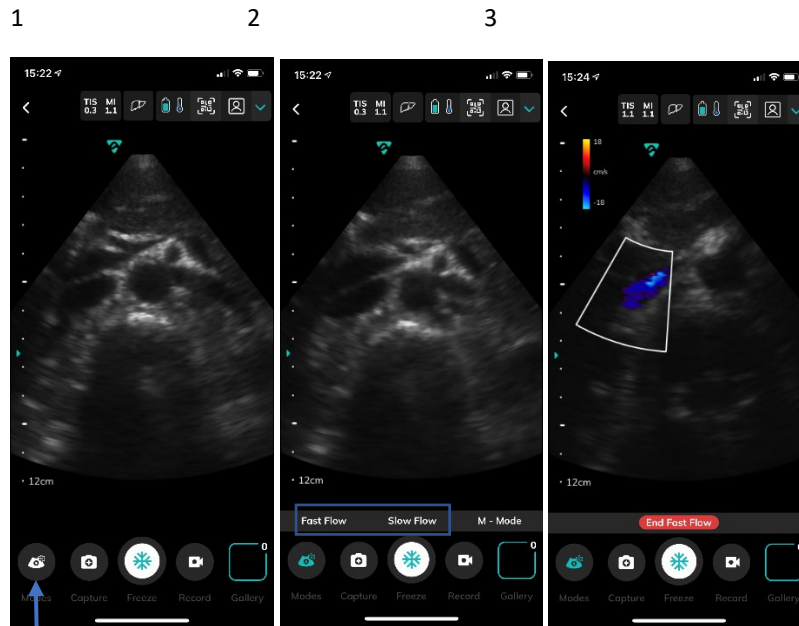
B-Mode

When you start an exam, the Vave Probe defaults to B-Mode — or brightness mode, sometimes referred to as "2D Mode" with two-dimensional imaging displayed in grayscale.



Color Doppler Mode

- 1 Tap the Mode control.
- 2 To access Color Doppler Mode, tap either Fast Flow or Slow Flow in the Mode bar.
- 3 Adjust your region of interest — indicated by a white line — by pinching your app screen to adjust the width and lateral position, and the proximal and distal bounds of the box.

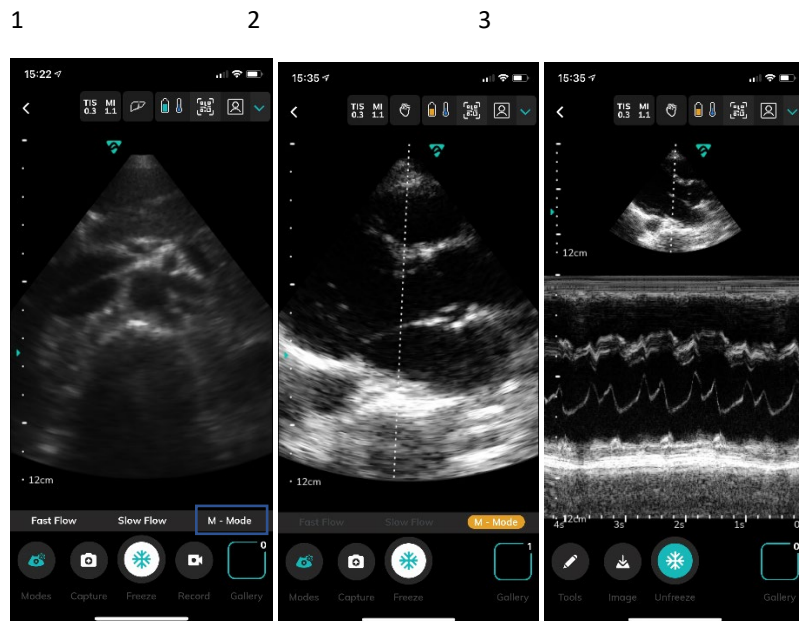


» Note

You can also drag and drop the region of interest to a different location.

M-Mode

- 1 Choose M-Mode in the Mode bar.
- 2 Initiate M-Mode by setting your M-Mode cursor.
- 3 When you release the M-Mode cursor, the M-Mode strip appears just below the B-Mode reference image.



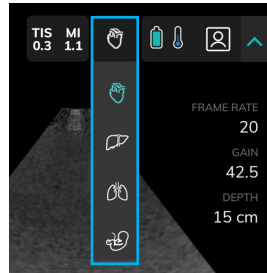
» Note

You can further adjust the M-Mode cursor on the B-mode reference image while the M-Mode strip is displayed. After pressing the freeze button, you can scroll back and forth through the M-Mode strip.

Select Application Preset

Select the exam's application preset:

- * **Cardiac**
- * **Abdominal**
- * **Lung**
- * **OB/GYN**



Adjusting the image

- **To adjust Depth**, swipe up (shallower) or down (deeper) over the ruler on the left side of the screen
- **To manually adjust Gain**, swipe left-to-right (increase) or right-to-left (decrease) on the ultrasound image
- **You can adjust the Focal Point** to a depth of 8 cm or less with a long press on the desired location in the ruler area. The teal triangle to the left of the ruler indicates the current focal depth.
- Zoom In/Zoom Out Captured Images (not while scanning)



- Use the pinch/zoom gesture to zoom in/out of an area on the image.
- Once zoomed in, you can move the image by dragging your finger.

Snap, Freeze/Unfreeze, Save Image and Cines

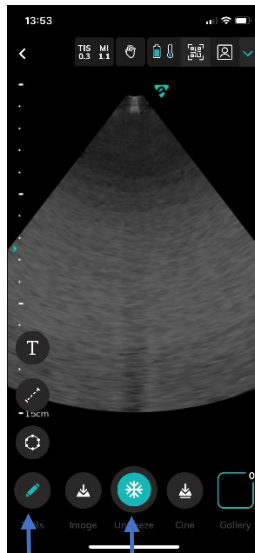
- **To save an image** directly to the gallery, tap the camera icon
- **To freeze/unfreeze** a live image, tap the snowflake icon and then adjust the frame by horizontally sliding the frame slider.
- **To save a frozen image**, tap the save image icon to the left of the freeze button. To save the frozen 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, and your recording will be automatically saved to the Exam.

Measurements and Annotations

From scanning screen, after freezing the image, you can access the following tools: Linear Measurements, Area Measurements and Text Annotations:

Performing Measurements and Annotations

- 1 Press Freeze.
- 2 To measure, select Measurement Tool (Linear or Area Tool). -or- Tap the "T" Type icon to activate annotations.



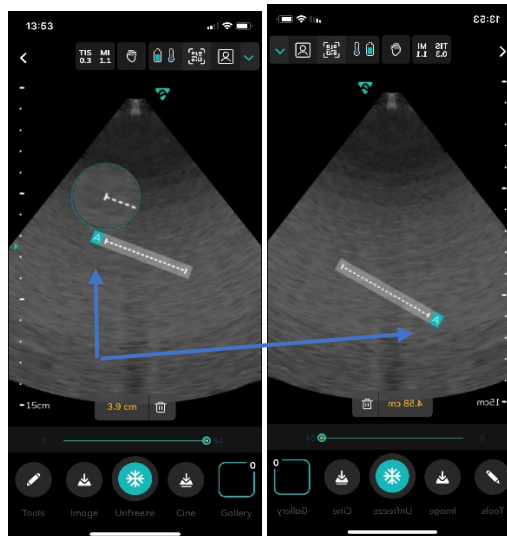
2 1

Linear Measure



Note

To move a linear measurement, drag and drop the ends of the line.



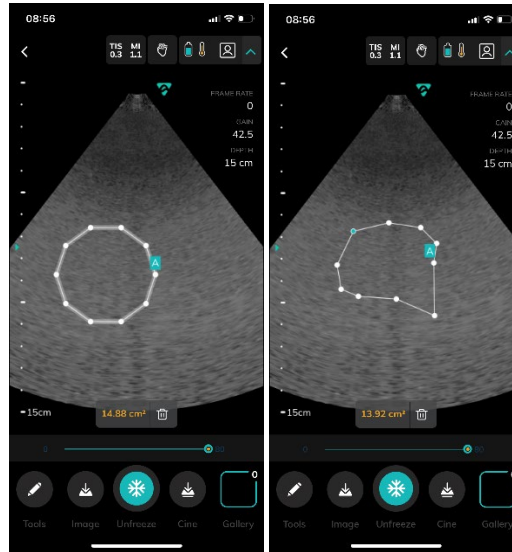
Area Measure

Note

To adjust an area measurement, drag and drop the whole area measurement

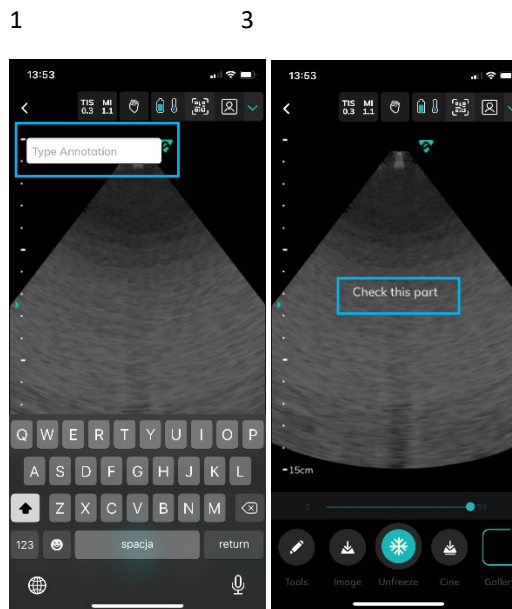
--or--

adjust size and shape by dragging and dropping individual points of the area outline.



Text Annotations

- 1 A text box and keyboard appears. Start typing notes.
- 2 When finished, tap the image. The text box and keyboard disappears and the text turns green.
- 3 When positioned, tap the image to complete the annotation, and the text will turn to white.



Note

Drag the text to any point on the screen, or delete it, by tapping the trash can at the bottom.

Vave Cast™

To allow others to view a live scanning session, tap the QR code icon on the scanning screen to broadcast your imaging session.

Vave Cast™

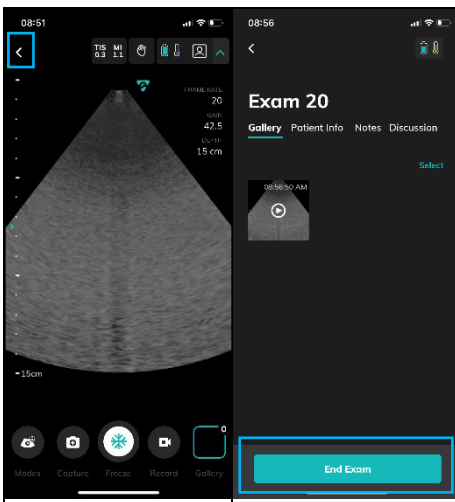
» Note

Your potential viewers will need to sign in to the Vave Health App to join. This allows them to view images, but does not allow them to make any adjustments.



Ending an Exam

To end an exam, tap the back button in the top left corner of the imaging screen or choose “End Exam” on the Gallery screen.



Review Findings

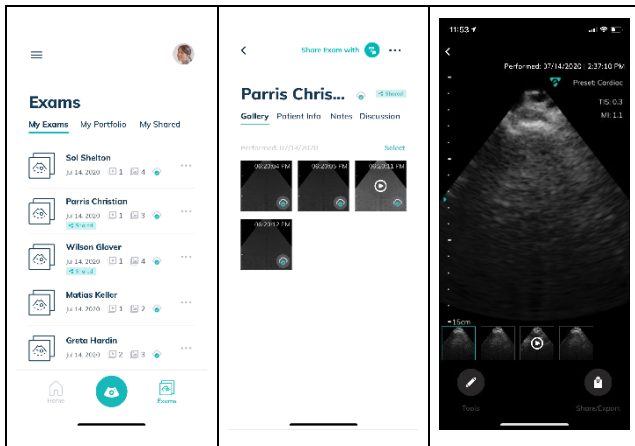
When you have finished imaging, evaluate and edit the exam images and cines.

Saved Exams:

- To view your saved exams, tap the Exams icon in the bottom menu from your Home screen, where you will see three sections: “My Exams”, “My Portfolio” and “My Shared”
- Each section can have several folders — tap a folder name to open and view the ultrasound images
- In the “My Portfolio” section you can collect and organize ultrasound images
- To add a new folder, tap “+ Create New Folder” and name the folder

Reviewing Images and Cines

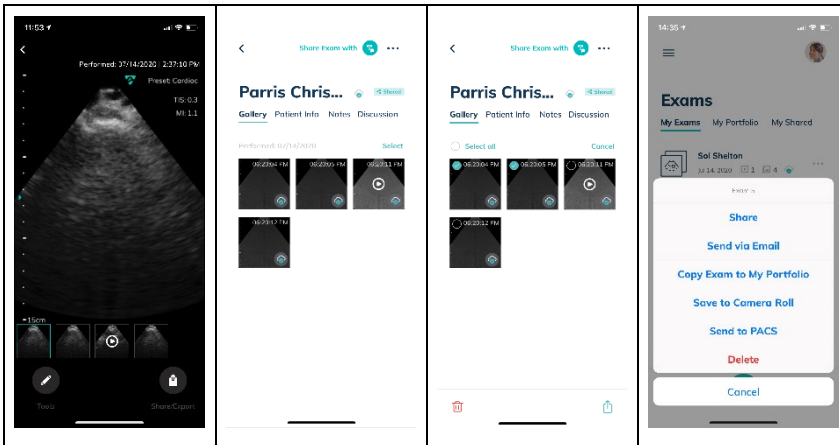
Go to My Exams. Tap on a specific exam, then select Gallery to view all images from that exam. In the Gallery, you can review saved images/cines — and simply tap on an image to open a detailed image view.



Manage Images

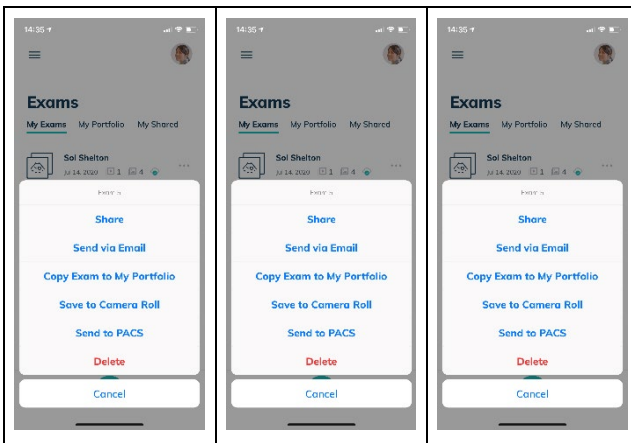
- **To select several images/cines:** tap the select option and tap the images/cines you want to select.
- **To delete images/cines:** select the image(s)/cine(s) and tap the trash icon.
- To export/share images/cines:
 1. Select the image(s)/cine(s) and tap the Share icon
 2. Export/share Options will appear:
 - Send via Email
 - Copy Exam to my Portfolio
 - Save to Camera Roll
 - Send to PACS (if configured)

Choose your desired export option, follow the instructions, and a de-identified copy of the image will be exported:



To add images/cines to a saved scan folder:

1. Select the images and cines you wish to share
2. Tap the Share Icon for a popup list of potential places to send the files
3. Select “Copy to My Portfolio” and select the folder where you would like to store the documents — or tap + to add a new folder.
4. A de-identified copy of the images will be added to your chosen folder.

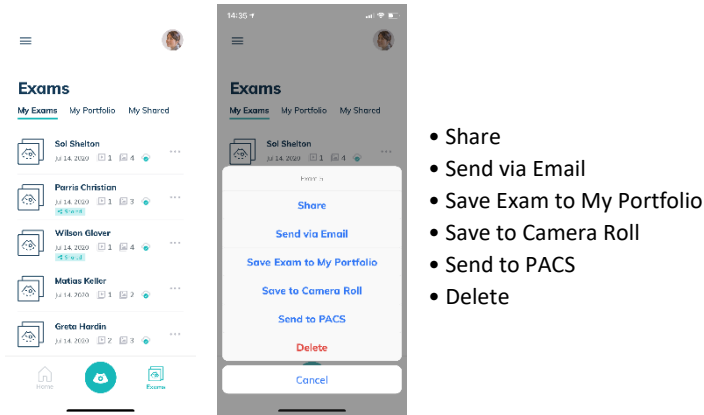


Note

Exported images will be de-identified to remove any Patient Health Information (PHI). Make sure you follow hospital procedures regarding PHI.

Manage Exams

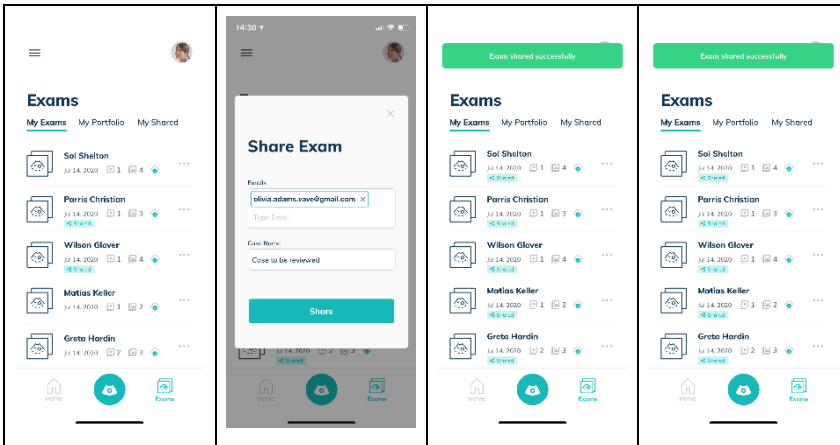
1. Tap the three dots to the right of your desired exam.
2. Options to export and share your exams will appear:



- Share
- Send via Email
- Save Exam to My Portfolio
- Save to Camera Roll
- Send to PACS
- Delete

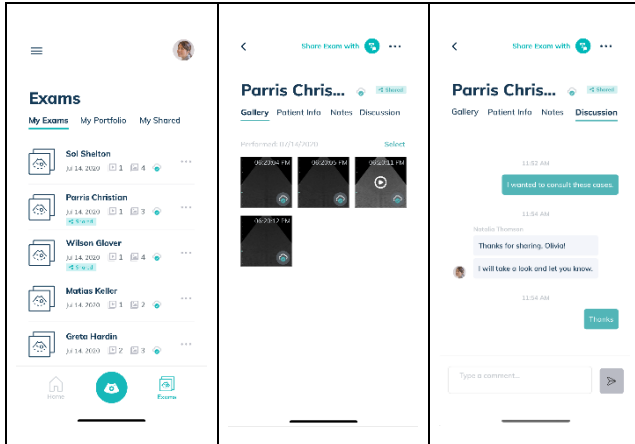
To Share:

1. On the Exams screen, tap the session you would like to share and input your recipient's email address.
2. To review your shared Exams, go to the "My Shared" tab and select "Shared by me" or "Shared with me"



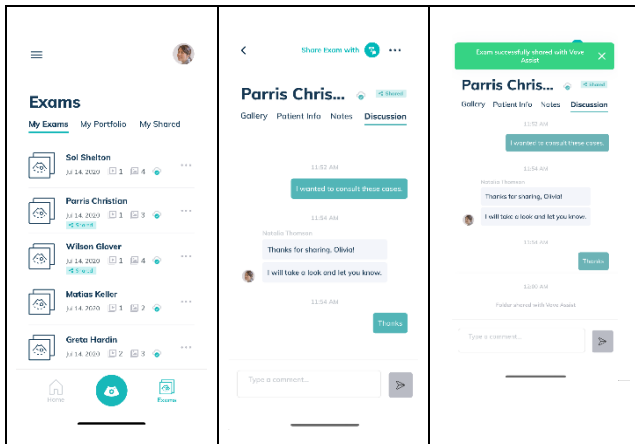
Exam Discussion

The person you share an exam with can take part in your exam discussion. To view the discussion, go to the Exams screen, tap on the specific exam and then tap the Discussion tab.



Vave Assist™

To access Vave Assist, tap the Exams button in the lower right corner and open the exam you want to share. The "Share Exam with" icon will appear in the top right corner — just tap the icon, and the exam will be shared for feedback.



After Each Exam

Always follow these steps after completing each patient's exam.

After Each Use

1. After each use, carefully inspect the probe. Always inspect the probe before and after cleaning, disinfection, or use.
2. Clean and disinfect the Vave Probe and battery.
3. Clean the iOS or Android device, as required.
4. Recharge the battery, as necessary.
5. Store appropriately.



Warning:

The following actions may cause serious or fatal injury.

- Continuing use after the first sign or suspicion of system malfunction or defect — if suspected, contact Vave immediately.

The only maintenance required is to clean and disinfect the Vave Probe and battery.



Caution:

The system must be serviced by trained personnel only. Failing to regularly maintain or verify your Vave Probe may lead to undetected performance errors.

Cleaning and Disinfecting the Vave Probe and Battery



Caution:

- 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.
- Use only cleaning solutions approved by Vave Health, as other solutions may be incompatible and damaging
- Wear appropriate personal protective equipment (PPE), such as eyewear and gloves, as recommended by the chemical manufacturer
- The Vave Probe is not designed for sterilization and cannot be sterilized before or between uses.

Cleaning the Vave Probe and Battery

Before cleaning, visually inspect the probe and battery 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 separately 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 and battery, wipe the exterior surface with a clean, non-abrasive, dry cloth

Cleaning the Charger

Before cleaning, visually inspect the charger 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. Unplug the charger cable from the power source.
2. Disconnect the cable from the back of the charger.
3. Wipe down all surfaces using a premoistened disinfectant wipe. Do not submerge the charger in any liquid.
4. After cleaning the charger, wipe the exterior surface with a clean, non-abrasive, dry cloth

Disinfecting the Vave Probe and Battery

Before you begin disinfection, make sure you have cleaned the Vave Probe and battery. Next, determine the level of cleaning and disinfection required for your Vave Probe and battery, based on the Spaulding classification system listed below. 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)



Note

Different levels of disinfection require different steps, not just different solutions.

Intermediate-Level Disinfection

After cleaning, choose low- or intermediate-level disinfectants compatible with your Vave Probe and battery. Follow the label instructions for preparation, temperature, solution strength, and duration of contact. Make sure to remove the battery and clean the Vave Probe before beginning disinfection.

1. Use a compatible premoistened disinfectant wipe (CaviWipes™) to wipe the probe and battery separately for 1 minute
2. Air-dry the probe and battery or towel-dry with a clean, non-linting cloth
3. Examine the probe and battery 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.

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 separately 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.

After cleaning and disinfecting the probe and battery, let them air dry and then wipe down the exterior surfaces with a clean, non-abrasive, dry cloth.

Cleaners and Disinfectants

The following table lists the cleaners and disinfectants compatible with your Vave Probe 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.

Recharging the Battery

Please refer to *Charging the Battery* for instructions.

Note

- Because the Vave Probe is battery-operated, you must recharge the battery when necessary. An empty battery takes approximately 6 hours to fully charge. Once fully charged, a battery has approximately 3 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 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 the Vave Probe

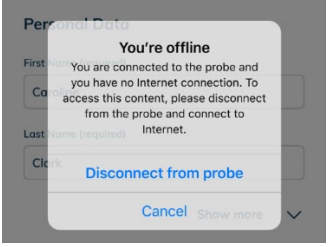
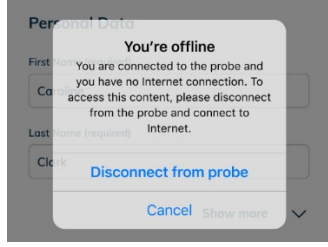
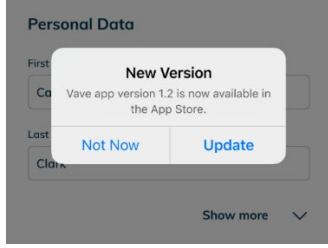
To protect your Vave Probe:

- Dry thoroughly before storage
- Avoid storing in extreme temperatures
- Avoid placing under direct sunlight for prolonged periods of time, as it may discolor the housing’s finish but will not impact the Vave Probe’s safety and performance
- Store separately from other equipment. Refer to the “Environmental Operating, Transient and Storage Conditions” section in Chapter 5.

Troubleshooting the Vave Probe

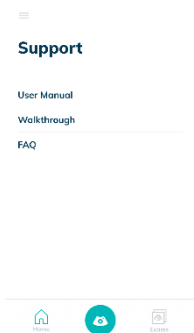
Use the table below to identify and understand alerts displayed in the Vave interface.

<p>Password</p>	<p>Password Error If you do not enter the correct password, you will be prompted to try again to enter the correct password.</p>
<p>Email</p>	<p>Wrong Email Format You’ll see this warning when the email address you entered is not typed with an “@” symbol or does not meet internet email format standards.</p>
<p>Login failed. Invalid email or password.</p>	<p>Sign-in Failure This alert will appear if you submitted a password doesn’t match the email address you entered —or if no account has been created with the email address you entered.</p>
<p>Login failed. Invalid email or password.</p>	<p>Low Battery If your probe is running out of battery power, a low battery alert will appear on top of the screen.</p>
<p>Login failed. Invalid email or password.</p>	<p>Temperature Alerts To protect your device, the probe’s software will alert you to potential overheating, and if the probe gets too hot, it will give you a 30-second warning before automatically shutting down.</p>

 <p>The screenshot shows a 'Personal Data' form in the background with fields for 'First Name', 'Last Name (required)', and 'Click'. A modal dialog titled 'You're offline' is overlaid on top. The dialog text reads: 'You are connected to the probe and you have no Internet connection. To access this content, please disconnect from the probe and connect to Internet.' There are two buttons at the bottom: 'Disconnect from probe' and 'Cancel'. A 'Show more' link with a downward arrow is at the bottom right.</p>	<p>No Wi-Fi This alert shows up if you are not connected to the internet when trying to register new probe.</p>
 <p>This screenshot is identical to the one above, showing the 'You're offline' alert modal dialog over the 'Personal Data' form.</p>	<p>Required Update If there is a required update for the probe available, you will see a required update alert.</p>
 <p>The screenshot shows the 'Personal Data' form in the background. A modal dialog titled 'New Version' is overlaid. The dialog text reads: 'Vave app version 1.2 is now available in the App Store.' There are two buttons: 'Not Now' and 'Update'. A 'Show more' link with a downward arrow is at the bottom right.</p>	<p>Optional Update If there is an optional update for the probe available, you will see an optional update alert.</p>

Additional Help

For Support, tap the hamburger menu (☰) in the upper left corner of the screen. There you can access the User Manual, a video Walkthrough, and Frequently Asked Questions (FAQs):



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

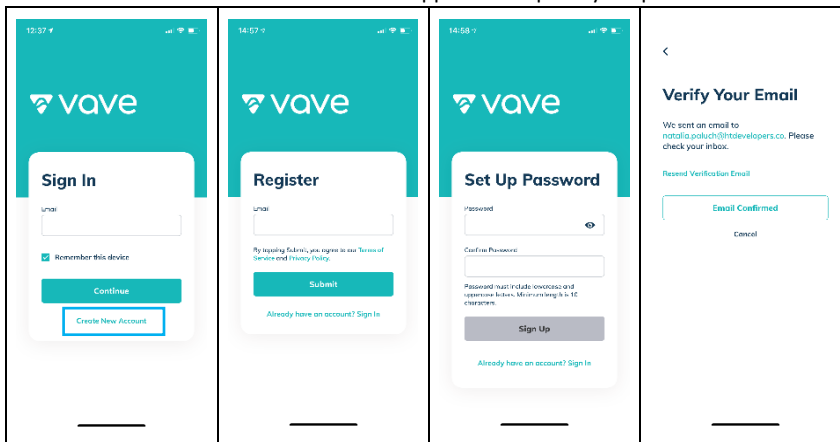


3 System Setup and Administrator's Guide

Account Creating, Signing In and Out

Creating An Account

1. Open the Vave Health App and tap the “Create New Account” button on the Sign In screen
2. Enter your email address and create a password that you will use each time you sign in
3. Read and agree to the Terms of Service and Privacy Policy
4. Open your email account and follow the link to validate your email sent by Vave Health
5. Now return to the Vave Health App and complete your profile



Register/Sign-In with Invitation Link

If your account is being set up or provisioned by your organization's administrator, you will receive an email with a link inviting you to register or sign-in to your account. Simply follow the link to finish creating your profile.

Signing In

To sign in, open your App and enter your email and Password.

Signing Out

You can log out of your account at any time from your profile settings page.

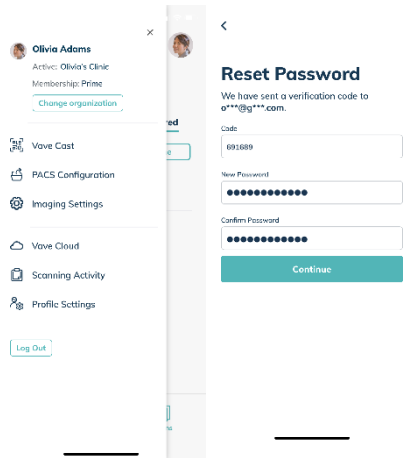
» **Note** You will be automatically signed out after 30 days.

Forgotten Password

1. To reset your password, enter the email address you used to sign up and tap the “Continue” button
2. When the app prompts you to enter your password, tap the “Forgot password?” link, then enter your email address and tap “Continue” to receive your verification code
3. Now go to your email account and copy the verification code
4. Enter the verification code in the app and create your new password
5. Your new password is set — just reenter it one more time to proceed

Organizations

If you are affiliated with an organization for which you perform ultrasound exams, your organization's admin will need to add you as a member.

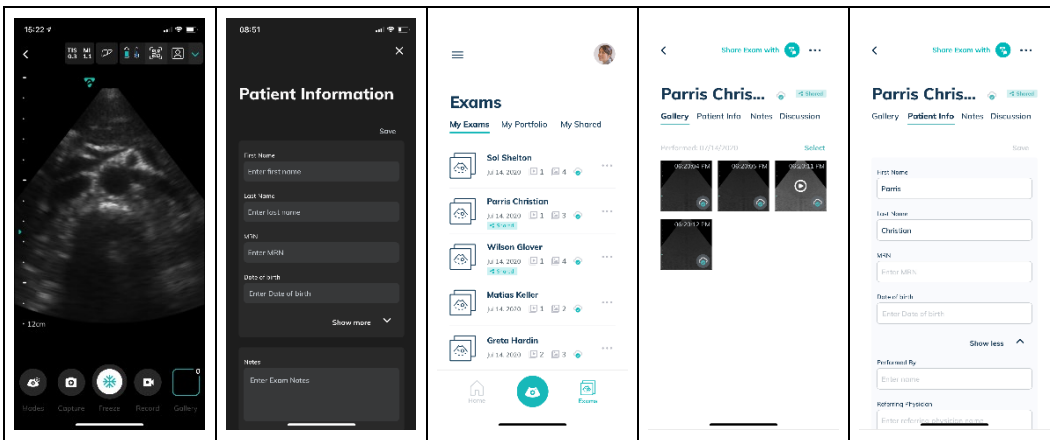


- If you belong to multiple organizations, you can switch between them by tapping the hamburger menu (☰) at the top left of the Home screen
- Exams are tied to the organization selected when scanning
- When you change organizations, you will only see Exams cataloged for that organization

Managing Patient Information

Entering Patient Information

You can enter Patient Information either during a scanning session by selecting the Patient Icon on the top menu or in the Exams tab by selecting the “Patient Info” section in the Exams detail screen.

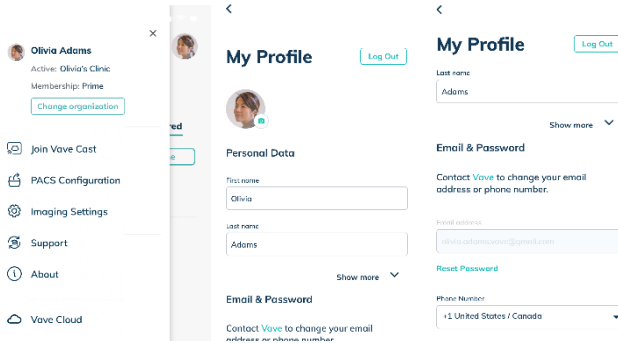


Please make sure that you entered the correct patient information and always be sure to follow your institution’s policies regarding Patient Health Information.

Settings

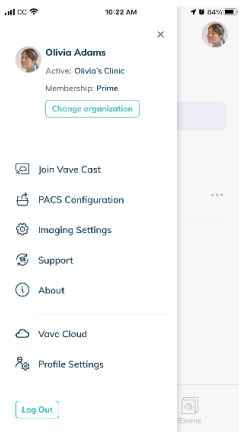
Profile Settings

From the Home screen, you can tap on the user avatar in the upper-right corner to open profile settings. There, you can change your profile, log out of your account or reset your password. You can also change your avatar by uploading an image/photo. 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.



Settings

You can access the Settings menu panel by tapping the hamburger menu (☰) in the top left corner. On the side menu:

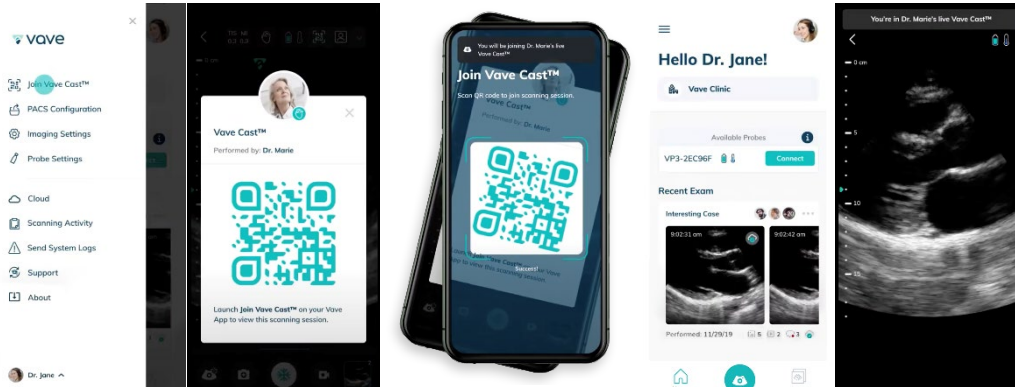


Join Vave Cast™

- PACS Configuration
- Imaging Settings
- Support
- About
- Vave Cloud
- Profile Settings

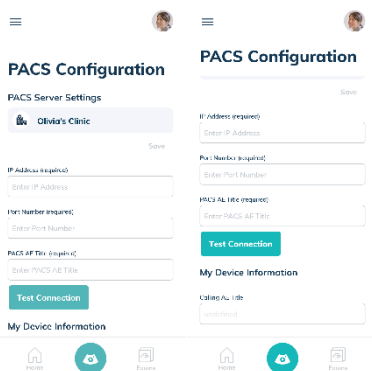
Join Vave Cast™

This allows you to view someone else's Vave Cast session. At the beginning of a session, a QR code will be displayed on the scanning screen. Simply position your device's camera over the QR code and tap accept to start viewing their screen. This is a view-only mode, so you will not be able to make adjustments to the image.



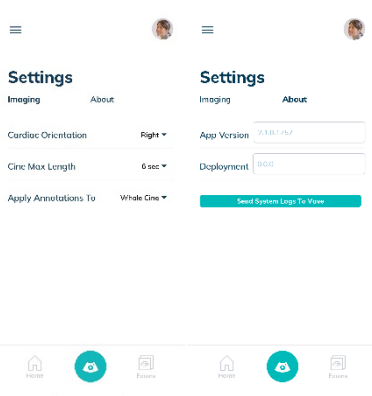
PACS Configuration

You can select an existing PACS configuration or set up a new one — to set up a new one, you will need to contact your Organization Admin to get the Organization IP Address and Port Number.



Imaging Settings

You can adjust the Cardiac Probe Marker Orientation and the Cine Length:



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.

Cine Max Length: The dropdown menu gives you the option to adjust the time a forward recorded cine will be recorded by number of frames.

Apply Annotations To: By default, annotations get applied to the whole cine, but you can change to single-frame annotation.

In the About Section, you can view your App version and Firmware version (if connected to your Vave Probe).

Vave Cloud™



Vave Cloud

Sync Settings



- Images you acquire are automatically uploaded and synced to the Vave cloud by default
- If you wish to disable automatic image uploading and sync, you may turn off Vave Cloud Sync in Sync Settings
- NOTE: When Cloud Sync is disabled, you cannot access powerful features such as exam discussion, sharing, etc.

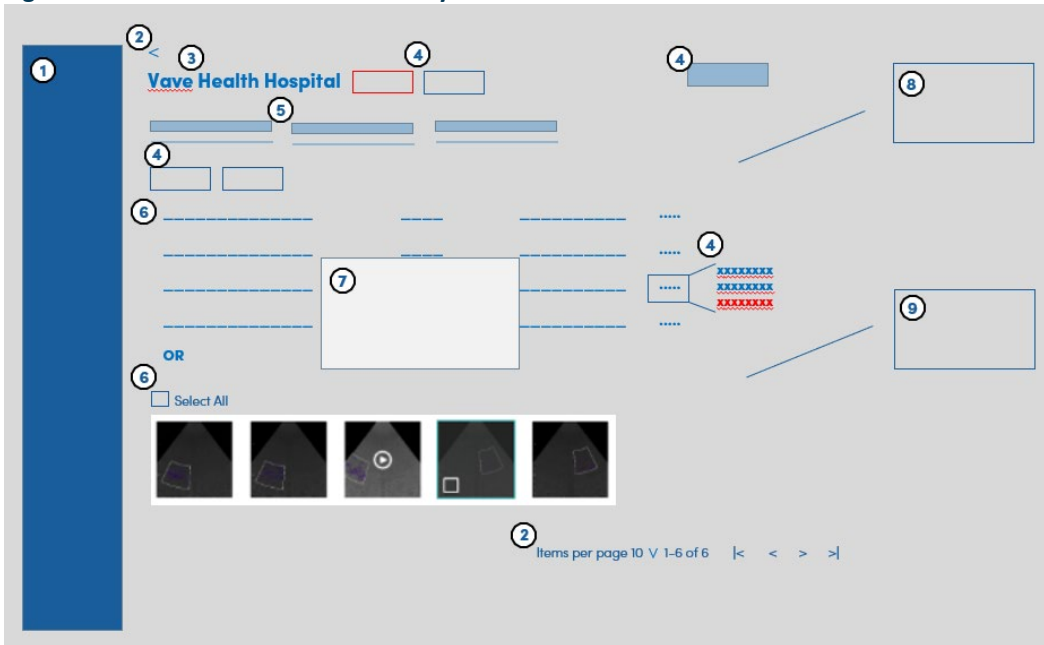


Vave Web Portal Guide for Administrators

Web Portal User Interface Layout and Usage

The Vave Web Portal enables you to manage all organizations, probes and exams that are synced to the cloud. There are four levels: Vave Admin, Organization Administrator, Regular User, and All.

Figure 3.1 Web Portal User Interface Layout



Item	Usage
1	User, Role, Administrative Functional Categories: Organization, Users, Probes, Exams, Scanning Activity, Profile
2	Screen Navigation Controls
3	Organization Name
4	Actions that can be taken as an administrator, i.e., “delete,” “edit,” etc. Click on the Ellipses to bring up a list of actions. Other actions appear throughout the screen as button boxes, i.e., “Create User,” “Add Member,” “Add Probe,” “Create Folder,” “Share Exam,” etc.
5	Tabs listing additional functionality for each Administrative Category. Organization: General Information, Members, Probes, PACS Configuration. Exams: My Exams, My Portfolio, My Shared. Scanning Activity.
6	Lists Organizations, Members, Users, Probes, Exams, Scanning Activity, Image Gallery, or Exams
7	Pop-up Action or Confirmation of Action (i.e., “Delete”) Menu
8	Discussion box
9	Exam Details

Administrative Tasks

Creating an Organization (Vave Administrator Task)

This task is performed by a Vave Administrator. Please contact Vave Health for more information.

Managing an Organization

To manage an organization, click the *ellipsis (...)* in the row of the organization you would like to change. A drop-down menu appears that allows you to *Edit* or *Delete* the organization. In the *Edit Organization* dialog box, you can also change the organization's name and profile picture.

To change the organizations details, click the *Edit* button (when you click on *Organizations* in the side menu, the *General Information* tab displays).

To remove the *Organization*, click the *Delete* button.

On the right, the number of *Membership Seats* is shown for each plan, along with the renewal date for Plus Memberships. Basic memberships do not have an expiration date

Adding a Member

To add an existing Vave Health App user to an organization, click on the *Add Member* button and enter the new member's email address from their account and then allocate their *Membership Seat*.

Editing a Member's Status

To edit a member's status, click the *ellipsis (...)* at the right of the member's row to *Remove from Organization*, *Revoke Admin Rights*, or to *Change Membership*.

Creating a Probe (Vave Administrator Task)

Probes need to be created/deleted by a Vave Admin before they appear on the Web Portal. Please contact Vave Health for more information.

Managing an Organization's Probes

To view all probes attached to the current organization, click the *Probes* tab.

To add a probe, click the *Add Probe* button in the upper right corner and select the new probe's serial number from the drop-down list. Organization Admins cannot add a probe to the portal, but an Organization Admin can add probes to the organization where they can be used by members in that organization to perform exams.

To remove a probe from an organization, click on the *Remove* button on the probe line in the probe listing, then conform removal by clicking the *Remove* button on the *Remove Probe from Organization* dialog box.

Creating a New User

To create a new User, click the *Create User* button in the upper right corner and enter information about the User (only the user's email is required; the rest of the fields are optional).

Managing Users

To manage users (add/modify/delete), click on *Users* in the side menu, then click the *ellipsis (...)* at the right of a User's row and a drop-down menu appears that allows you to open the *Edit User* dialog box and update the user's details.

To view a user's details, click the name in the *User's* list to display *Personal Data*, *Email*, and *Organization* membership.

To update a member's status (*Remove from Organization*, *Revoke Admin Rights*, or *Change Membership*), click the *ellipsis (...)* to the right of an Organization.

To add a user to an Organization/Multiple Organizations, click the *Add Organization* button.

To remove a user from an Organization, click the *ellipsis (...)* on the row of the organization you want to remove and select *Remove* from the drop-down menu.

Managing Exams (Discussion and Exam Details)

To display all exams that are synced to the cloud, click *Exams* in the side menu. The *My Exams* tab shows all exams that you performed. Beneath that tab, you can select exams you wish to view from the drop-down menu, by organization. From there, you can share, rename, and delete exams by clicking the *ellipsis (...)*.

To display more details of an exam, click on a single exam row. You can view all the files (images and cines) that are included in each exam. On the right, there is a record of any *Discussion* around that exam where you can add comments and share them with others regarding the exam. You can edit and view *Patient Data* and *Notes* in the *Exam Details* module, located below the *Discussion*.

To edit *Patient Data*, click *Patient Data* tab and then click the *Edit* button in the *Exams Details* module, then press *Save*.

To edit *Notes*, click the *Notes* tab and then click the *Edit* button to access the *Edit Exam Notes* dialog box where you can update exam notes as needed, then press *Save*.

To enlarge an image for review, click on the image you want to see for an expanded view.

Managing Images and Cines

To display the images and cines that you have collected in folders, click the *My Portfolio* tab.

To create a new folder location for saved images and cines, click the *Create Folder* button, name the folder, then click *Save*.

To share folders, click the *Share Folder* button in the upper right corner, enter the email of the person you want to share the folder with, then press *Save*.

To revoke a share, click the *Revoke Sharing* button above the *Shared With* drop-down list, select the revoke, then confirm by clicking *Revoke* on the *Revoke Sharing* dialog box.

» Note Anyone with whom you shared the package loses access to these files when you select Revoke Sharing. These files will be deleted from their portals. You cannot undo this action.

To manage (rename and delete) folders, click on the folder name, then choose to *Rename Folder*, *Delete Folder*, or *Share Folder*.

To view and participate in a shared discussion of the images in this *Portfolio Folder*, review the *Discussion* module.

Managing Exam Folders

To see all your shared packages of files, click the *My Shared* tab. To see items that other Vave Health users have shared with you, click on *Shared with Me*. To see item(s) you have shared with other Vave Health users, click on *Shared by Me*.

To delete single exam files, select each file you wish to delete – a check mark appears in the lower left next to each thumbnail indicating your selection(s) – then, click the *Delete* button to complete the action.

Sharing Exams

To share an exam with someone, click the *Share Exam* button in the upper right corner, then enter the email(s) of the person(s) you want to share the exam with. By default, the name of the package you are sharing appears in the *Note* field, where you can type in a message to your recipient.

» Note *Shared Exams* are automatically de-identified so they do not reveal any sensitive Patient Health Information (PHI). Please be certain you follow your organization's PHI protocols.

Copying Exams

Copying Exams to My Portfolio:

Select the images you want to copy, click *Copy Exams to My Portfolio*, then select the folder in your portfolio where you would like to copy the images.

Copying Exams from One Folder to Another Folder:

Select the files in the folder in *My Portfolio*, then copy them to another folder.

Or, create a *New Folder*, and then copy the files there after typing in a new folder name.

Managing Your Profile

To view and edit your profile information (*Personal Data, Scanning Activity, Email, Password, Organizations* you belong to, and *List of Devices* you have used to log into), click *Profile* in the side menu.

Resetting Your Password

To reset your password, click the *Reset Password* in the upper right corner.

Viewing Activity

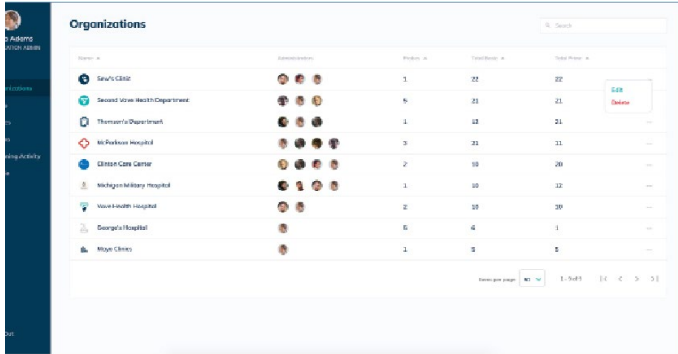
To view your scanning activity, and the scanning activity of all members that belong to your organization, click *Scanning Activity*.

Administrator Screen layouts are shown below.

Organizations

Admins can view, edit, and delete organizations under their management from this menu.

Figure 3.2 Organizations Page



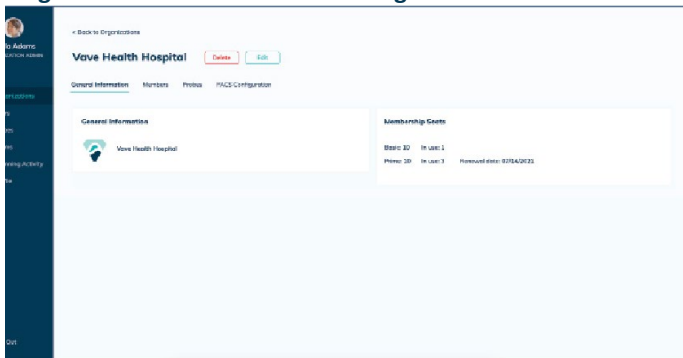
Available Actions:

- Edit (change organization name and profile picture)
- Delete

General Information Page

Organization Details: Contact Information, Membership Seats. Renewal date for Plus Memberships. Basic memberships do not have an expiration date.

Figure 3.3 General Information Page



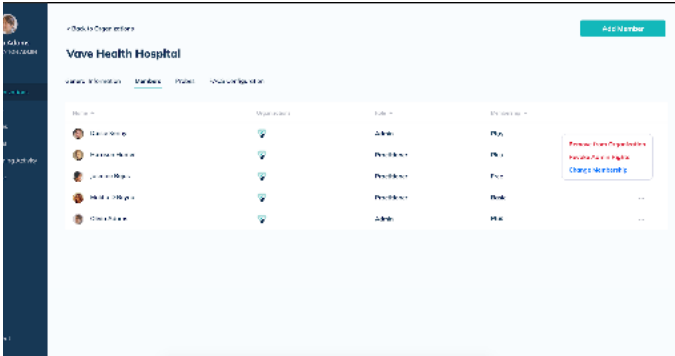
Available Actions:

- Edit Organization
- Delete (removes the Organization)

Members

Displays all the members in that organization.

Figure 3.4 Members Page



Available Actions:

- Add Member (Add new member’s email address, then allocate their Membership Seat)
- Remove from Organization
- Revoke Admin Rights
- Change Membership

Probes

View all probes attached to the current organization.

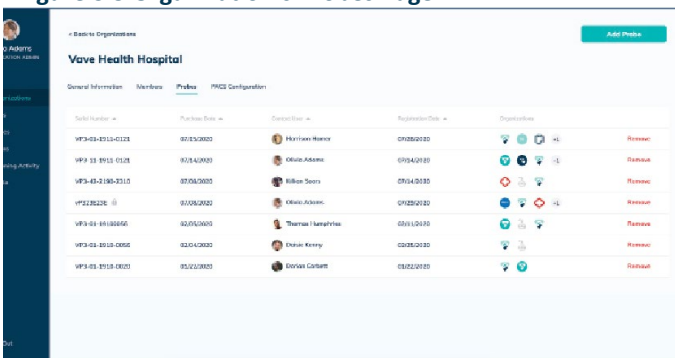


Note

Probes need to be created by a Vave Admin before they will appear on the portal. Organization Admins cannot add a probe to the portal but can add probes to the organization, where they can be used by members in that organization to perform exams.

Organization Admin cannot delete the probe from the portal but can remove it from the organization.

Figure 3.5 Organization’s Probes Page



Available Actions:

- Add Probe to Organization (Select new probe’s serial number from the drop-down list.)
- Delete probe from Organization

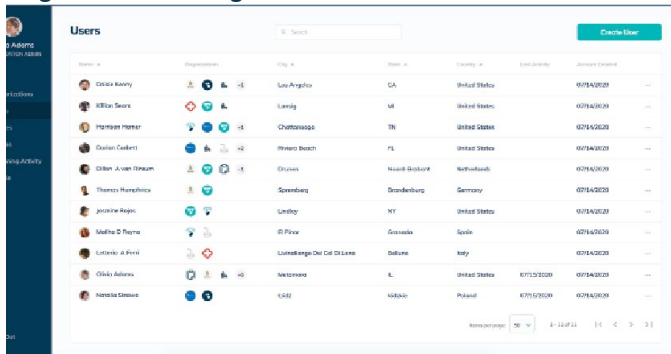
PACS Configuration

Contact Vave Health to configure PACS.

Users

Manage users within an organization.

Figure 3.6 Users Page



Name	Organization	City	State	Country	Email Address	Account Created
Chelsa Avery	USA	Los Angeles	CA	United States	017943020	...
SEENA Sears	USA	Lansing	MI	United States	017943020	...
Theresa Porter	USA	Chattanooga	TN	United States	017943020	...
David Gubert	USA	Riviera Beach	FL	United States	017943020	...
Oliver A van Steen	USA	Orlando	FL	Netherlands	017943020	...
Theresa Hranovica	USA	Schenberg	Germany	Germany	017943020	...
Jessica Ryan	USA	Utterby	NY	United States	017943020	...
Malina D Payne	USA	El Paso	Guatemala	Spain	017943020	...
Lutheke A Ford	USA	Luchaberg-Old Gut D Lanes	Belarus	Italy	017943020	...
Olivia Adams	USA	Wettersen	IL	United States	017943020	...
Harold Green	USA	Madison	Poland	Poland	017943020	...

Available Actions:

- Create User (user's email required)
- View User's Details (click on the user's name)
- Edit User
- Add to Organization(s)
- Remove from Organization(s)
- Revoke Admin Rights
- Change Membership

Probes

View and Manage probes connected to an organization.

Note One probe can be connected to multiple organizations.

Figure 3.7 Probes Page

Serial Number	Product Code	Contact Name	Registration Code	Organization	Manage
VP2-02230	079847030	Oliver Adams	091260010	[Organization Icon]	Manage
VP3-01-21040-2110	079847030	Miller Stone	091400110	[Organization Icon]	Manage
VP2-01-4410-0420	079137020	Jessica Rojas	091290210	[Organization Icon]	Manage
VP1-11-0911-0920	079147030	Oliver Adams	091400110	[Organization Icon]	Manage
VP3-04-0911-0920	079137020	Heather Kramer	091380010	[Organization Icon]	Manage
VP1-08-010104-05	090137020	Harold Fisher	091390010	[Organization Icon]	Manage
VP1-09-0910-0920	030947030	Deane Kenney	091360010	[Organization Icon]	Manage
VP3-01-01100800	030957030	Thomas Langhills	091310010	[Organization Icon]	Manage
VP1-08-0910-0920	010107030	Darion Corbett	091350010	[Organization Icon]	Manage

Available Actions:

- Add Probe to Organization (Select new probe’s serial number from the drop-down list.)
- Delete probe from Organization

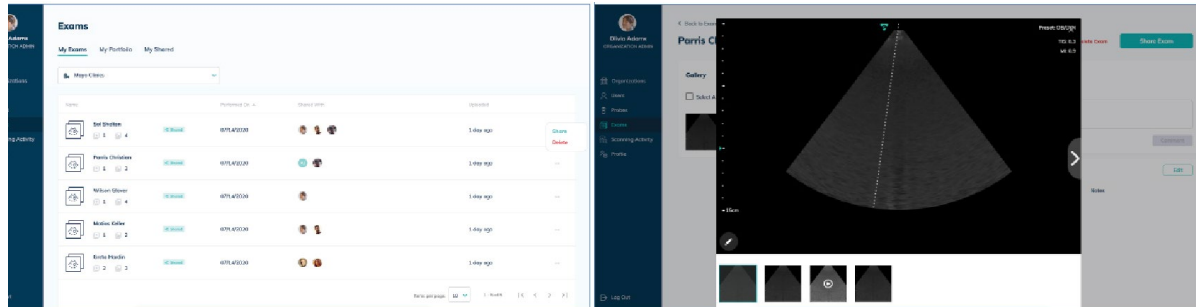
Exams

My Exams, My Portfolio, and My Shared. Click on the image you want to see for an expanded view.

My Exams

Shows all exams that you performed.

Figure 3.8 My Exams Page, Expanded Image View Page



Available Actions:

- View Details (click on the exam's name) of all images and cines in each exam, Patient Data, Notes, and any Discussion around that exam.
- Edit Patient Data
- Edit Exam Notes (click on Notes Tab, then click Edit)
- Rename Exam
- Share Exam
- Delete Exam



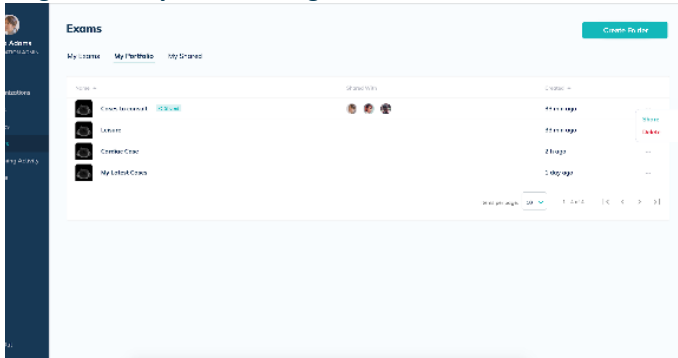
Note You can delete single exam files. Select each file you wish to delete – a checkmark appears on each thumbnail to be deleted.)

My Portfolio

Displays the images and cines that you have collected in folders.

Note Clicking on a folder name allows you to review its contents, which is similar to My Exams, but without the patient data and notes from the exams.

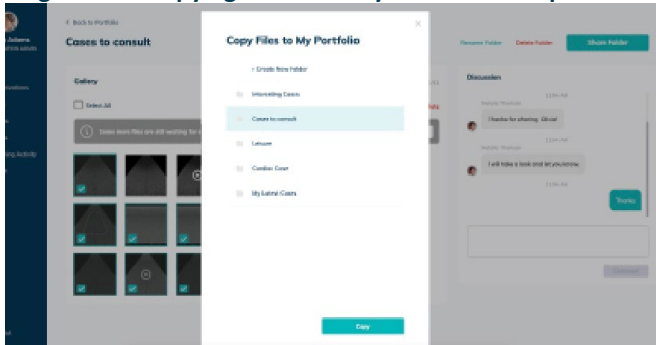
Figure 3.9 My Portfolio Page



Available Actions:

- Create Folder (to save images)
- Rename Folder
- Share Folder
- Copy Files
- Delete Folder
- Discussion Module (You can view and participate in a shared discussion of the images in this Portfolio Folder.)

Figure 3.10 Copying Exams to MyPortfolio Example



My Shared

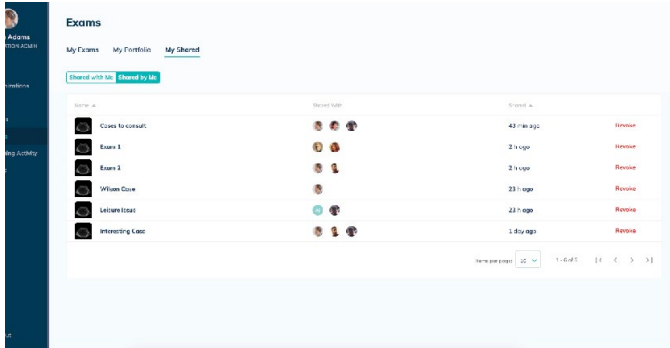
Shared by Me (Displays items you have shared with other Vave Health users.)

- Shared with Me (Displays items other Vave Health users have shared with you.)
- Shared by Me (Displays items you have shared with other Vave Health users.)



Important Note Shared Exams are automatically de-identified so they do not reveal any sensitive Patient Health Information (PHI). Please be certain you follow your organization’s PHI protocols.

Figure 3.11 My Shared Page



Available Actions:

- Share with more people (Enter email of person you want to share the exam with. The name of the package you are sharing appears in the “Note” field, where you can type in a message to the recipient.)



Note Once an exam has been shared, you can share with more people and manage sharing options

- Revoke sharing (Select the name of the revoke from the drop-down list).

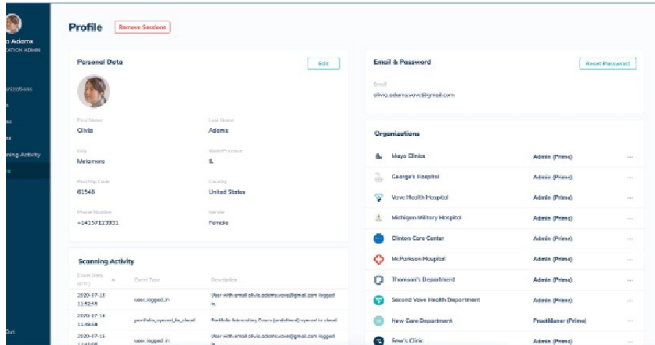


Note You cannot undo this action. Anyone with whom you shared the package will lose access to these files, and these files will also be deleted from their portals.

Profile

Your profile contains Personal Data, Scanning Activity, Email, Password, Organizations you belong to, and a list of devices you have used to log in.

Figure 3.12 Profile Page



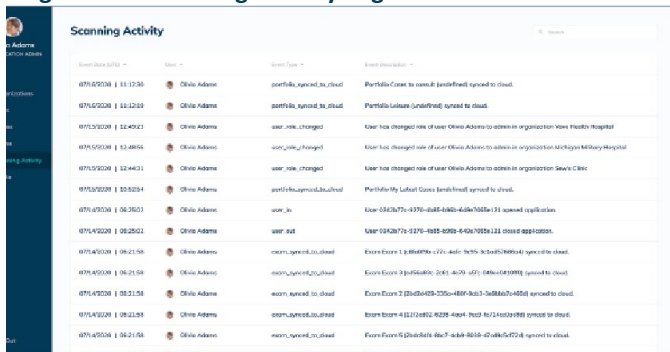
Available Actions:

- View Profile
- Edit Profile
- Reset Password (Click on Reset Password button.)

Scanning Activity

One can view their own activity and the activity of all members that belong to your organizations.

Figure 3.13 Scanning Activity Page



Available Actions:

- View Activity (users and members of their organization)

About and Support

About: Privacy Policy, Terms of Service, and Firmware Version.
 Support: User Manual and Frequently Asked Questions

4 Product Safety

These instructions describe how to use the Vave Probe and App safely. These two safety levels note two types of safety information:

**Danger:**

A danger indicates information critical to safe operation, noting where a severe or substantial hazard may exist to the operator or to the patient through improper use or conditions, resulting in fatal personal injury or significant property damage.

**Warning:**

A warning indicates information critical to safe operation, noting where a severe or substantial hazard may exist to the operator or to the patient through improper use or conditions, resulting in significant personal injury or significant property damage.

**Caution:**

A caution indicates information critical to safe operation, noting where a potential hazard may exist to the operator or to the patient through improper use or conditions, resulting in minor injury or minor property damage.

Diagnostic Ultrasound Imaging

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.

Ultrasound principles of operation

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.

Ultrasound exams

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).

Ultrasound biological interactions

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.

Important Safety Warnings

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

The Vave Wireless Ultrasound is intended for use by trained healthcare professionals. Do not use the Vave Wireless 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.

Patient, Personnel, and Product Safety

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

Product Warnings



Warning: 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 use.



Warning: Product Compatibility

The Vave Probe includes a battery, battery charger and a power supply for the charger. Do not use your Vave Probe or Vave Battery Charger with other products or components made by another manufacturer, unless approved by Vave.

Modifications to the Vave Wireless Ultrasound can only be made only by Vave or by third parties approved by Vave. Any modification must comply with applicable country and regional regulations and laws.

Modifications made using unapproved parts or made without appropriate training, may cause personal injury or damage the system.



Warning: Notifications and alerts from third-party applications

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

- **If the vibration range is too high**, this may cause the scanner to malfunction during an exam.



Warning: Using an improper gel type or combining gel types

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

**Warning: Battery Safety**

If the battery performance appears abnormal during use, while being recharged, or after being stored, emits an odor, is warm/hot to the touch, discolored, or malformed, discontinue use and contact Vave immediately.

Replace the battery if it fails to charge fully.

When disposing of the battery, dispose of in accordance with local custom or facility requirements. Do not discard the battery by fire. Contact Vave Health if further information is required.

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

**Warning: Maximum Probe Temperature**

The system limit for patient contact temperature is 43°C (109°F). The Vave probe will shut down to prevent overheating.

Biopsy Safety**Warning: Biopsy Safety**

The needle must be visible when performing a biopsy procedure.

- Verify the needle's position – needles can bend upon insertion.
- Be aware that reverberation or other tissue artifacts may cause a false needle image.

Electrical Safety**Electrical Safety**

- Before use, carefully inspect the probe. Always inspect the probe before and after cleaning, disinfection, or use. Visually inspect the probe face and housing. If damaged, cracked, chipped, or torn, discontinue use and contact Vave Health.
- Remove probe from the patient before applying high-voltage defibrillation.
- Do not use with pacemaker as high-frequency signals may interfere with a pacemaker.
- Do not connect accessories unapproved by Vave as these could result in electrical shock and/or increased emissions.
- The Vave probe is susceptible to RF interference as Electrosurgical units (ESUs) and other scanners intentionally introduce RF electromagnetic fields (currents) into patients.
- Do not use scanners with high-frequency surgical equipment. A burn hazard may result as the Vave probe has no means of shielding someone from a defect in the high-frequency surgical neutral electrode connection.

**Warning: Defibrillator Safety**

Do not use with Defibrillator. BEFORE defibrillation, remove any part of the system that is in contact with the patient.

Electromagnetic safety



Electromagnetic Safety

The Vave Wireless Ultrasound uses wireless technology to communicate with your iOS/Android device. Wireless communication may be subject to disruption by severe weather conditions and radio frequency interference. Without impacting the safety of the Vave Wireless Ultrasound, the captured image may show signs of unwanted. The Vave Wireless Ultrasound is designed to minimize these affects but may not eliminate them entirely.

Electromagnetic Compatibility

The Vave Probe is compatible with existing electromagnetic requirements and complies with electromagnetic compatibility standards. This compliance provides reasonable protection against harmful interference in a typical medical installation.

Review the environment where you use the Vave Wireless Ultrasound frequently to ensure that the presence of an electromagnetic field is not causing degraded image quality.

Electrostatic Discharge (ESD) Precautions

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

To reduce ESD:

- Use anti-static spray.
- Use a ground wire connection between the Vave Probe and the patient table/bed.
- Do not touch the connector pins on the battery.

Electromagnetic Emissions



System performance may be degraded.

Ensure that the Vave Wireless Ultrasound is used only in those operating environments indicated in the following table.

Declaration of Electromagnetic Emissions

Figure 4.1 Electromagnetic Emissions Compliance

Emission Test	Compliance	Electromagnetic Environment
RF emissions, CISPR 11	Group 1, Class B	The system uses RF energy for its internal function and for wireless communication in the ISM bands. Therefore, its RF emissions outside the ISM bands are very low and are not likely to cause any interference in nearby electronic equipment.
Magnetic Effects, RTCA DO-160G Section 15.0	Equipment Category Z	
Radiated RF Emissions, RTCA DO-160G Section 21.5	Equipment Category M	
Harmonic Emissions, EN/IEC 61000-3-2	Not applicable	Power Line/Signal Line testing is not applicable since the system is a portable device with no signal cables.
Voltage Fluctuations/Flicker Emissions, EN/IEC 61000-3-3	Not applicable	

Electromagnetic Immunity

Figure 4.2 Immunity Test, Test Level, and Compliance Level

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level
ESD EN/IEC 61000-4-2	+/-2kV, +/-4kV, +/-6kV, +/-8kV Contact +/-2kV, +/-4kV, +/-8kV, +/-15kV Air	+/-2kV, +/-4kV, +/-6kV, +/-8kV Contact +/-2kV, +/-4kV, +/-8kV, +/-15kV Air
Radiated, radio frequency electromagnetic field immunity EN/IEC 61000-4-3	10 V/m, 2 Hz modulation 10 V/m, 1 kHz modulation	10 V/m, 2 Hz modulation 10 V/m, 1 kHz modulation
Power frequency magnetic field immunity test EN/IEC 61000-4-8	30 A/m, 50 Hz frequency range 30 A/m, 60 Hz frequency range	30 A/m, 50 Hz frequency range 30 A/m, 60 Hz frequency range

Electromagnetic Interference (EMI)

The impact of electromagnetic interference (EMI) from other equipment upon the Vave Wireless Ultrasound is depending upon the system’s operating mode, image control settings, and the type and level of electromagnetic interference -- which may be intermittent and difficult to locate the source.



Caution: EMI may disrupt the image quality, use caution and relocate the system as necessary.

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.

Questions to ask when trying to locate sources of RF interference:

- Is the interference intermittent or constant?
- Does the interference show up only with one scanner or with several scanners?
- Is the interference present if the system is moved to a different location in the facility?
- What other electronic devices are in the vicinity of the scanner, i.e., printer, other smart devices, radio, TV, etc.?

Recommended Separation Distance

The table below provides guidance on conducted and radiated interference from portable and fixed RF transmitting equipment and recommended separation distances between the system and any RF-transmitting equipment. Follow the recommended separation distance to reduce the risk of interference. Ensure compliance for each frequency range, as noted in the table.

Figure 4.3 Recommended Separation Distances by Transmitter Frequency

Rated Maximum Output Power of Transmitter (Watts)	80 to 2700 MHz	5.2 GHz to 5.8 GHz
0.1	--	15.2 m (49.9 ft)
2.2	3 m (9.8 ft)	--

For example, if a portable transmitter has a maximum radiated power of 2.2W and an operating frequency of 384 MHz, it can be operated at distances greater than 3 m (9.8 ft) from the system.

Biological Safety

Allergic Reactions



Allergic Reaction: Latex Safety

Contact with natural rubber latex may cause a severe anaphylactic reaction.

The Vave Probe does not contain any natural rubber latex. However, be aware of other instances of items containing latex (probe covers, gloves, etc.). Ensure you read the package labeling to determine latex content.

Bioeffects



Bioeffects

- **Thermal (TI):** Thermal bioeffects refers to the heat created by ultrasound energy and tissue's absorption characteristics:
 - **TIB -- Bone:** Dense bone absorbs energy very quickly, which causes the temperature to rise.
 - **TIS -- Soft tissue:** Soft tissue absorption varies by organ. The tissue density within a particular organ is also not always the same.
- **Mechanical (MI):** Mechanical bioeffects, such as cavitation, occur when output exceeds a certain level. This threshold varies depending on tissue type.

References:

- EN/IEC 60601-2-37 – Medical electrical equipment. Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.
- EN/IEC 62359: Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasound fields.
- FDA guidance document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Scanners," September 2008.

ALARA Principles



ALARA Principles

ALARA Principle (As Low As Reasonably Achievable)

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.

Additional considerations:

- Minimize scan time by performing only medically required ultrasound scans
- Use diagnostic ultrasounds efficiently and effectively
- Select the correct scanner application

ALARA Training Reference:

The American Institute of Ultrasound in Medicine provides training in the Medical Ultrasound Safety booklet. This training provides principles of basic ultrasound, possible biological effects, derivation and significance of the indices, and ALARA principles with examples. It is acceptable to the FDA as an effective ALARA educational program. More information can be found here:

In the US: by telephone at 1-800-638-5352

By mail:

AIUM

14750 Sweitzer Lane, Suite 100

Laurel, MD, USA 20707-5908

Output Display



Output Display

The output display provides the user with an indication of the potential for. With this information, users can ensure that diagnostic information is obtained with minimal risk to the patient. Always practice ALARA.

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:
 - Approximate index for the application: TIS is used for imaging soft tissue, TIB for a focus at or near bone.
- **MI:** This is continuously displayed over the range of 0.0 to 1.9, in increments of 0.1.

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.

Controls Affecting Display Indices

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. Use system controls to change the TI and MI values. When a new imaging mode is selected, both the TI and MI may change to default settings. The system will return to the previously selected settings if a mode is turned off and then reselected.

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.
- **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.

Acoustic Power



Acoustic Power

The system limits acoustic output values to their respective U.S. Food and Drug Administration limits. In an over-current condition, the scanner is shut off immediately.

Acoustic Measurement Precision and 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.

Figure 4.4 Acoustic Measurement Precision and Uncertainty

	Precision	Uncertainty (Percentage, 95% Confidence Value)
Pr	<1%	+/- 8.4%
Wo	7.6%	+/- 16.8%
fc	<1%	< +/- 1%
P11.3	2.8%	+/- 16.2%

Notes :

Pr=the underrated peak rarefactional pressure measured in megapascals (MPa)
 Wo=the ultrasonic power in milliwatts (mW)
 Fc=the center frequency in megahertz (MHz) (NEMA UD-2 definition)
 P11.3=the derated spatial-peak pulse intensity integral in joules per square centimeter (j/cm²)

Device Labels



Device Labels

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.

Figure 4.5 Symbols table.

Label	Label Identifier and Purpose
	Company name and logo.
	QR Code
 	Legal Medical Device Manufacturer’s name and address. ISO 7000-3082 Country and Date of Manufacture (United States). IEC 60417-6049
or 	Model Number. IEC 60417-6050 – or - Serial Number. ISO 7000-2498
	Type BF Applied Part (man in the box) symbol. IEC 60417-5333
	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences. ISO 7000-0434A
IP67	The Vave Ultrasound Scanner and Battery can be completely submerged up to 1 meter in water. IEC 60529
	Indicates the need for the user to consult the instructions for use. ISO 7000-1641
	This WEEE symbol indicates that waste electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment. Standard: EN 50419
	Unique Device Identifier (UDI). Indicates a carrier that contains Unique Device Identifier information

Label	Label Identifier and Purpose
	Recycle according to local custom and regulation.
	Battery Charger
	Class II Equipment. IEC 60417-5172
	Federal Communications Commission Identification number. IC ID The Canadian certification ID number relating to radio apparatus and broadcasting equipment. FCC Part 15: Sub-part CRSS-247
	Indicates the temperature limits to which the medical device can be safely exposed. ISO 7000-0632
	Indicates the range of humidity to which the medical device can be safely exposed. ISO 7000-0224

5 Specifications and References

Compliance Statement

The Vave Wireless 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.

The Vave Wireless Ultrasound System

Product Classification

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

- Non-AP/APG

Product Model Number

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

Figure 5.1 Product Model Number

Product Name	Model Number Reference
Vave Wireless Ultrasound	VUSP
Vave Phased Probe	VP3
Vave App	VUA
Vave Battery	VBT
Vave Battery Charger	VCG
Probe Cap	VCP
Lanyard	VLN

Each probe 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: VP3-01-1809-0001

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:

Figure 5.2 Environmental Conditions

	Operating Limits	Transient Operating Limits (1)	Storage Limits
Pressure	620 hPa to 1060 hPa	n/a	n/a
Humidity	15% to 90% non-condensing	15% to 90% non-condensing	5% to 90% non-condensing
Temperature	0°C (+32°F) to + 40°C (+104°F)	-20°C (-4°F) to + 50°C (+122°F)	-40°C (-40°F) to + 70°C (+158°F)

(1) The conditions under which the scanner can operate, for at least 20 minutes, immediately after being removed from an environment of 20°C (60°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 (118°F). The patient contact area will not exceed 43°C (109°F) 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.

System Dimensions

Figure 5.3 System Dimensions

	System Dimensions
Vave Probe	Dimensions: 169 x 54 x 38 mm (including battery) Weight: 205 g (without battery) Frequency Range: 1.5 MHz to 3.5 MHz
Vave Battery	Dimensions: 83.4 x 54 x 21.8 mm Weight: 115 g
Vave Charger	Dimensions: 104 x 59.9 x 44.9 mm Weight: 130 g

Accessories

The following two accessories are provided as part of the Vave Wireless Ultrasound Solution (one battery and one battery charger per system). If you would like to purchase additional batteries or chargers, please contact Vave Health.

Before you begin using your Vave Battery or Battery Charger, clean and disinfect it according to the Cleaning and Disinfecting instructions in Chapter 2.

Figure 5.4 Accessories

Accessory	Description
Battery	The Vave Battery is a removable Li-ion battery, rechargeable only through the Vave Battery Charger. The battery is rated for IP67 and has been tested to IEC 62133 to ensure patient and operator safety.
Battery Charger	The Vave Battery Charger is a charging unit exclusively intended to charge the Vave Battery. The charger consists of electronic components that control the charge profile and an LED light to indicate the charging status of the battery. The battery charger unit includes an off-the-shelf, medical-grade AC/DC wall adapter. The battery charger has been tested to IEC 60601-1 and IEC 60601-1-2 to ensure patient and operator safety.

iOS/Android Specifications



Caution:

Using the Vave Wireless Ultrasound with a smart device that does not meet the minimum requirements may result in low-quality images, unexpected results and possible misdiagnoses.

iOS Devices:

Minimum Device Requirements

- Operating System: iOS 12+
- Processor: CPU: A10+
- Technical Features: GPU: PowerVR Series 7+. RAM: 2 GB+

Recommended Requirements

- Operating System: iOS 13+
- Processor: CPU: A11+
- Technical Features: Apple GPU. RAM: 3 GB+

Android Devices

Minimum Device Requirements

- Operating System: Android™ 6+
- Processor: CPU: Quad-core+
- Technical Features: GPU: Dedicated GPU. RAM: 3 GB+

Recommended Requirements

- Operating System: Android™ 8+
- Processor: CPU: Octa-core
- Technical Features: GPU: Dedicated GPU. RAM: 3 GB+

Battery Specifications

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

Battery Specifications:

Figure 5.5 Battery Specifications

Battery Specifications	Description
Battery Manufacturer	Vave Health, Inc.
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/4800mAh (part VA-0239) 3.7 V/7000 mAh (part VA-0089)
Charge Time	< 12 hours from an empty battery to full charge
Scan Time	Over 1 hour of continuous operation in B-Mode

Hardware

Figure 5.6 Hardware Warranty and Disposal

Warranty/Disposal	Hardware
Warranty	Vave's current warranty policy is pushed on the website, https://www.vavehealth.com . Consult your purchase terms and conditions for specific details.
Disposal	Vave Probe and Accessories can be environmentally hazardous if improperly disposed. Please follow all local, state, and federal regulations and dispose of according to local custom.

Standards

Biocompatibility

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

Electrical Safety

The Vave Wireless 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

Federal

The Vave Wireless Ultrasound System complies with part 15 of the FCC Rules.

Labeling

ISO 60417:2014 — Graphical symbols for use on equipment. See Symbols Glossary in the Safety Chapter.

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

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
- Post Market Management of Cybersecurity in Medical Devices — Guidance for Industry and Food and Drug Administration Staff

Wireless

- U.S. • FCC15.247

Wireless Compliance with FCC and ISED

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 license-exempt RSSs. Operation is subject to the following two conditions:

- (1) This device may not cause interference; and
- (2) This device must accept any interference, including interference that may cause undesired operation of the device.

ISED Radiation Exposure Statement

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

Acoustic Output Tables

B-Mode Operation

Figure 5.7 B-Mode Fundamental Acoustic Output Table

Index Label	MI	TIS		TIB		TIC	
		At Surface	Below Surface	At Surface	Below Surface		
Maximum Index Value	1.01	0.43		0.43		n/a	
Index Component Value	-	0.43	0.43	0.43	0.43	-	
Associated Acoustic Parameter	$p_{r,\alpha}$ at Z_{MI} (MPa)	1.657	-	-	-	-	
	P (mW)	-	71.2		71.2		n/a
	$P_{1 \times 1}$ (mW)	-	33.1		33.1		-
	Z_s (cm)	-	-	n/a	-	-	-
	Z_b (cm)	-	-	-	-	n/a	-
	Z_{MI} (cm)	4.538	-	-	-	-	-
	$Z_{P_{II,\alpha}}$ (cm)	4.538	-	-	-	-	-
	f_{wf} (MHz)	2.719	2.719		2.719		n/a
Other Information	prf (Hz)	1720	-	-	-	-	
	srr (hz)	20	-	-	-	-	
	η_{pps}	1	-	-	-	-	
	$I_{pa,\alpha}$ at $Z_{P_{II,\alpha}}$ (W/cm^2)	207.2	-	-	-	-	
	$I_{spta,\alpha}$ at $Z_{P_{II}}$ (mW/cm^2)	11.04	-	-	-	-	
	I_{spta} at $Z_{P_{II}}$ (mW/cm^2)	25.35	-	-	-	-	
	p_r at $Z_{P_{II}}$ (MPa)	2.54	-	-	-	-	
	Operating Conditions	Preset	Lung	Lung		Lung	
Focus (mm)		50	50		50		

Tissue Harmonic B-Mode Operation

Figure 5.8 Tissue Harmonic B-Mode Acoustic Output Table

Index Label	MI	TIS		TIB		TIC	
		At Surface	Below Surface	At Surface	Below Surface		
Maximum Index Value	1.11	0.21		0.21		n/a	
Index Component Value	-	0.21	0.21	0.21	0.21	-	
Associated Acoustic Parameter	$p_{r,\alpha}$ at Z_{MI} (MPa)	1.451	-	-	-	-	
	P (mW)	-	73.8		73.8		n/a
	$P_{1 \times 1}$ (mW)	-	34.3		34.3		-
	Z_s (cm)	-	-	n/a	-	-	-
	Z_b (cm)	-	-	-	-	n/a	-
	Z_{MI} (cm)	5.15	-	-	-	-	-
	$Z_{P_{II,\alpha}}$ (cm)	5.15	-	-	-	-	-
	f_{wf} (MHz)	1.694	1.694		1.694		n/a
Other Information	prf (Hz)	1320	-	-	-	-	
	srr (hz)	30	-	-	-	-	
	η_{pps}	1	-	-	-	-	
	$I_{pa,\alpha}$ at $Z_{P_{II,\alpha}}$ (W/cm^2)	134.9	-	-	-	-	
	$I_{spta,\alpha}$ at $Z_{P_{II}}$ (mW/cm^2)	16.27	-	-	-	-	
	I_{spta} at $Z_{P_{II}}$ (mW/cm^2)	29.13	-	-	-	-	
	p_r at $Z_{P_{II}}$ (MPa)	1.96	-	-	-	-	
Operating Conditions	Preset	Cardiac	Cardiac		Cardiac		
	Focus (mm)	75	75		75		

M-Mode Operation

Figure 5.9 M-Mode Acoustic Output Table

Index Label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value		1.11	0.08		0.08		n/a
Index Component Value		-	0.08	0.07	0.08	0.08	-
Associated Acoustic Parameter	$p_{r,\alpha}$ at z_{MI} (MPa)	1.451	-	-	-	-	-
	P (mW)	-	73.8		73.8		n/a
	$P_{1 \times 1}$ (mW)	-	34.3		34.3		-
	z_s (cm)	-	-	2.504	-	-	-
	z_b (cm)	-	-	-	-	4.856	-
	z_{MI} (cm)	5.15	-	-	-	-	-
	$z_{P_{II,\alpha}}$ (cm)	5.15	-	-	-	-	-
	f_{wf} (MHz)	1.694	1.694		1.694		n/a
Other Information	pr (Hz)	480	-	-	-	-	-
	srr (hz)	7.5	-	-	-	-	-
	n_{pps}	n/a	-	-	-	-	-
	$I_{pa,\alpha}$ at $z_{P_{II,\alpha}}$ (W/cm ²)	134.9	-	-	-	-	-
	$I_{spta,\alpha}$ at $z_{P_{II}}$ (mW/cm ²)	27.65	-	-	-	-	-
	I_{spta} at $z_{P_{II}}$ (mW/cm ²)	51.28	-	-	-	-	-
	p_r at $z_{P_{II}}$ (MPa)	1.96	-	-	-	-	-
Operating Conditions	Preset	Cardiac	Cardiac		Cardiac		-
	Focus (mm)	75	75		75		-

Color Doppler Mode Operation

Figure 5.10 Color Doppler Mode Acoustic Output Table

Index Label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value		0.96	1.26		1.26		n/a
Index Component Value		-	1.26	1.26	1.26	1.26	-
Associated Acoustic Parameter	$p_{r,\alpha}$ at z_{MI} (MPa)	1.41	-	-	-	-	-
	P (mW)	-	170.8		170.8		n/a
	$P_{1 \times 1}$ (mW)	-	79.4		79.4		-
	z_s (cm)	-	-	n/a	-	-	-
	z_b (cm)	-	-	-	-	n/a	-
	z_{MI} (cm)	4.74	-	-	-	-	-
	$z_{P_{II,\alpha}}$ (cm)	4.74	-	-	-	-	-
	f_{wf} (MHz)	2.15	2.15		2.15		n/a
Other Information	pr (Hz)	2077	-	-	-	-	-
	srr (hz)	23.6	-	-	-	-	-
	n_{pps}	8	-	-	-	-	-
	$I_{pa,\alpha}$ at $z_{P_{II,\alpha}}$ (W/cm ²)	305.4	-	-	-	-	-
	$I_{spta,\alpha}$ at $z_{P_{II}}$ (mW/cm ²)	180.83	-	-	-	-	-
	I_{spta} at $z_{P_{II}}$ (mW/cm ²)	364.22	-	-	-	-	-
	p_r at $z_{P_{II}}$ (MPa)	2.01	-	-	-	-	-
Operating Conditions	Preset	Cardiac	Cardiac		Cardiac		-
	Focus (mm)	50	50		50		-
	ROI Span (degrees)	18.8	56.2		56.2		-

Acoustic Output Table Key

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 $[(4/\pi)(W_0/ITA(z))]^{0.5}$, 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 in 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 $[\min(W3(z), ITA.3(z) \times 1 \text{ cm}^2)]$, where $z \geq z_{bp}$ 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, $z_{sp} = z_{b.3}$) in centimeters.
- **z@PII.3max** The axial distance corresponding to the maximum of the derated spatial-peak pulse intensity integral (megapascals).

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.