vave

Vave Wireless Ultrasound

User Manual

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About This Manual

Note: This document is meant to be used with Vave Health Mobile App version 4.0 and above.

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

Manufacturer:

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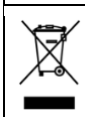
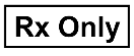
www.vavehealth.com

Symbols Glossary

The symbols listed here may be used in our product literature, this manual, on the Vave probe, its accessories, or packaging, in compliance with ISO and IEC regulatory standards.

Symbol	Title & Description
	Legal Medical Device Manufacturer's name and address. ISO 7000-3082
	Indicates the date when the medical device was manufactured. IEC 60417-6049
	Indicates to read the instruction manual/booklet before starting work or before operating equipment or machinery.
	Indicates device Model Number. IEC 60417-6050
	Indicate device 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
	Indicates that the device poses unacceptable risks to patients, medical staff, or others in the MR (magnetic resonance) environment and must not be brought into the MR environment
IP67	The equipment bearing this mark is dust-tight and protected against temporary immersion in water up to 1 meter in depth for up to 30 minutes, in accordance with IEC 60529
IP22	The equipment bearing this mark is protected against the ingress of solid objects greater than 12.5 mm (such as fingers) and against vertically falling drops of water when the enclosure is tilted up to 15°, in accordance with 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

Symbol	Title & Description
	
	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
	Indicates a medical device that has not been subjected to a sterilization process.
	Caution: United States Federal law restricts this device to sale by or on the order of a physician.
	Indicates the product is a medical device.

1 About the Vave Ultrasound System

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.

Caution

- 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.
- Do not operate the system in the presence of flammable gases, anesthetics, vapors, or liquids. Operation of electronic equipment in such environments presents a significant risk of fire or explosion. To minimize this risk, ensure adequate ventilation and maintain the system in proper working condition, including regular inspection of electrical components.
- 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 Wireless Ultrasound System includes Phased and Universal array probes to support a range of clinical indications.

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.

Product Usage

Indications for use and contraindications are noted below:

Intended Use

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

Rx Only
Caution

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

Indications for Use

The Vave Wireless Ultrasound System is intended to be used by qualified and trained healthcare professionals or practitioners that are legally authorized or licensed by law in the country, state or other local municipality in which he or she practices. The users may or may not be working under supervision or authority of a physician. Users may also include medical students working under the supervision or authority of a physician during their education / training.

The Vave Wireless Ultrasound System is a transportable system that is intended for use in environments where healthcare is provided by trained healthcare professionals. (e.g., Hospital, clinic, medical office), home environment, road/air ambulance and other environments where healthcare is provided. The Vave Charger is to be used in a stationary setting.

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

The following tables show the specific clinical applications and modes of operation for the Vave Wireless Ultrasound System.

Figure 1.1: Vave Ultrasound System Clinical Applications and Modes of Operation

Clinical Application		Mode of Operation			
General	**Specific**	**B**	**M**	**Color Doppler**	**Combined (Specify)**
Fetal Imaging & Other	Fetal/OB	X	X	X	B+M, B+C
	Abdominal (gynecology, renal, and urology)	X	X	X	B+M, B+C
	Pediatric	X	X	X	B+M, B+C
	Small Organ (breast, thyroid, and scrotum)	X	X	X	B+M, B+C
	Musculo-skeletal (Conventional)	X	X	X	B+M, B+C
	Musculo-skeletal (Superficial)	X	X	X	B+M, B+C
	Other (Thoracic/Pleural)	X	X	X	B+M, B+C
Cardiac	Cardiac Adult	X	X	X	B+M, B+C
	Cardiac Pediatric	X	X	X	B+M, B+C
Peripheral Vascular	Peripheral Vessel (arteries, veins)	X	X	X	B+M, B+C
	Other (Non-Vascular image guidance for needle/catheter placement)	X	X	X	B+M, B+C
X = Indication					

Figure 1.2: Vave Phased Probe Clinical Applications and Modes of Operation

Clinical Application		Mode of Operation			
General	**Specific**	**B**	**M**	**Color Doppler**	**Combined (Specify)**
Fetal Imaging & Other	Fetal/OB	X	X	X	B+M, B+C
	Abdominal (gynecology, renal, and urology)	X	X	X	B+M, B+C
	Pediatric	X	X	X	B+M, B+C
	Small Organ (breast, thyroid, and scrotum)				
	Musculo-skeletal (Conventional)				
	Musculo-skeletal (Superficial)				
	Other (Thoracic/Pleural)	X	X	X	B+M, B+C
Cardiac	Cardiac Adult	X	X	X	B+M, B+C
	Cardiac Pediatric	X	X	X	B+M, B+C
Peripheral Vascular	Peripheral Vessel (arteries, veins)	X	X	X	B+M, B+C
	Other (Non-Vascular image guidance for needle/catheter placement)	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 Guidance for nerve block procedures.					

Figure 1.3: Vave Universal Probe Clinical Applications and Modes of Operation

Clinical Application		Mode of Operation			
General	**Specific**	**B**	**M**	**Color Doppler**	**Combined (Specify)**
Fetal Imaging & Other	Fetal/OB	X	X	X	B+M, B+C
	Abdominal (gynecology, renal, and urology)	X	X	X	B+M, B+C
	Pediatric	X	X	X	B+M, B+C
	Small Organ (breast, thyroid, and scrotum)	X	X	X	B+M, B+C
	Musculo-skeletal (Conventional)	X	X	X	B+M, B+C
	Musculo-skeletal (Superficial)	X	X	X	B+M, B+C
	Other (Thoracic/Pleural)	X	X	X	B+M, B+C
Cardiac	Cardiac Adult	X	X	X	B+M, B+C
	Cardiac Pediatric	X	X	X	B+M, B+C
Peripheral Vascular	Peripheral Vessel (arteries, veins)	X	X	X	B+M, B+C
	Other (Non-Vascular image guidance for needle/catheter placement)	X	X	X	B+M, B+C
X = Indication					

Contraindications

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

Essential Performance

For the portable ultrasound system, including the probe, battery, charger, and mobile application, essential performance comprises the ability to generate and transmit ultrasonic energy within specified output limits; receive and process echo signals; transmit data and display diagnostic-quality ultrasound images on the mobile application; and maintain sufficient battery capacity to support continuous operation during intended use.

Operating Position and Visibility

The system is intended to be used with the operator holding the probe and viewing the mobile device screen within the normal field of vision during scanning, at a typical viewing distance of up to 45 cm. The operator is expected to continuously observe the display during image acquisition.
The operator should remain within reach of the patient and near the area being scanned. The patient may be positioned as appropriate for the clinical application (e.g., lying down or standing).
The examination may be performed in the presence of other individuals, provided they do not interfere with the operation of the system or the conduct of the examination.

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

Sheath damage may occur during instrument manipulation. All instruments should be carefully inspected before and after use to reduce this risk. If the sheath is damaged during a procedure, discontinue use, remove and dispose of the sheath, and reprocess the probe in accordance with the cleaning and high-level disinfection instructions provided above. A new sheath must be applied before continuing use

Additional Usage Notes

Caution

- 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.
- Prolonged use of color Doppler should be avoided whenever possible. Color Doppler modes typically involve higher acoustic output, making tissues more susceptible to potential bioeffects such as thermal or mechanical changes. Limit exposure by using the lowest power settings and the shortest duration necessary for accurate assessment.
- Vave ultrasound should not be used in oxygen-rich environments. Chemicals and gases in a surgical environment and altitudes below -382m or above 40000m in the patient's environment may adversely impact the scanner and the exam.
- 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 may include trained healthcare professionals, healthcare students, and in-home users under the supervision of a physician. Use by untrained individuals may result in unsafe operation or misinterpretation of results
- Use of this equipment adjacent to or stacked with other equipment should be avoided, as it may result in improper operation. If such use is necessary, verify that both this equipment and the other equipment operate normally.
- Do not modify any component of the Vave Ultrasound System. Modifications may compromise safety and essential performance and will void the warranty.

Security and Incident Response

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.
- Vave will provide software update in case of any security vulnerabilities.

Please contact Vave support in case Vave mobile application can't connect to Vave probe device. Vave support will evaluate the issue and advise you properly for your probe to become active.
Vave probes can detect fraudulent apps and Vave App can detect fraudulent probe and deny connectivity. App can present user a message in case of the latter.
Security is baked in the device and mobile application. Users do not need to do anything specific to secure the device. Users should follow the security instructions and best practices of their organization.

Recommended Cybersecurity Controls and Product Specification

1. Anti-Malware Software

- Recommendation: Install reputable anti-malware software or the one recommended by your IT team.
- Instructions: Ensure the software is always up-to-date and run regular scans to detect and remove any malware.
- Product Specifications: Compatible with the device's operating system (e.g., iOS, Android). Ensure the anti-malware software supports real-time protection.

2. Use of a Firewall

- Recommendation: Please follow your IT groups security policy. If the IT team is unavailable, please enable and configure a firewall to monitor and control incoming and outgoing network traffic according to predefined security rules.
- Instructions:
- For mobile devices: Use the built-in firewall settings, if available, or a reputable firewall app.
- For computers: Utilize the built-in firewall features in Windows or macOS or consider third-party firewall solutions for enhanced protection.
- Product Specifications: Product is compatible with the device's network configuration and operating system.

3. Password Requirements

- Recommendation: Please follow your IT team's recommendation. Implement strong password policies for your mobile devices.
- Instructions:
    - Use complex passwords that include a combination of letters (upper and lower case), numbers, and special characters to access your mobile device. Optionally enable biometrics.
- Avoid using easily guessable information such as birthdays or common words.
    - Change passwords regularly and do not reuse passwords across different accounts.
    - Enable multi-factor authentication (MFA) where possible.
- Product Specifications: Vave password management service provides a second level of protection.

4. Software Updates

- Recommendation: Regularly update the device's operating system and all installed applications.
- Instructions: Enable automatic updates to ensure the latest security patches are applied promptly.
- Product Specifications: Ensure the device has sufficient storage and processing capability to handle updates efficiently.

5. Encryption

- Recommendation: Use encryption to protect sensitive data.
- Instructions:
    - For mobile devices: Enable device encryption through the settings menu.
- For computers: Use built-in encryption tools such as BitLocker (Windows) or FileVault (macOS).

- Product Specifications: Ensure the device supports the required encryption standards and has the necessary hardware capabilities. Vave application stores images in secure encrypted folder on the device

6. Network Security

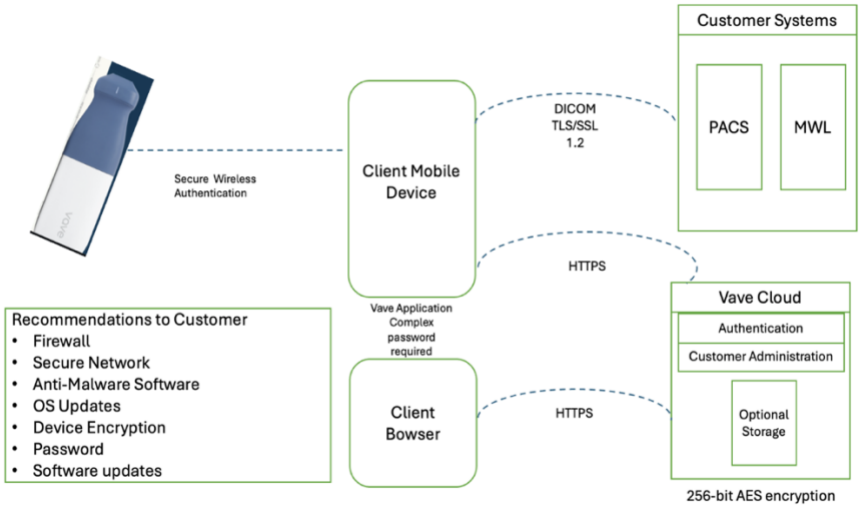
- Recommendation: Secure the network environment.
- Instructions:
  - Use WPA3 or at least WPA2 encryption for Wi-Fi networks.
  - Change default router passwords and update firmware regularly.
- Product Specifications: Ensure the networking equipment is compatible with modern encryption standards and supports firmware updates.

7. User Access Controls

- Recommendation: Implement strict user access controls.
- Instructions:
  - Limit administrative privileges to necessary personnel only.
  - Use role-based access control (RBAC) to restrict access to sensitive information.
- Product Specifications: The system should support RBAC and other access control mechanisms.

Here is a network security diagram that captures the recommended cybersecurity controls:

Figure 1.4: Network Security Diagram



- Mobile and web application connect to backend services using https protocol on port: 443/8443.
- All ports are both incoming and outgoing.
- Mobile application sends information to customer's PACS server over TLS/SSL (Transport Layer Security 1.2/Secure Socket Layer). Data is encrypted data during transmission to ensure privacy and data integrity.
- PACS servers are deployed at customer site. Customer configures our application with proper information to connect with their PACS server. Customer is responsible for configuring their PACS server to protect it from Cybersecurity attack. Vave application sends patient information (name, MRN number, etc.), images and cine to Customer's PACS server. Port number is configured by customer.
- As depicted in the network security diagram, the approved destination endpoints are:
  - Vave Mobile application on Client Mobile device
  - Client Browser
  - Vave Cloud and
  - Customer system: PACS server
- Customers should make sure that they are using secure ports and follow their IT policies.

Decommissioning Mobile devices:

If you intend to decommission your mobile device:

- iOS: Remove the Vave Mobile App to remove any sensitive information from the mobile device.
- Android: Uninstall Vave Mobile App to delete any sensitive information from the mobile device.

Note: A machine-readable version (JSON) of the Software Bill of Materials (SBOM) can be obtained by contacting our support team via email at support@vavehealth.com

Document Conventions

Figure 1.5: 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 1.6: 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 1.7: Screen Icons

	Abdominal
	Cardiac
	Lung
	OB/GYN
	Vascular
	Bladder
	Soft Tissue
	Musculoskeletal
	Scanning Button
	Freeeze
	Gain
	Mode Select
	Capture Image
	Record Cine
	Save Single Frame
	Save Frames Range
	Tools

	Text Annotation
	Line Measurement
	Area Measurement
	Bladder Volume
	Exam Folder
	Videos
	Images
	Cine Indicator
	Share
Shared	Shared Indicator
	Sync Not Started Yet
	Sync in Progress
	Sync Done
	File not Physically on the Device (but on the Cloud)
	Downloading from Cloud in Progress
	Syncing Versioning Conflict

	Eco Mode
	Probe Temperature
	Low Probe Temperature
	Medium Probe Temperature
	High Probe Temperature
	Temperature Warning
	Battery Full
	Battery 30%
	Battery 5%
	Battery Empty
	Battery warning
	Patient Data
	Notes
	Help
	More Icon

	Password Shown
	Password Hidden
	Export Destination
	Organization
	Vave Cast
	Settings
	Support
	Account
	Logout

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 that the mobile device is secured with a passcode, PIN, pattern, or biometric authentication to prevent unauthorized access and potential data leakage. Configure the device to automatically lock after a maximum of 15 minutes of inactivity. Ensure that the mobile device complies with applicable institutional security policies.

Downloading the Vave Health App

The Vave App is available as a free download from the Apple App Store and Google Play Store. A Vave account and the Vave App are required to operate the Vave Ultrasound System.

It is recommended to always install the latest version of the Vave App.

Information on the latest software version, including embedded and supplemental software and the Vave App, is available at: https://www.vavehealth.com/release-notes

Note Some sections of this User Manual may not apply to earlier versions of the Vave App. Make sure you have the latest version of the Vave app.

To download Vave App on an iOS device

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

To download Vave App on an Android device

1. Go to the Google Play Store and search for the "Vave Wireless Ultrasound"
2. To download, tap the Install button and follow the on-screen instructions
3. To launch, tap the Open button

Note

- If you can't find the Vave App, your device might not meet the minimum requirements, or the App might not be available in your country.
- The Vave App has limited functionality on 32-bit Android devices.

Interfaces & Communication Protocol

The Vave mobile application uses the following interfaces and communication protocols:

- Interfaces
  - Wi-Fi 2.4 GHz, Wi-Fi 5 GHz
  - BLE
  - Cellular
- Communication protocols

- HTTPS; TCP; UDP
- User should make sure that Wi-Fi and Bluetooth are turned on for Vave mobile application and device to connect and operate device properly.
- Vave mobile application is designed to connect to probes WIFI even when the probe is not connected to Internet after initial user registration. User needs connectivity to internet every 30 days.
- Minimum Networking Requirements
  - Vave ultrasound device connects to Vave-mobile application using our built in WIFI router.
- Supported Encryption Interfaces
  - HTTPS and TLS 1.2 are used for data transfer.
  - Data at rest is AES 256 encrypted.
- Responding to Cybersecurity Vulnerabilities or Incidents
  - Customer's IT team should implement continuous monitoring tools to detect unusual or unauthorized activity.
  - Customer should contact Vave at support@vavehealth.com to report any suspicious activity.

Updating the Vave Probe

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

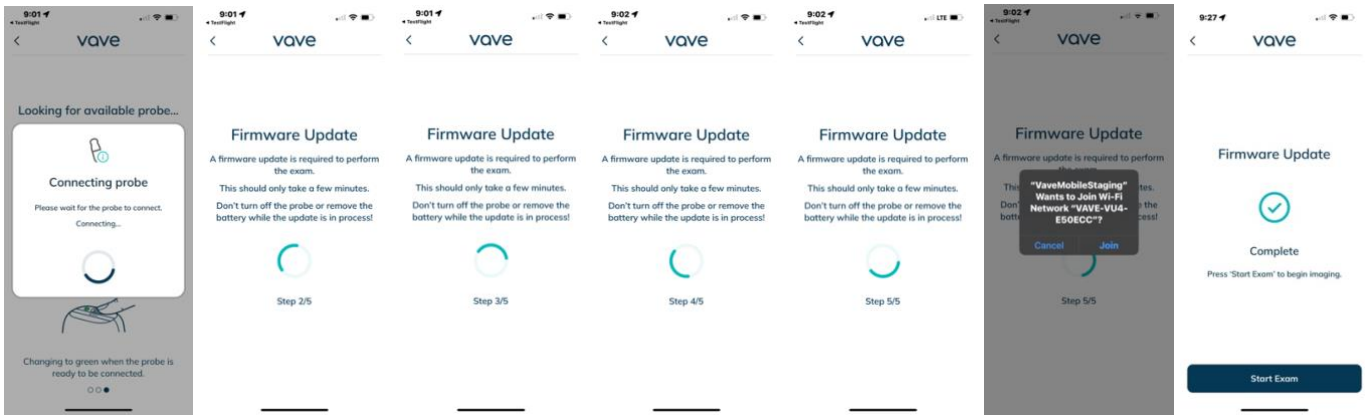
Software Updates

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

The Firmware update will automatically start when there is a new Firmware version available in the Vave mobile application. The Firmware update may stop if the battery is not charged above 25%. The Firmware update will go through the following 5 step process:
Step 1: App will connect to probe and start the update process
Step 2: Probe LED light will begin blinking white
Step 3: Probe LED light will turn sold white
Step 4: Probe LED light will turn solid blue
Step 5: Probe LED light will turn solid green

If the update is successful, the application will prompt the user to connect to the probe's WIFI and show the firmware update complete screen. The User can click on "Start exam" button to start exam. If the screen stating that the upgrade was not successful appears, a prompt to try again will appear that the user should follow.



The Vave support team will address all customer concerns, including any cybersecurity concerns. Vave will push all software updates by releasing a new version of the software and using App Store and Playstore distribution mechanism to make it available to customers.

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, below
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.

Note that Vave batteries are interchangeable with all other Vave probes.

Figure 2.2: Inserting the Battery

Removing the Battery

To remove the battery from the Vave Probe:

1. Pull the battery away from the nosepiece of the Vave Probe
2. Slide it all the way off

Turning the Vave Probe and Vave App 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.

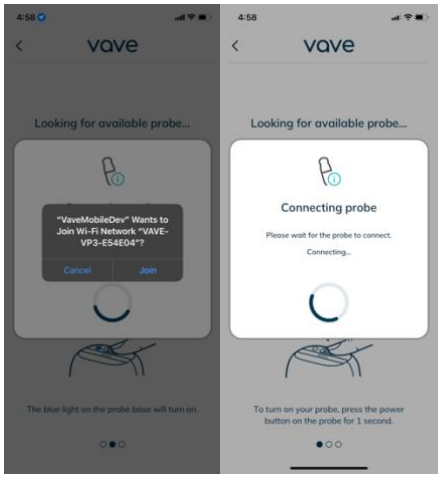
Figure 2.3: Probe On/Off

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

1. Please read Interface and Communication section of this manual before proceeding.
2. Open the Vave Health App and turn on your probe.
3. 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.
4. The App guides you through the connection process where you will join the probe Wi-Fi and when connected, the Imaging screen appears, and you can start an ultrasound scan.



Automatic Probe Shutdown

To conserve battery life, the probe will automatically shut down if it is not connected to the Vave App after a set period.

Account Lockout After Multiple Failed Login Attempts

After 5 or more failed attempts, an error message is displayed and you need to wait a specific time (depending on the failed attempts) until you can log in again.

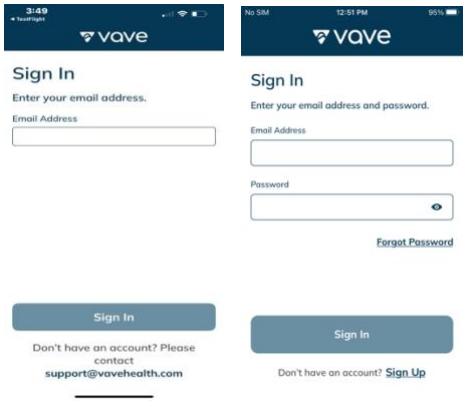
Exam Workflow Overview

Caution

The probe should be inspected before and after each use, as well as before and after cleaning and disinfection. Regular, thorough inspection helps prevent patient injury and ensures high-quality imaging.

Sign-In Page

When you open the Vave Health App, it displays an email validation screen. After the user has entered an email, the App will either request to validate the email or display 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.

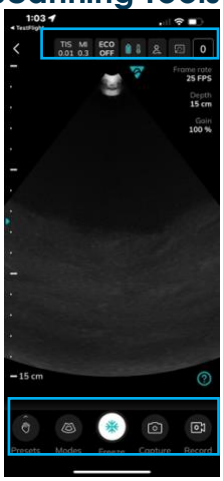


Menu Options

Note: Starting with 4.4 Release, the Home Screen is the My Exams screen.

Note: In My Exams screen, you can pull down the exam list to sync data

Scanning Tools



1 2 3 4 5 6

1 Acoustic Power, TIS/MI
2 ECO Mode button
3 Battery and Temperature
4 Patient Info
5 VaveCast QR Code
6 Image Gallery

7 8 9 10 11

7 Application Preset
8 Image Mode
9 Freeze
10 and 11 Single and Multiple image capture (cine)

How to Begin Scanning

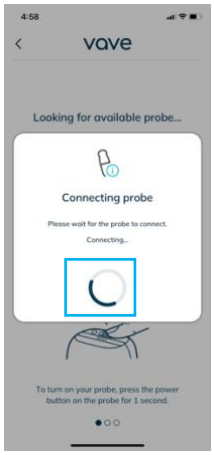
1 Once you're signed in, you will see the Home screen. Turn on the probe. Tap the circular Scan Start Exam in the center of

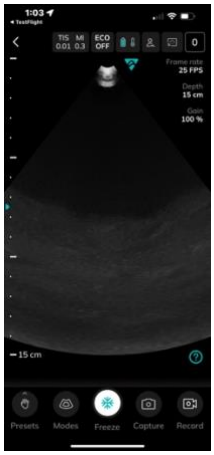
1 2 3

the bottom menu to start scanning.

2 The app guides you through the connection process.

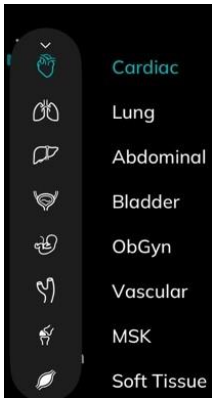
3 Once you're connected to the probe, you can start the ultrasound scan.





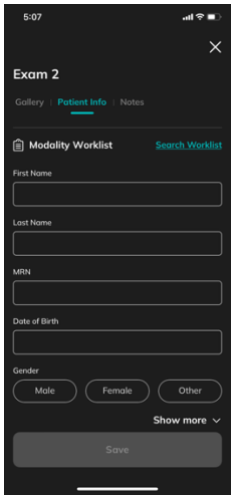
Select Application Preset

Depending on the clinical indication, choose the desired preset. The system will start with the Cardiac preset the first time its used, and automatically load the last preset used (or the default preset set in settings) after that.



Enter Patient Information

Tab more icon and click Patient information



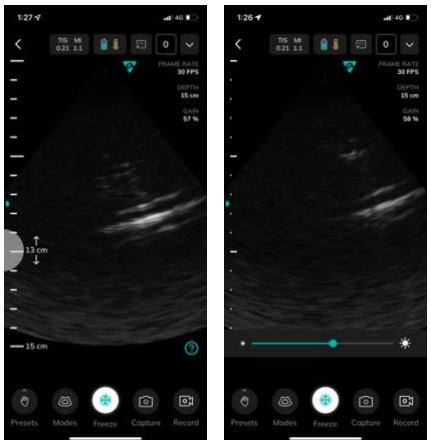
Imaging Screen

Here you can:

1 Manipulate the depth, gain, and focus position of the image.

2 Freeze or save images/movie clips.

1 2



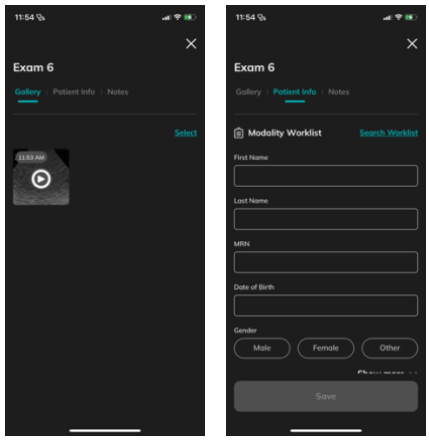
Gallery

During imaging sessions, you can:

1 Evaluate and edit images and cines acquired during the exam.

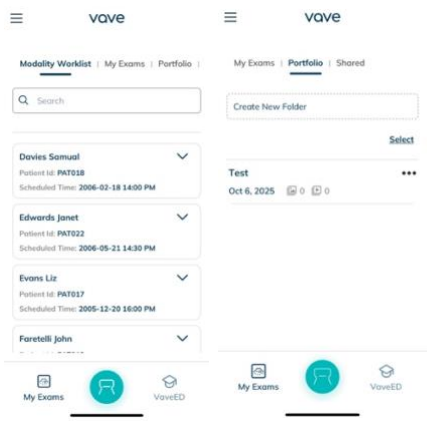
2 Access Patient Data, Exam Notes and Discussions.

1 2



Exams Screen

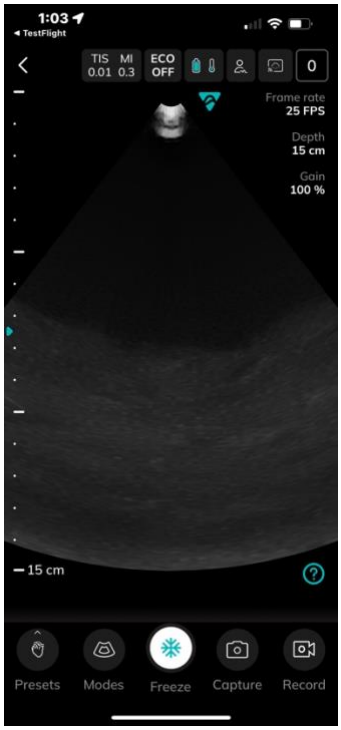
Tap the Exams option in the menu of your Home screen to review all of your Exams and access the Modality Worklist, Portfolio, and Shared tab.



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. Longer scanning sessions (>15min) are possible but may incur a thermal buildup noticeable to the user. In the event this occurs the system may undergo an automatic thermal shutdown to prevent excessive heat accumulation or any potential harm.

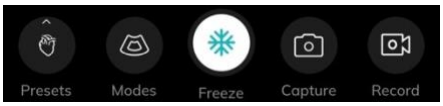
Imaging Display Overview



The imaging display screen includes:

- Exam Information (TIS Value: 0.01 and MI Value: 0.3)
- Image Information (Preset, Frame Rate, etc.)
- An ultrasound image in the center of the screen

Modes, Capture tools Gallery Icons:




Mode Select (Fast/Slow Flow, M-Mode, return to 2D)


Image/Video Capture


Freeze Button


Record CINE

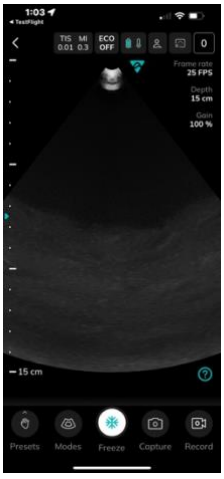
Image Gallery

Selecting the 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 at the bottom of the screen.
Some of the modes may not appear on each probe.

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 (if

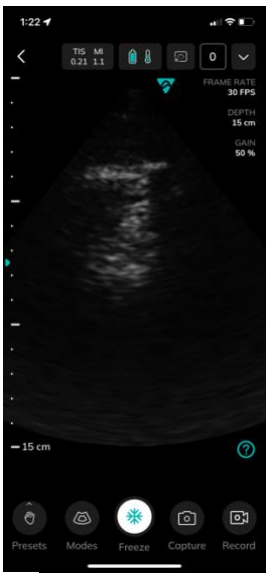
1 Tap the Mode control.

available on probe)

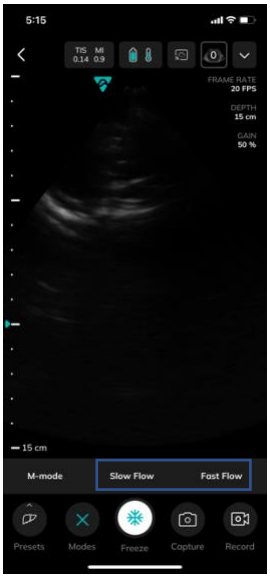
2 To access Color Doppler Mode, tap either Fast Flow or Slow Flow in the Mode bar.

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.

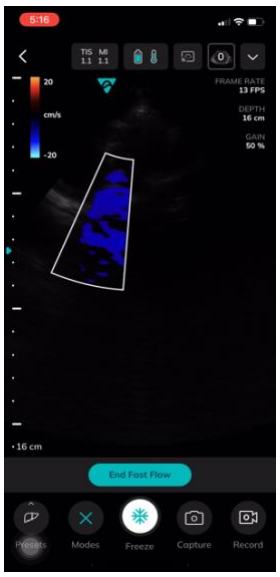
1



2



3



Note

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

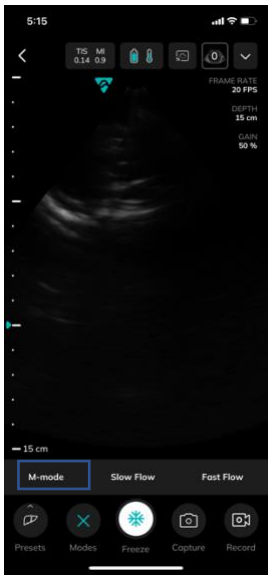
M-Mode (if available on probe)

1 Choose M-Mode in the Mode bar.

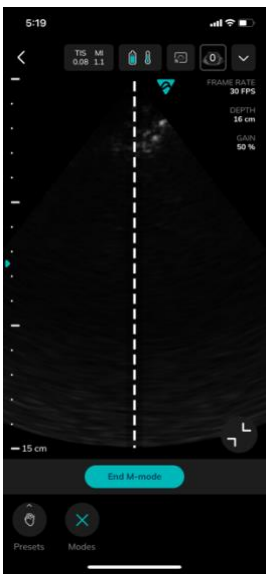
2 Initiate M-Mode by positioning your M-Mode cursor.

3 When you release the M-Mode cursor, the M-Mode strip appears just below the B-Mode reference image.

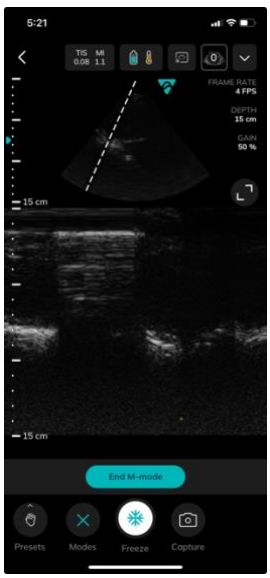
1



2



3



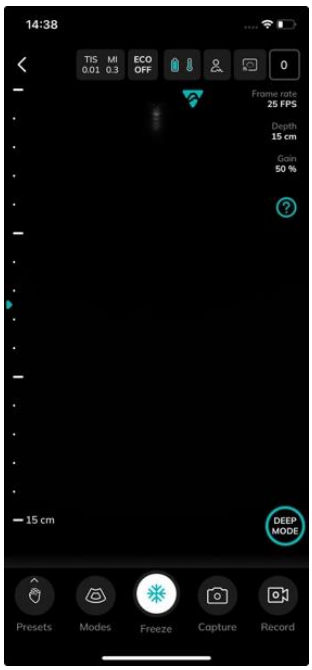
Note

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.

Deep Mode

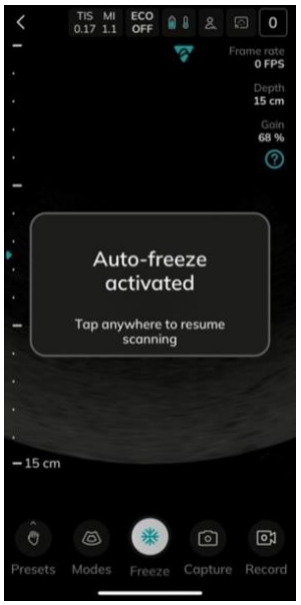
To optimize visualization of deeper anatomical structures, the system includes a Deep Mode feature available in the Cardiac and Abdominal presets. When activated, the system automatically adjusts imaging parameters to enhance image quality at greater depths. How to activate:

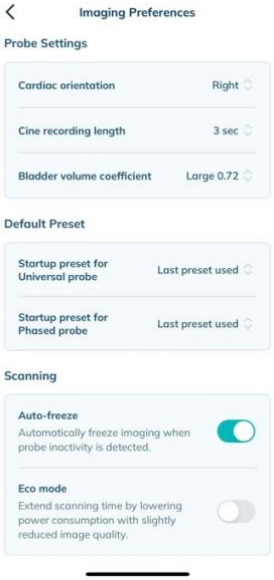
- Select the Abdominal or Cardiac preset
- Tap the Deep Mode button to enable.



Auto Freeze

For optimized heat management, the system includes an Auto Freeze feature. If no changes are detected in the scan image, the system will automatically freeze to prevent unnecessary power consumption and heat buildup. Scanning can be resumed by tapping on the screen to unfreeze the image.





You can manage this feature through the Imaging Preferences tab:

- The "Auto Freeze" toggle is ON by default.

- To disable Auto Freeze, navigate to Imaging Preferences > Scanning > Auto Freeze and switch it OFF.

Adjusting the image

- **To adjust Depth**, swipe up (deeper) or down (shallower) 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** 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. It will be positioned to the closest focal point available by the system.
- **To show or hide a centerline**, tap the Centerline (triangle) icon.
- **To zoom into a frozen image,** use pinch gestures to zoom in or out and drag to reposition the magnified view as needed. You can also double tap to zoom, and double tap again to return back to the default size.

Snap, Freeze/Unfreeze, Save Image and Cines

- **To save an image** directly to the gallery, tap the camera icon. The number displayed will increment with each capture.
- **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.

Centerline

A Centerline tool is available during scanning. How to use it:

- Select any imaging preset.
- Tap the Centerline (triangle) icon to show or hide the centerline.

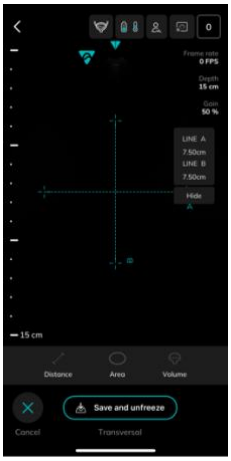
Bladder Volume Tool

The Bladder Volume tool allows you to estimate bladder volume. How it works:

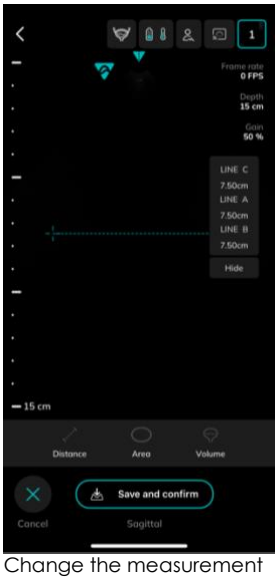
- From the scanning screen, choose the Bladder preset.
- Press Freeze and choose the Volume tool.
- Use the bladder volume tool to adjust preplaced linear measurement calipers along the bladder borders in 1. Transverse and 2. sagittal view.

- The system automatically calculates the estimated bladder volume using the formula: **Volume = L × W × H × 0.72,** where L = length, W = width, and H = height of the bladder. Note: the coefficient is configurable from the settings screen to 0.72 or 0.52)

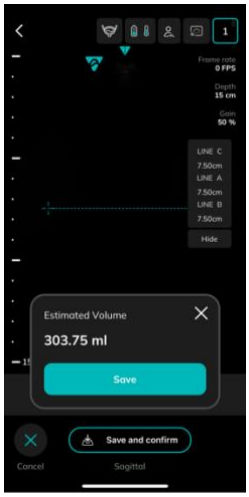
Note: Ensure the bladder is fully visualized and measurements are placed accurately for the best results.



After step 2: Change the measurement and click "Save and unfreeze" to adjust the sagittal view measurement.



Change the measurement and click on the save and confirm button.



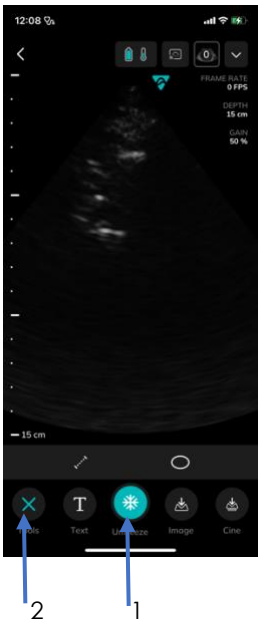
The measurement is being displayed.
Save the measurement or cancel by click on "x"

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

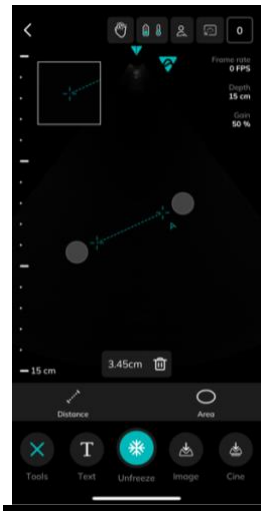
1. **Press Freeze.**
2. **To measure, select Measurement Tool (Linear or Area Tool). --or-- Tap the "T" Type icon to activate annotations.**



Linear Measure

Note

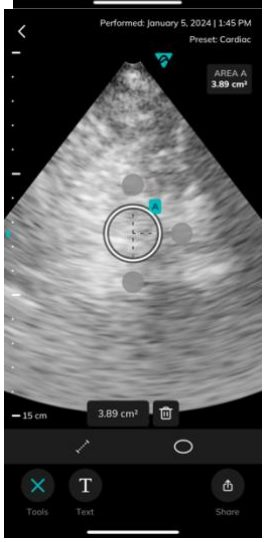
To move a linear measurement, drag and drop each end of the line individually. The displayed value will automatically update with each endpoint position change.



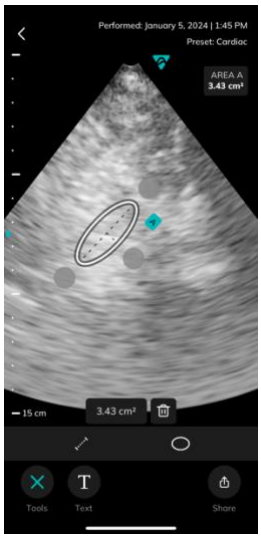
Area Measure

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 default area outline. The displayed value will update with each waypoint position change.



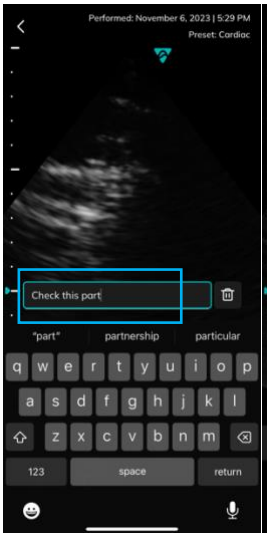
1

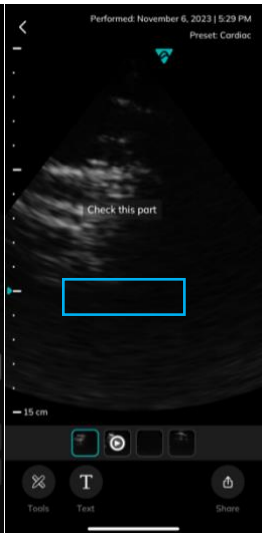


3

Text Annotations

1. A text box and keyboard appear. Start typing notes.
2. When finished, tap the image. The text box and keyboard disappears and the text turns green, indicating that the text can be dragged to the desired location.
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. Text and Measurements can be captured and saved to the image gallery.

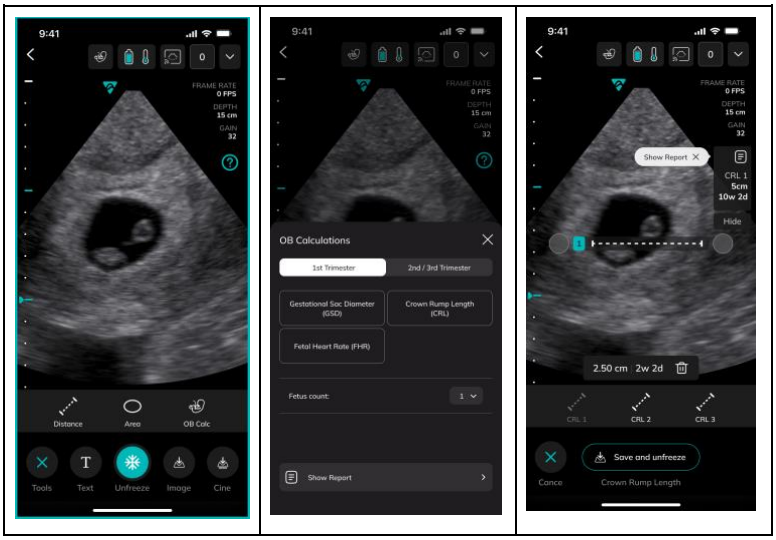
Obstetric (OB) Calculations

To measure fetal structures, the system supports Obstetric calculations. The OB preset includes a calculation module that enables fetal biometric measurements for 1st, 2nd, and 3rd trimester exams.

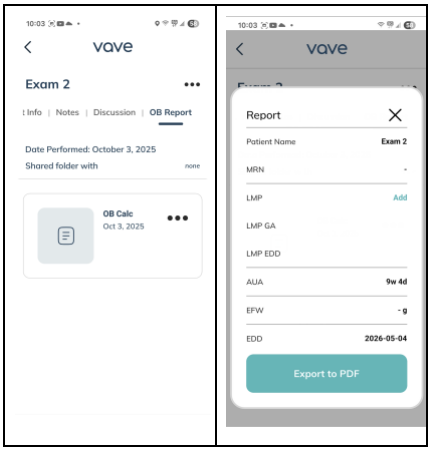
How to use:

1. Select the **OB preset**.
2. Freeze the image and tap the **Tool icon**.
3. Select **OB Calcs** to open the calculation module.
4. Choose the applicable trimester:
    - **1st Trimester:** Gestational Sac Diameter (GSD), Crown-Rump Length (CRL), Fetal Heart Rate (FHR).
    - **2nd/3rd Trimester:** Biparietal Diameter (BPD), Head Circumference (HC), Abdominal Circumference (AC), Femur Length (FL), Fetal Heart Rate (FHR).
5. Choose the number of fetuses, if more than one (the system accepts up to three)
6. Perform the measurement using standard caliper tools:
    - **Linear calipers** for GSD, CRL, BPD, FL.
    - **Elliptical calipers** for HC, AC.
7. Adjust calipers as needed before confirming.
8. Confirm to save the measurement to the exam.

A **report view** is available, summarizing all OB measurements performed during the exam. To show the report, tap the report icon on the right side of the screen above the measurements result, or the option to "Show Report" on the main OB Calculations window.
To change a measurement: delete the existing result and re-measure.



After the exam is performed, the report can be viewed from one of the Exam page tabs. Once opened, there is an option to Export the report in PDF format to the device, print or share it with others.



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.

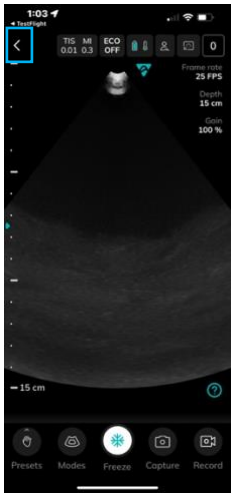
Vave Cast™

Note

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

Ending an Exam

Tap the back button located in the upper left corner of the imaging screen. There will be an option to also turn off the probe if no further imaging is going to be performed.



Review Findings

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

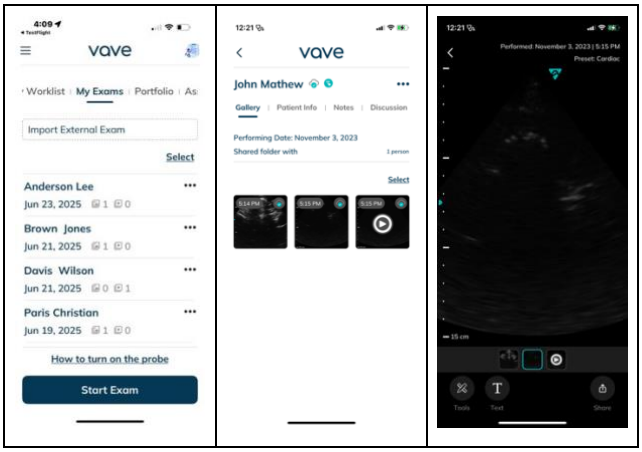
Saved Exams:

- 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”
  - My Exams – shows you all the exams that you have performed
  - My Portfolio – allows you to collect and organize ultrasound images for your “portfolio”
  - My Shared – allows you to manage the exams you have shared with others, and those others have shared with you
- Each section can have several folders — tap a folder name to open and view the ultrasound images
- To add a new folder, tap “+ Create New Folder" and name the folder

You can free up space from your local storage by deleting data files associated with exams in My Exams, Portfolio, and Shared folders. Click on “Select”, select all or select individual exams and click on the trash icon.

Reviewing Images and Cines

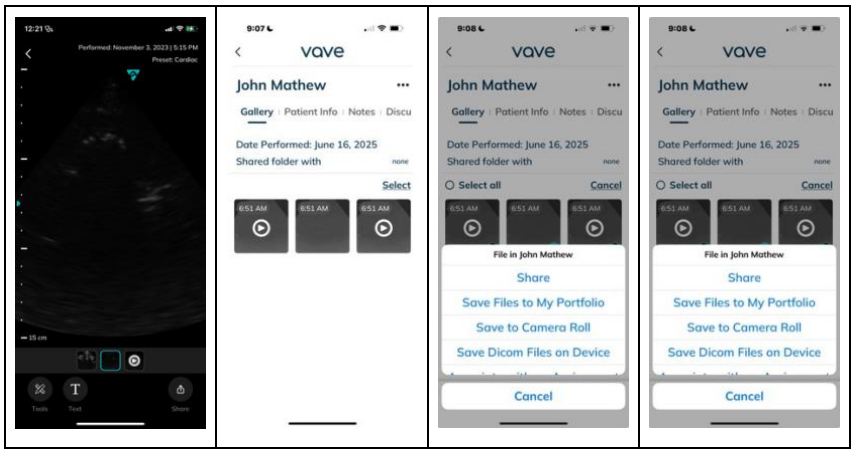
Go to My Exams. Tap on a specific exam, then select Gallery to view all images from that exam. In the Gallery, you can review saved images/cines — and simply tap on an image to open a detailed image view.



Manage Images

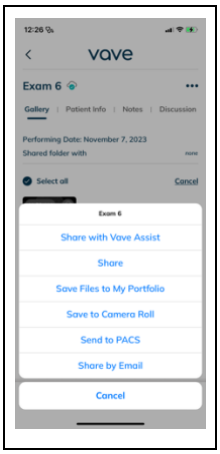
- **To select several images/cines:** tap the select option and tap the images/cines you want to select.
- **To delete images/cines:** select the image(s)/cine(s) and tap the trash icon.
- To export/share images/cines:
  1. Select the image(s)/cine(s) and tap the Share icon
  2. Export/share Options will appear:
     - Send via Email
     - Save 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 "Save Files 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 institutional procedures regarding PHI.

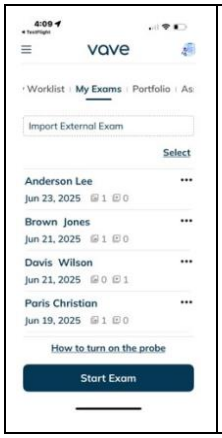
Operations available on an Exam

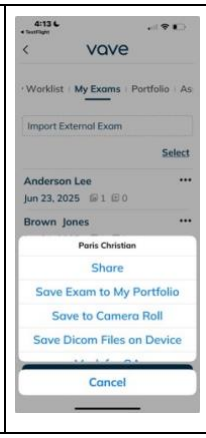
Save Exam to My Portfolio	Save all the cines/images in the exam in a portfolio
Save to Camera Roll	Save all the cines/images in the exam in photo folder of your device
Save Dicom Files to my Device	Save all the cines/images in the exam as Dicom file on user selected drive
Mark for QA	Exam is marked for QA. Only if QA is enabled for the organization
Send to PACS	All the files are sent to a PACS server
Share by Email	All the cines/images in exams are shared via email
Delete Locally	Deletes data from mobiles for the all the cines/images in a folder
Delete	Delete the whole folder.
Restore to Original	Ability for a user to restore to the original version of the exams. Annotations and measurements will be lost. Only available for exams available on device
Delete Backup	Delete the backup copy of the exam
Restore to Local Copy	Restore the exam to a local copy of the exam from the App.

Table: Exam level operations

Share Exams

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

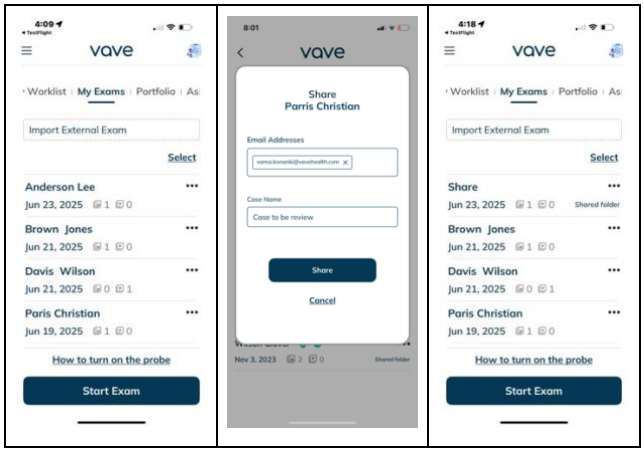




- Share
- Save Exam to My Portfolio
- Save to Camera Roll
- Save Dicom Files on Device
- Send to PACS
- Share by Email
- Restore to Local Copy
- Restore to Original
- Delete Original Backup
- Delete

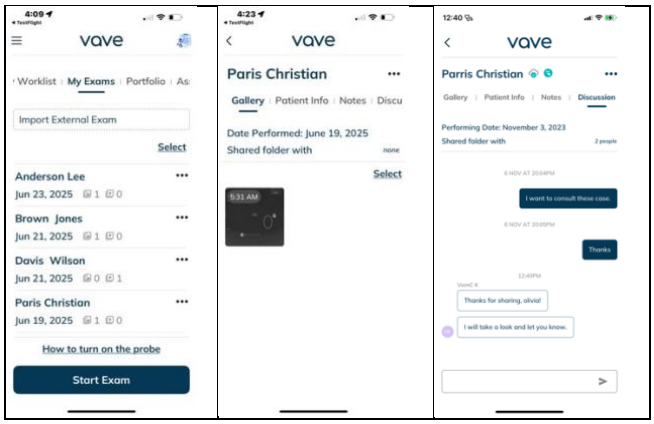
To Share:

1. On the Exams screen, tap the exam you would like to share and input your recipient's email address.
2. Tap the blue "Share" button.
3. You will see the response "Exam shared successfully" when complete.
4. To review your shared Exams, go to the "My Shared" tab and select "Shared by me" or "Shared with me"

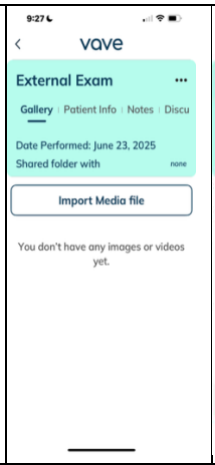
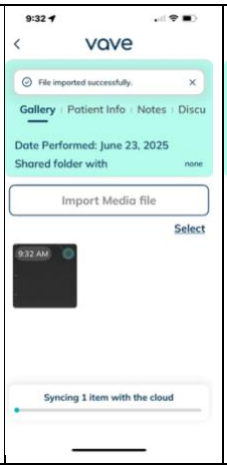
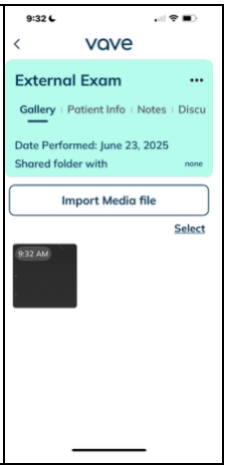


Exam Discussion

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.



Importing External Exam

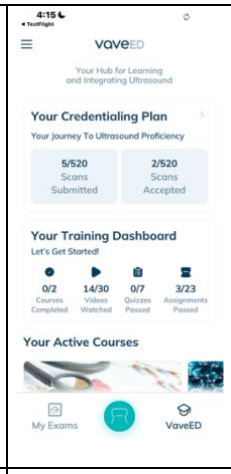
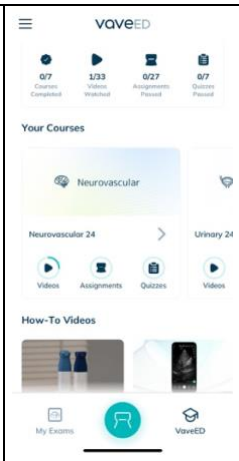
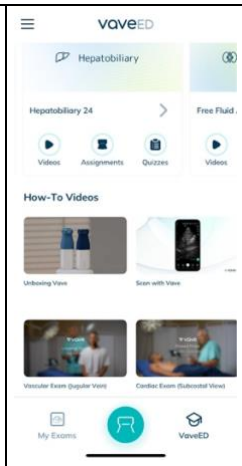
				
Click and type the name of the exam in the Import External Exam text field	A new exam is created. The background color is different for these exams. Click on the name of the exam to open.	Click on the "Import Media file". Select image/cine.	Image is imported and synced to cloud (if applicable).	Click on the image to view.

VaveED

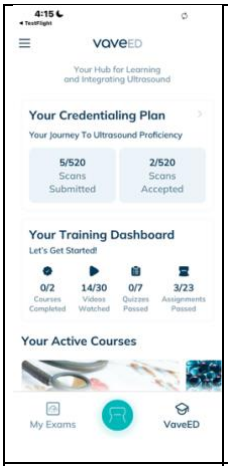
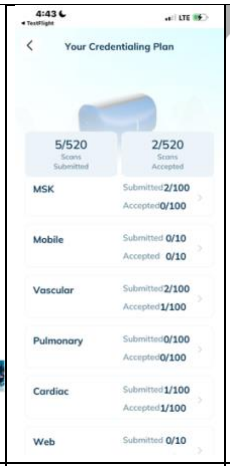
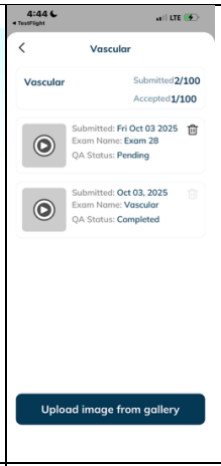
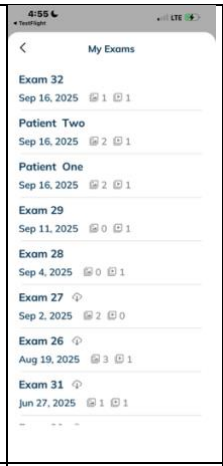
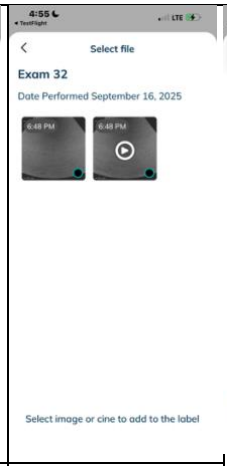
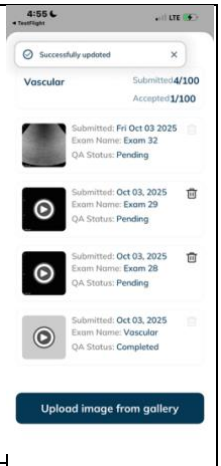
Note: The VaveED feature is available for selected users or may be purchased separately, depending on your account configuration and subscription plan.

On the App home screen, tap the **VaveED** button in the lower right corner to access the VaveED homepage. This section provides tools and resources to support your training and credentialing progress.

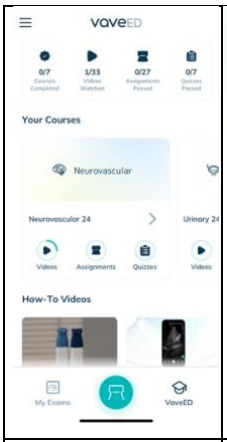
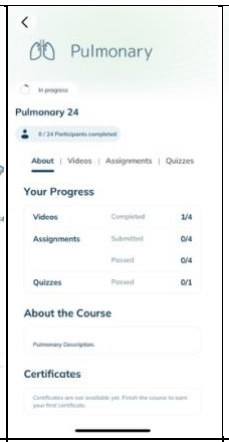
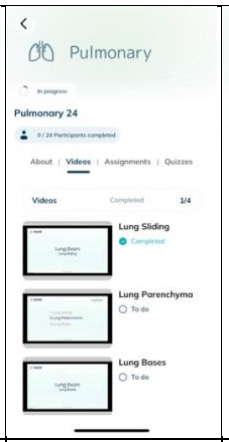
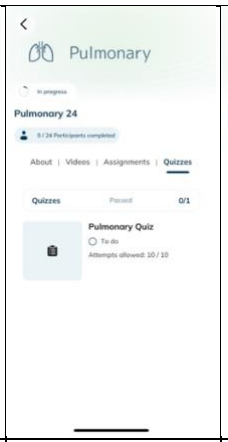
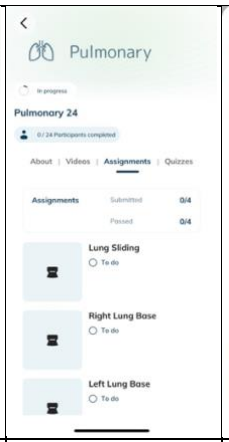
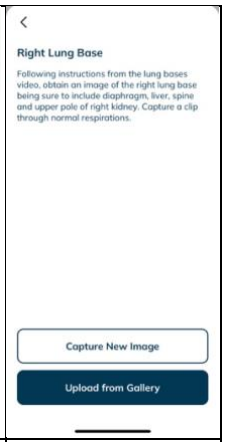
- **Your Credentialing Plan** – Displays your progress with a summary of scans submitted and accepted.
- **Your Training Dashboard** – Track completion of courses, videos watched, quizzes passed, and assignments completed.
- **Your Active Courses** – View and continue the courses you are currently enrolled in. Within each course you can navigate through tabs:
    - **About** – Course description and objectives.
    - **Videos** – Educational videos linked to the course.
    - **Quizzes** – Tests to check your knowledge.
    - **Assignments** – Upload scans from the gallery or capture new images directly, then submit them for QA review. Progress within each tab is tracked automatically.
- **How-to Videos** – Access short instructional videos to guide you through using the system and its features.

			
On the Home screen, click on the VaveED button. You will see your integrated learning hub page. It consists of: - Credential plan - Learning Education Module - How to Video's	Credential plan: This is available to a user when credential plan is turned on for an organization and the user is enrolled in a credential plan. Click on credential plan to see and fulfill your credential requirements.	Training dashboard: This is available to a user when learning module is turned on for their organization and they are enrolled in courses. Click on the course icon to learn more about courses and do the activities.	How to Video section: This is available to all users. You can click and see how to video's.

Interacting with Credential Plan

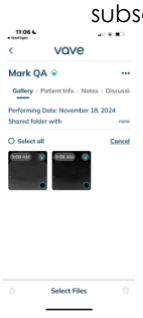
					
Click on the arrow next to "Your Credential Plan"	You will see a list of areas and required number of cines/images to be loaded to meet the requirement. You can click on a topic. Credential plan will be created by an Admin. Users are associated with a plan by the Admin also.	You can click on a topic to Upload a new image/cine or delete an existing image/cine. Click on Upload Image from gallery.	You will be taken to the exam gallery. Click on an exam.	Select one or more images/cines to associate it with the Image label.	

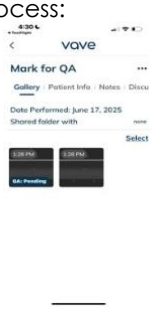
Interacting with Course

					
Click on one of the active courses.	You will see the following information: - About: Information and progress for the course. - Videos: Videos to be seen. - Quizzes : Quizzes to be taken. - Assignments: Assignments to be submitted.	You can click on a video to see the content. The status will be marked completed when the full video is seen.	Click on the Quizzes tab to see all the quizzes associated with a course. Click on the quiz to see and answer questions to quiz questions.	Click on Assignments to see all the assignments for this course.	Click on assignment. Replace with New Image: Enables you to do a live scan and capture an image. Replace from Gallery: Enables you to select an image from the exam gallery.

Submitting Exams for QA service

If you are part of an organization that is authorized to submit cines or images from exams for QA and has a subscription plan, you'll follow this process:



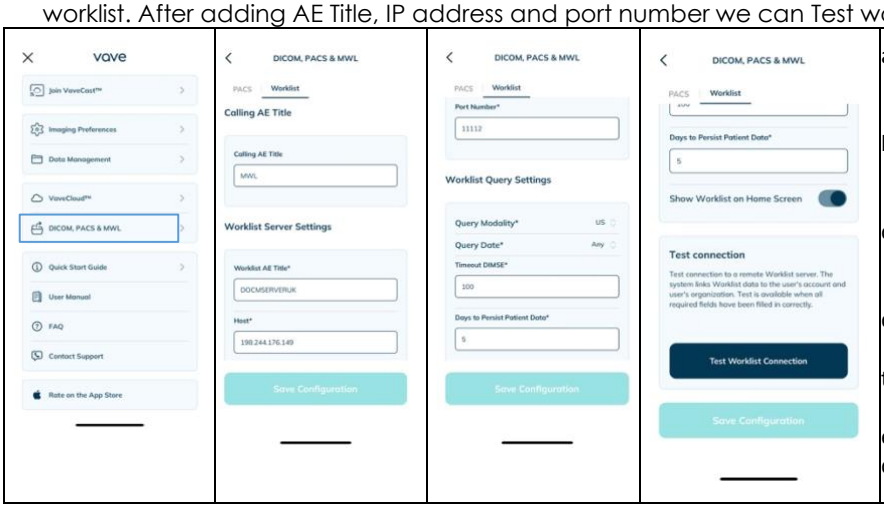



Click on the exam. Click on Select label	Select the image or cine to be submitted for QA. Click on the arrow at the bottom left	Click on "Mark for QA" option	Status of the exam will be changed to QA pending. You can add more images from the exam, if the QA is in pending status. A navy blue line will be shown underneath the image or cine	Once the images or cines have been QA'd, QA status will be changed to "Complete". Click on QA Completed tag to see your ratings	See QA feedback by scrolling down and up in the popup sheet.

An email will be sent to learner with the overall feedback after exam is completed.

Worklist Configuration

Tap the hamburger menu (☰) at the top left of the Home screen. Tap once on DICOM, PACS & MWL. We can see worklist. After adding AE Title, IP address and port number we can Test worklist connection and Save Configuration.



a. Query Modality (required)
Selects the imaging modality (e.g., US = Ultrasound).

b. Query Date (required)
Specifies the date range for the query.

c. Timeout DIMSE (required)
Timeout setting for DICOM DIMSE communication.

d. Days to Persist Patient Data (required)
Specifies how long patient data should be stored on the device.

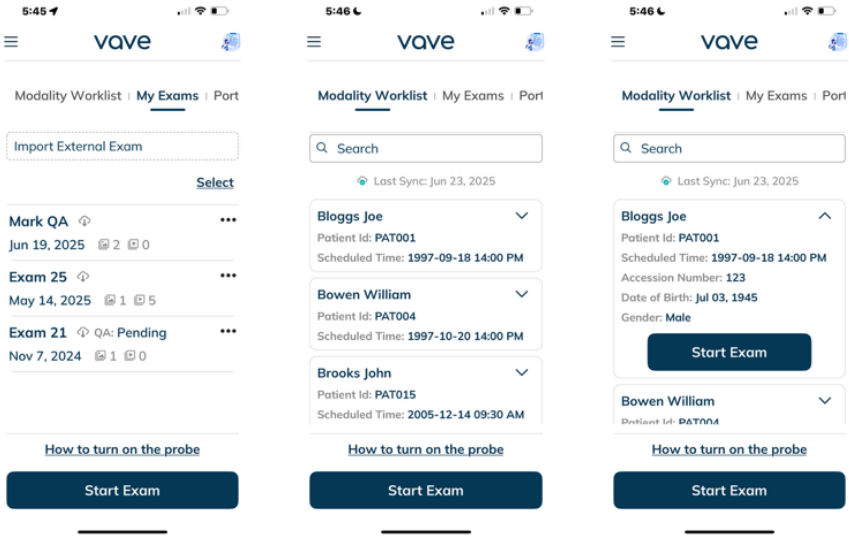
e. Show Worklist on Home Screen: Enables or disables display of the worklist on the exam screen.

Worklist Administration

1. An admin user can configure the work list configuration as shown above.
2. Admin users can also enable the availability of the worklist item in home screen.
3. Upon successful test of the worklist configuration, the "Search Worklist" button is displayed, allowing users to navigate to the Worklist page and view the patient list.
4. Software will automatically update the worklist when connect to network.

Import Modality Worklist

1. After signing in, the Exam screen is presented. User can click on Modality Worklist tab to see the list of patients if available.
2. Patient's name, patient id and scheduled time will be shown.
3. You can expand on patient by clicking the arrow "V" and start the exam for that patient
4. There is also an option to "Start Exam" on a patient whose name is not available in the list.



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 Wireless Ultrasound System (including the probe, battery, charger, and accessories) is supplied non-sterile. The system is not designed to be sterilized and must not be sterilized before or between uses. Attempting to sterilize any components may result in device damage, malfunction, or increased risk of patient injury or infection.
- This device is intended to be reused. Please follow cleaning and disinfection procedure in accordance with the validated instructions provided in this User Manual.
- The user and/or facility is responsible for the periodic and as-needed execution of the cleaning and disinfection procedures described in this manual. Ensure that these procedures are performed correctly. Failure to do so may result in device malfunction and/or contamination.

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

Cleaning the Display Device

Before cleaning, visually inspect the device for signs of damage or unacceptable deterioration. If damage is observed, discontinue use and replace the device with a compatible one.
If no damage is observed, proceed with cleaning as follows:

1. Turn off the device.
2. Clean all external surfaces using a pre-moistened disinfectant wipe. Do not immerse the device in liquid.
3. Allow the device to dry as required by the disinfectant manufacturer's instructions.
4. Turn the device back on.

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 mucus 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 validated cleaners and disinfectants compatible with your Vave Probe and accessories and have been tested and validated for efficacy.

Disinfection Level	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

Recharging the Battery

Please refer to *Charging the Battery*

- Connect the line cord of the AC power adapter to an indoor electrical outlet
- Connect the AC power adapter to the receptacle on the battery charger
- Note that the charger LED toggles between yellow and green when power is applied
- Remove the battery from the Vave Probe by following the instructions on Removing the Battery, below
- Insert the battery into a slot on the battery charger
- The LED will stay yellow when the battery is charging
- The LED will stay green when the battery is fully charged

Note

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

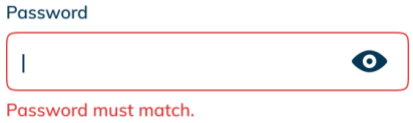
Storing the Vave Probe

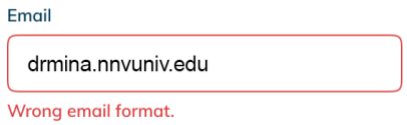
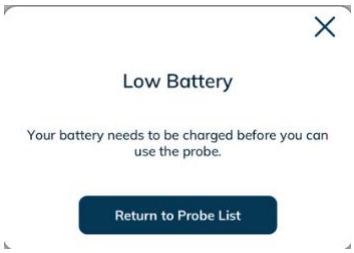
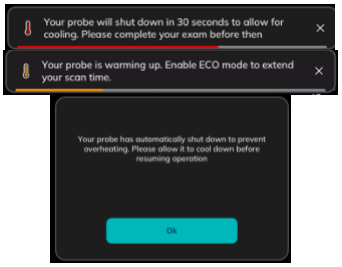
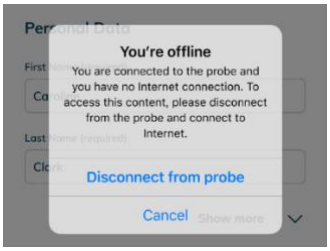
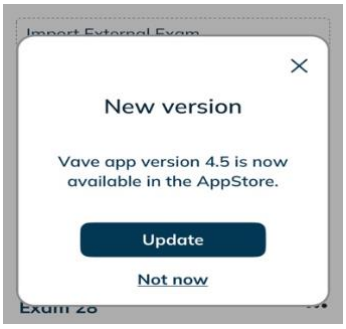
To protect your Vave Probe:

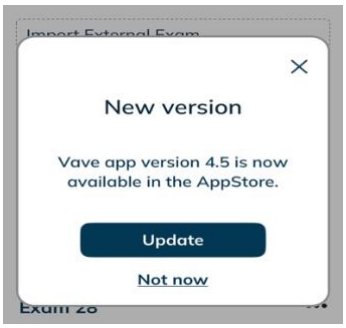
- Dry thoroughly before storage
- Avoid storing in extreme temperatures
- Avoid placing under direct sunlight for prolonged periods of time, as it may discolor the housing's finish but will not impact the Vave Probe's safety and performance
- Store separately from other equipment. Refer to the "Environmental 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.

	**Password Error** If you do not enter the correct password, you will be prompted to try again to enter the correct password.

	**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.
	**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.
	**Low Battery** If your probe is running out of battery power, a low battery alert will appear on top of the screen.
	**Low Battery** This alert is displayed if the battery level is too low for a connection.
	**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.
	**No Wi-Fi** This alert shows up if you are not connected to the internet when trying to register new probe.
	**Required Update** If there is a required update for the probe available, you will see a required update alert.

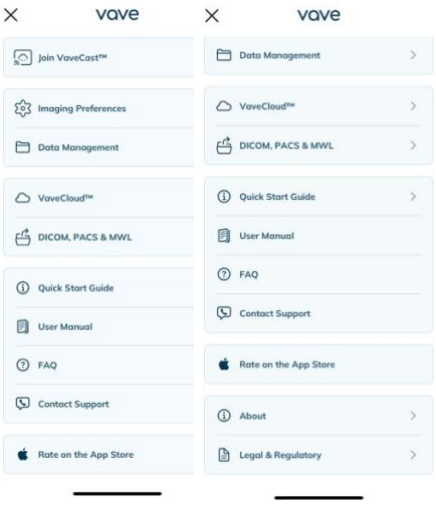
	**Optional Update** If there is an optional update for the probe available, you will see an optional update alert.
Unable to connect to probe	Ensure that the battery is fully charged before attempting to connect to the probe. The device will be unable to connect to the probe if the battery level is below 5%.
Firmware's OTA update not able to complete	Ensure that the battery is at least 25% charged before attempting an OTA (Over The Air) firmware update on the probe.

Data Storage and Migration

Users in supported regions will have their data stored securely on compliant servers. In cases where a backend server migration is required, users will receive the following notification during the migration: "*The exams in the organization are currently being migrated. Please check back later for access.*"
During migration, access to exams may be temporarily unavailable. All data will remain secure, and normal access will resume once the process is complete.

Additional Help

For Support, tap the hamburger menu (Ξ) in the upper left corner of the screen. There you can access the User Manual, a video Walkthrough, Privacy and Policy, Terms of Services (under Legal & Regulatory) and Frequently Asked Questions (FAQs):



If you require additional assistance, please contact Vave Health at support@vavehealth.com

3 System Setup and Administrator's Guide

Account Creating, Signing In and Out

Creating An Account

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

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 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 Automatic Logout: If you do not connect to the internet for **60 days**, you will be automatically logged out and required to reconnect.

Forgotten Password

1. When the app prompts you to enter your email and password, tap the "Forgot password?" link and follow the instructions
2. You will receive an email containing a verification code and a link to reset your password.
3. Open the link and follow the instructions to create your new password.
    - If the app is installed, the link will open the app directly to the password reset screen.
    - If the app is not installed, the link will open the Web Application.
4. Enter the new password and confirm it to complete the process.

Login Internet Connectivity & Connection Reminders

The Vave App requires periodic internet connectivity at least every 60 days, so that the app remains secure and updated.

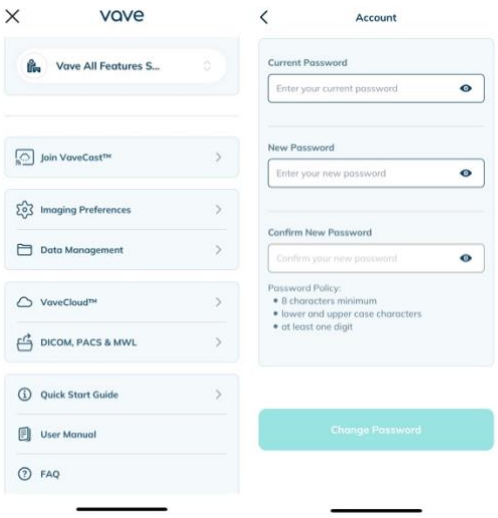
- After 45 days without an internet connection, reminder notifications will show up in the App and an email reminder will be sent via email.
- If no internet connection is established within 60 days, you will be logged out of the application.

Note: Multiple incorrect password: You will get the following message:

"Your account has been locked due to multiple incorrect password attempts. Please try again later or contact Vave Support at support@vavhealth.com.".

Organizations

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

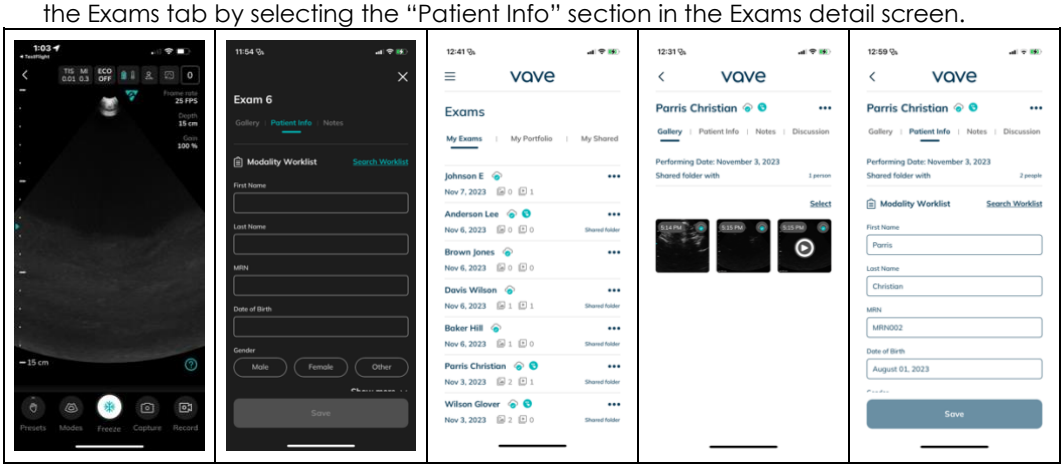


- If you belong to multiple organizations, you can switch between them by tapping the hamburger menu (☰) at the top left of the Home screen
- Exams are tied to the organization selected when scanning
- When you change organizations, you will only see Exams cataloged for that organization

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.

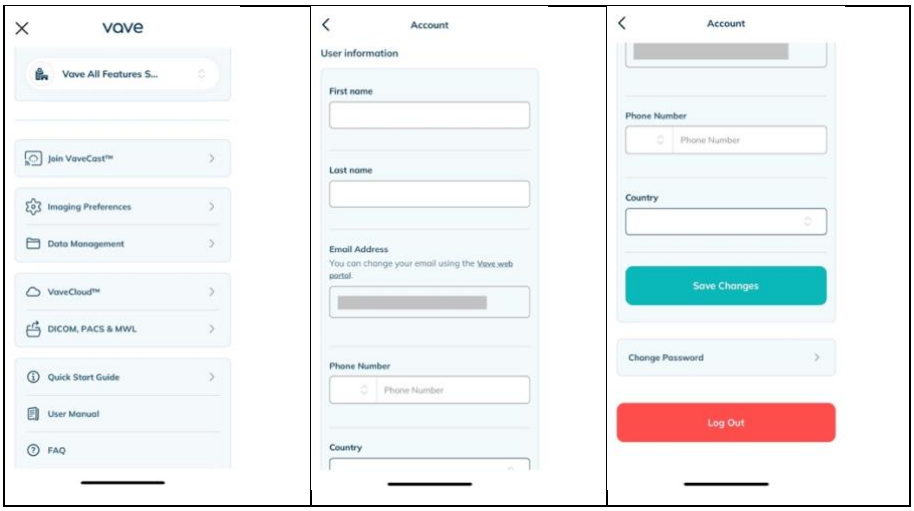


Please make sure that you entered the correct patient information and always be sure to follow your institution's policies regarding Patient Health Information.

Settings

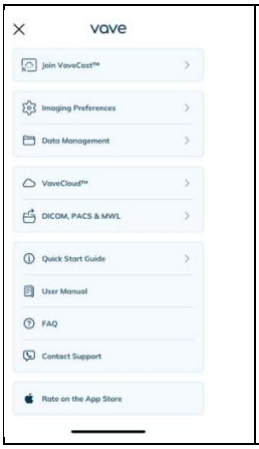
Profile Settings

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.

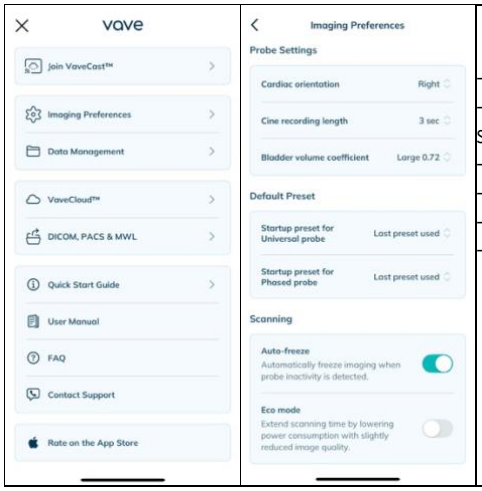


Settings

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



- Organization Name
- Join Vave Cast™
- Imaging Preferences
- Data Management
- VaveCloud™
- DICOM, PACS & MWL
- Quick Start Guide
- User Manual
- FAQ
- Contact Support
- Rate on the App Store
- About
- Legal & Regulatory



- Cardiac orientation: Changes the orientation to the two choices- Right & Left
- Cine Recording Length: User can change the default recording for cines to 3, 6 and 9 seconds
- Bladder Volume coefficient: Enables app to change the coefficient in formula.
- Default preset: Enables to change the default preset for each probe.
- Enable Auto freeze: Probe will stop scanning in case it is not being used.
- Current Frame Rate Mode: The App supports 2 modes
  ECO OFF: Default frame rate for each preset is applied
  ECO ON: Frame rate is lowered.

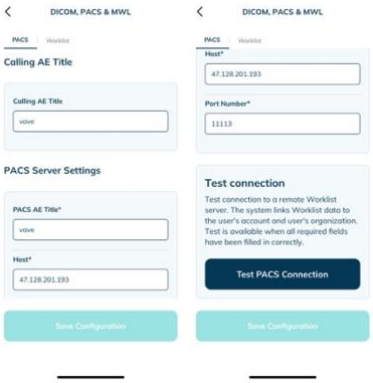
In the About Section, you can view your App version and Firmware version (if connected to your Vave probe).

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 adjust 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.



Vave Cloud™

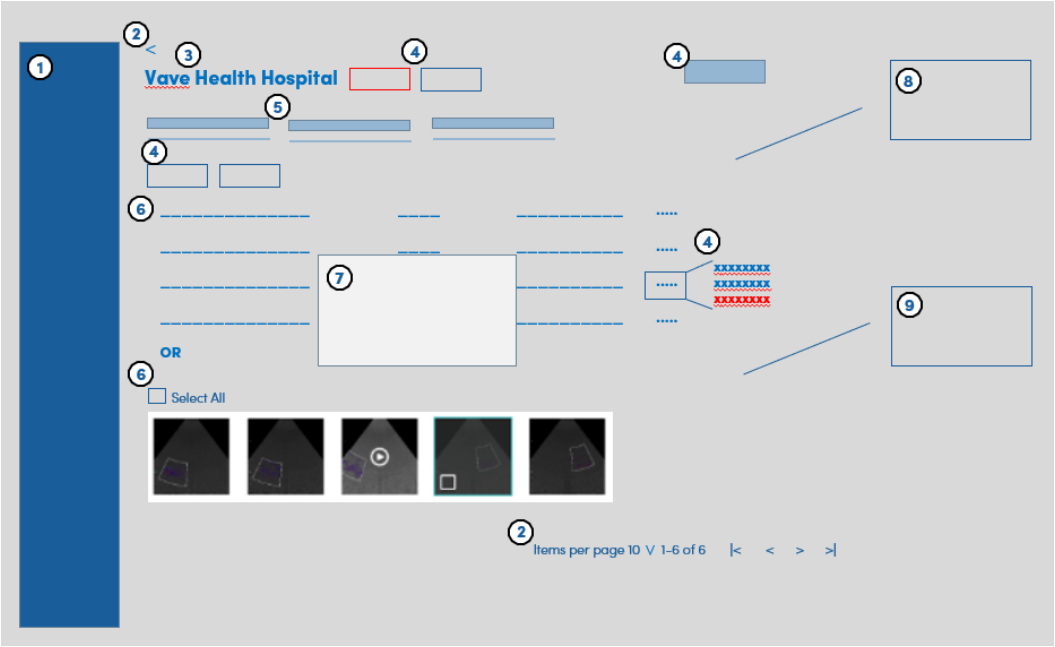
- If Cloud Sync is enabled, the images you acquire are automatically uploaded and synced to the Vave Cloud
- On Demand Download: To download an image/cine, need to click on Download cloud button available near the Exam name
- If you wish to disable automatic image uploading and sync, you may turn off Vave Cloud Auto 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

Account Lockout After Multiple Failed Login Attempts

To protect users against unauthorized access and automated password-guessing attacks, the system enforces an **account lockout policy**.

If a user enters an incorrect password repeatedly, the account will be temporarily locked.

- After **multiple consecutive failed login attempts**, the account is locked to prevent brute-force attacks.
- During the lockout period, login is disabled for that user account.
- Users can regain access after the lockout expires.

Change Password

To change your password-

- Click on the hamburger menu (Ξ) at the top left corner
- Click on Profile logo > Profile > Change Password

Request Account Deletion

To request deletion of your account-

- Click on the hamburger menu (Ξ) at the top left corner
- Click on Profile logo > Privacy Centre > Account & Data Controls > Delete My Account Request

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.

Creating/Inviting 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).
One can also invite a new user using "Invite Member" functionality. A reminder can be sent to invited users in case they have not self-registered themselves.
A member receiving an invite email can self-register themselves by clicking on the appropriate link in the email.

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.

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

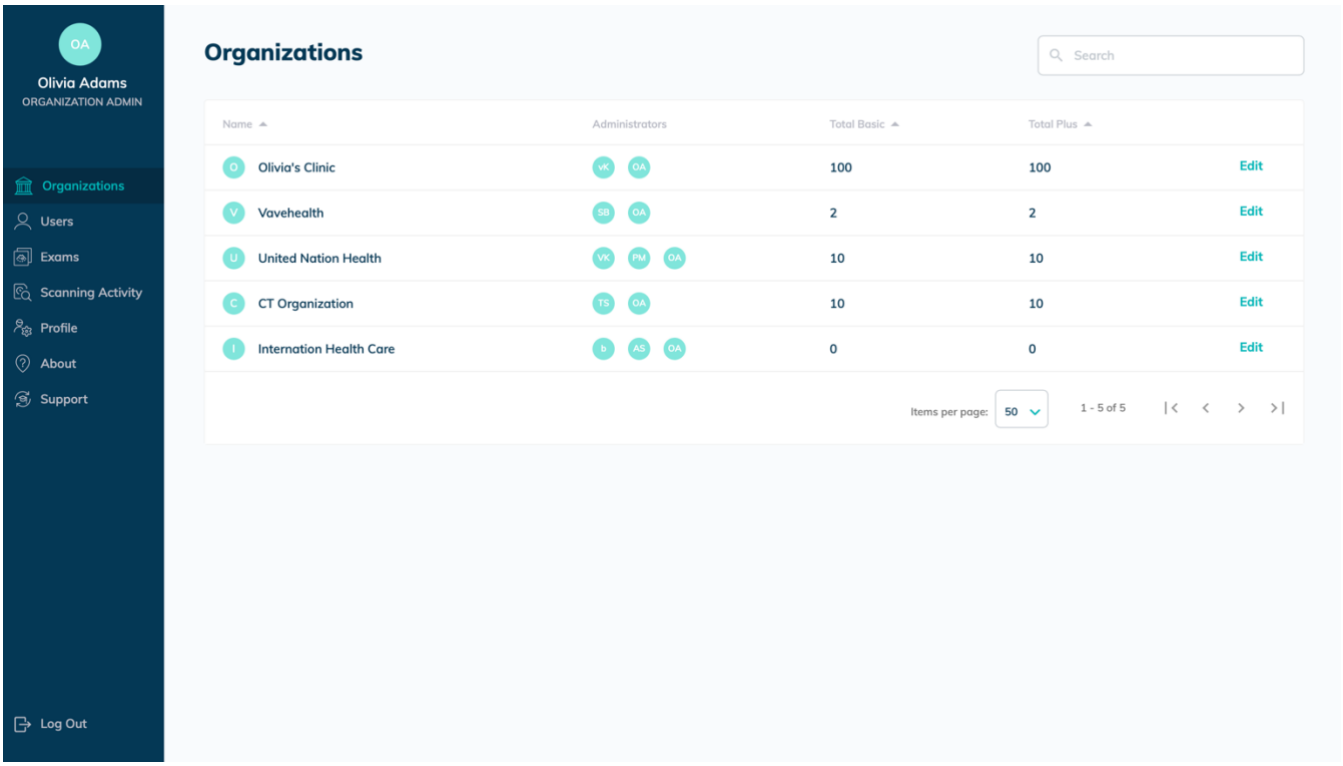
To view your scanning activity, and the scanning activity of all members that belong to your organization, click *Scanning Activity*.

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



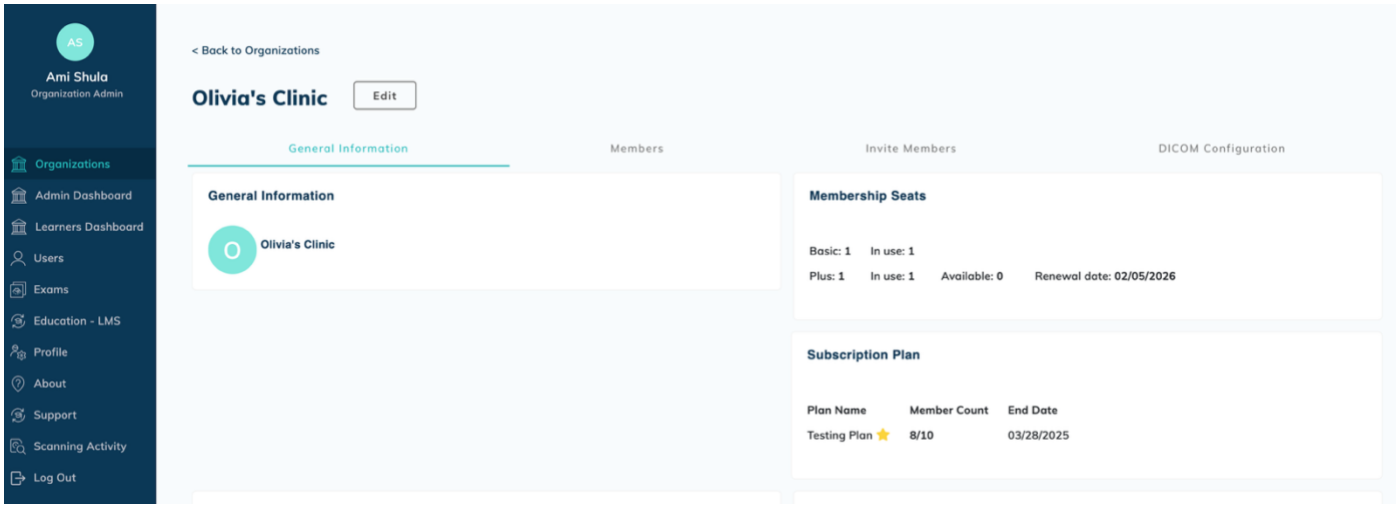
Available Actions:

- 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



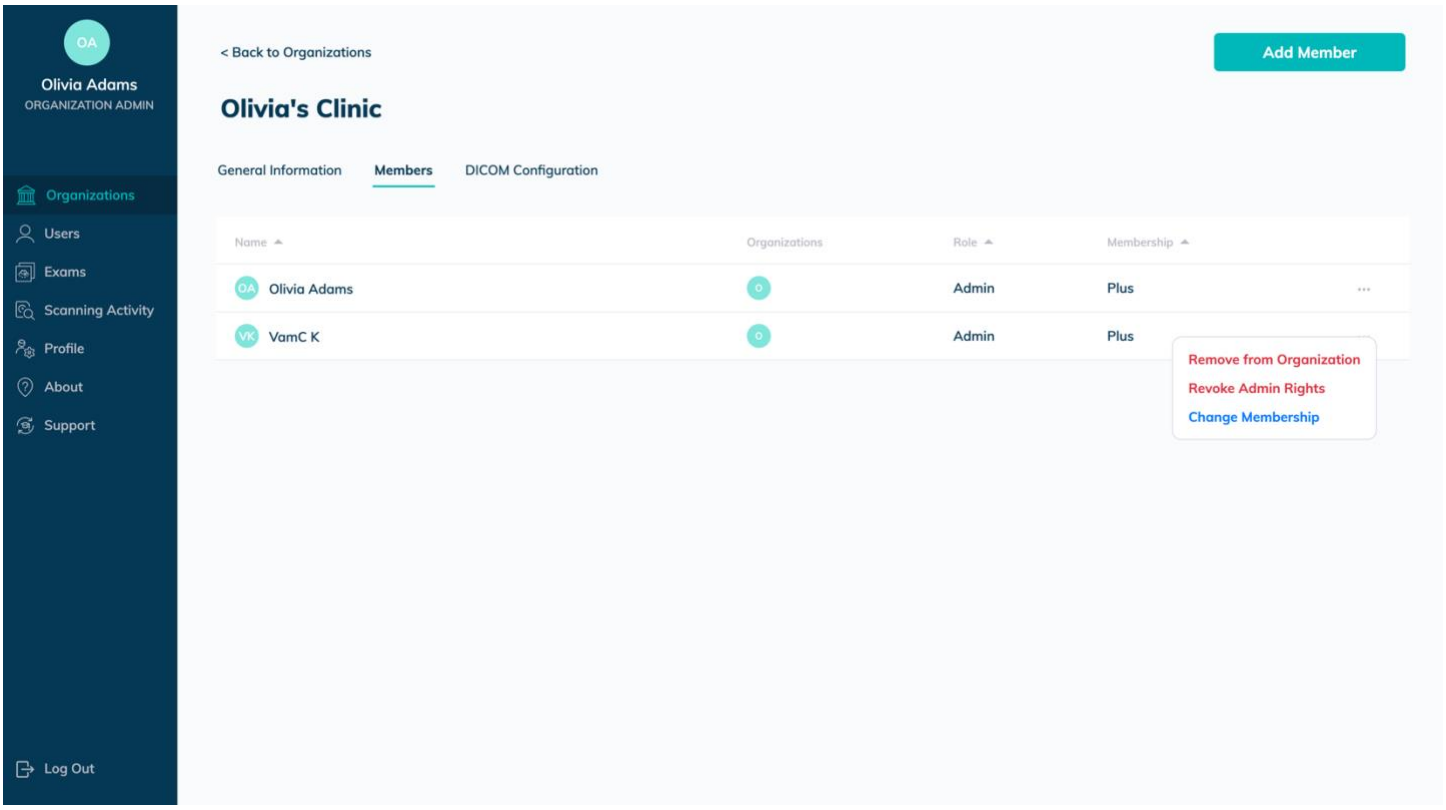
Available Actions:

- Edit Organization
- Delete (removes the Organization)
- Members – See all the members in the organization
- Invite Members – Invite members to join your organization
- DICOM Configurations – Set up PACS and Modality Work List

Members

Displays all the members in that organization.

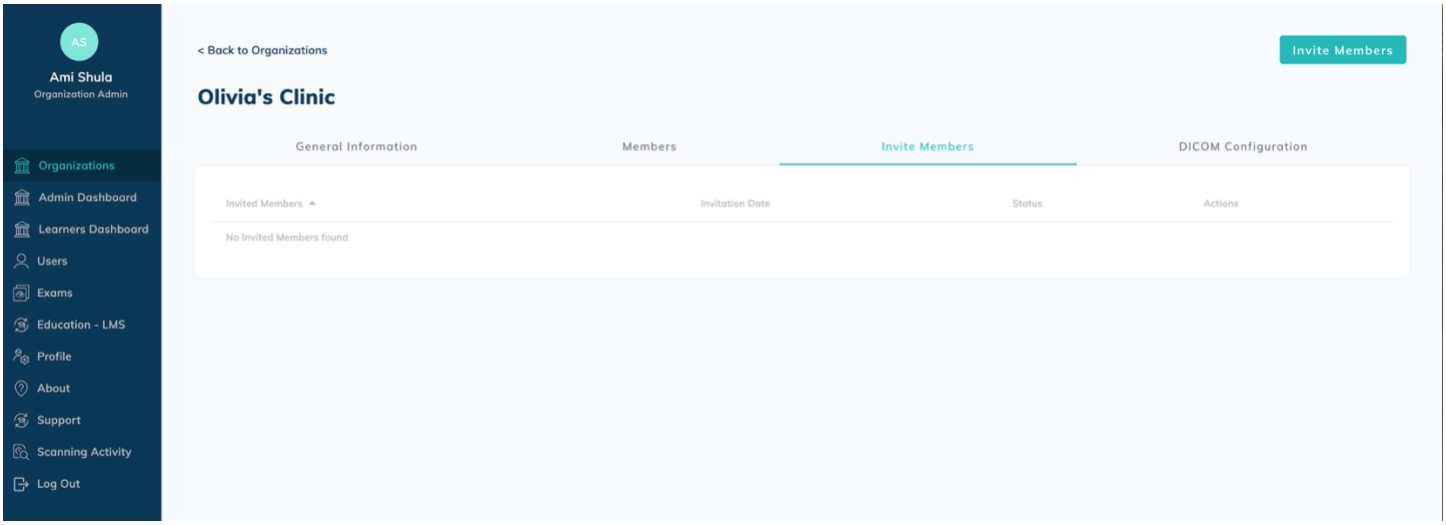
Figure 3.4: Members Page



Available Actions:

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

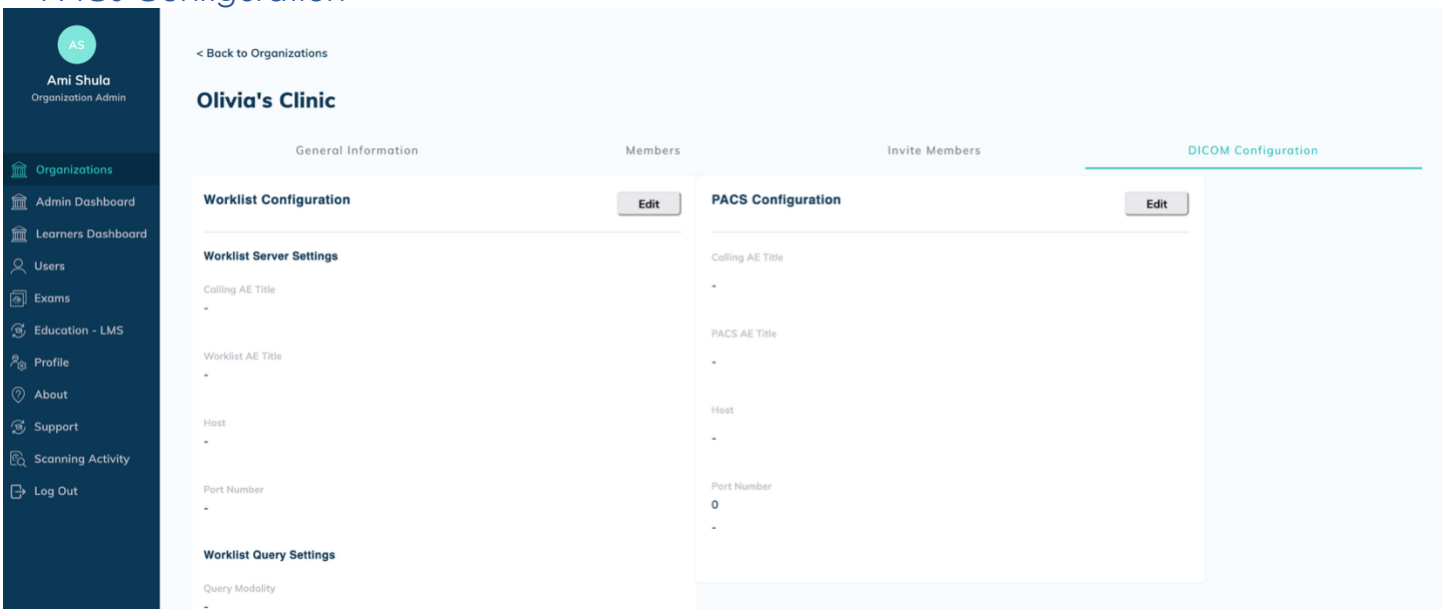
Figure 3.5: Invite Members Page



Available Actions:

- Invite Members

PACS Configuration



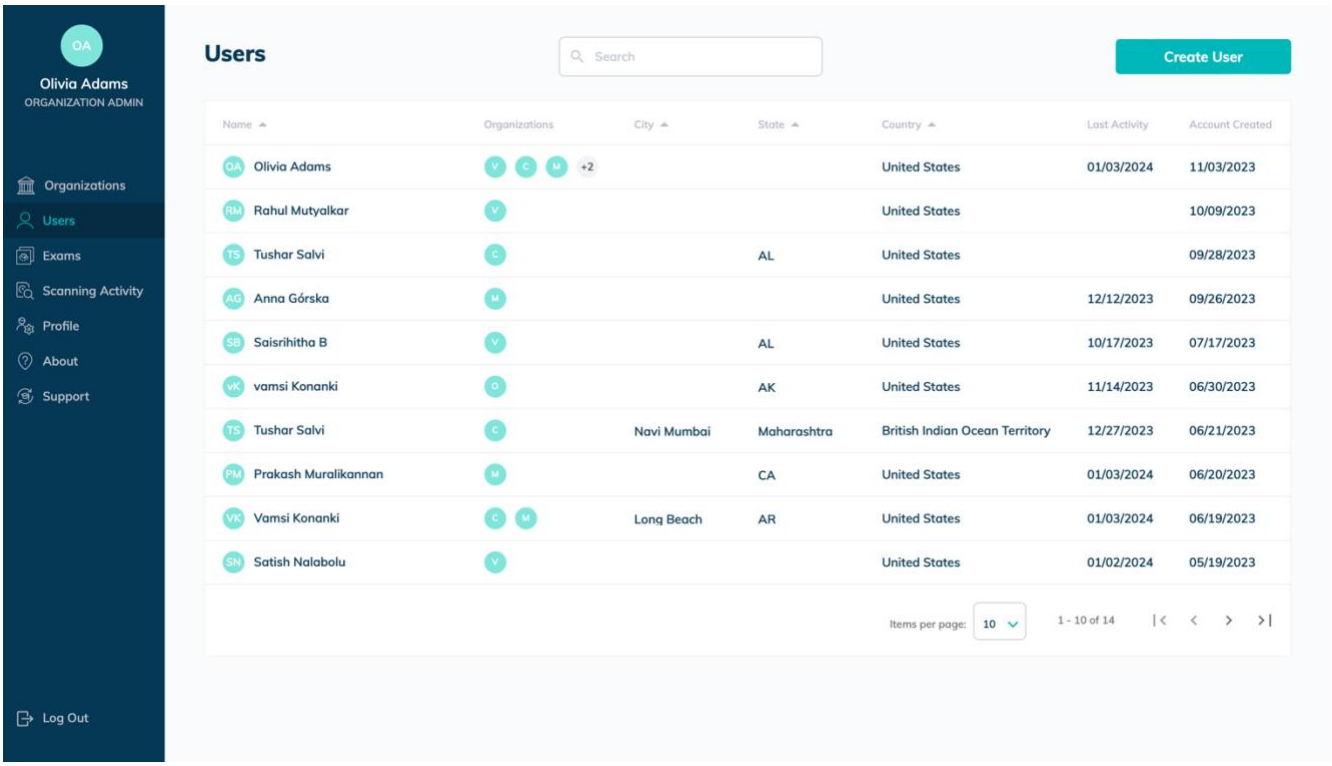
Available Actions:

- Edit Worklist Configuration
- Edit PACS configuration

Users

Manage users within an organization.

Figure 3.5: Users Page



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

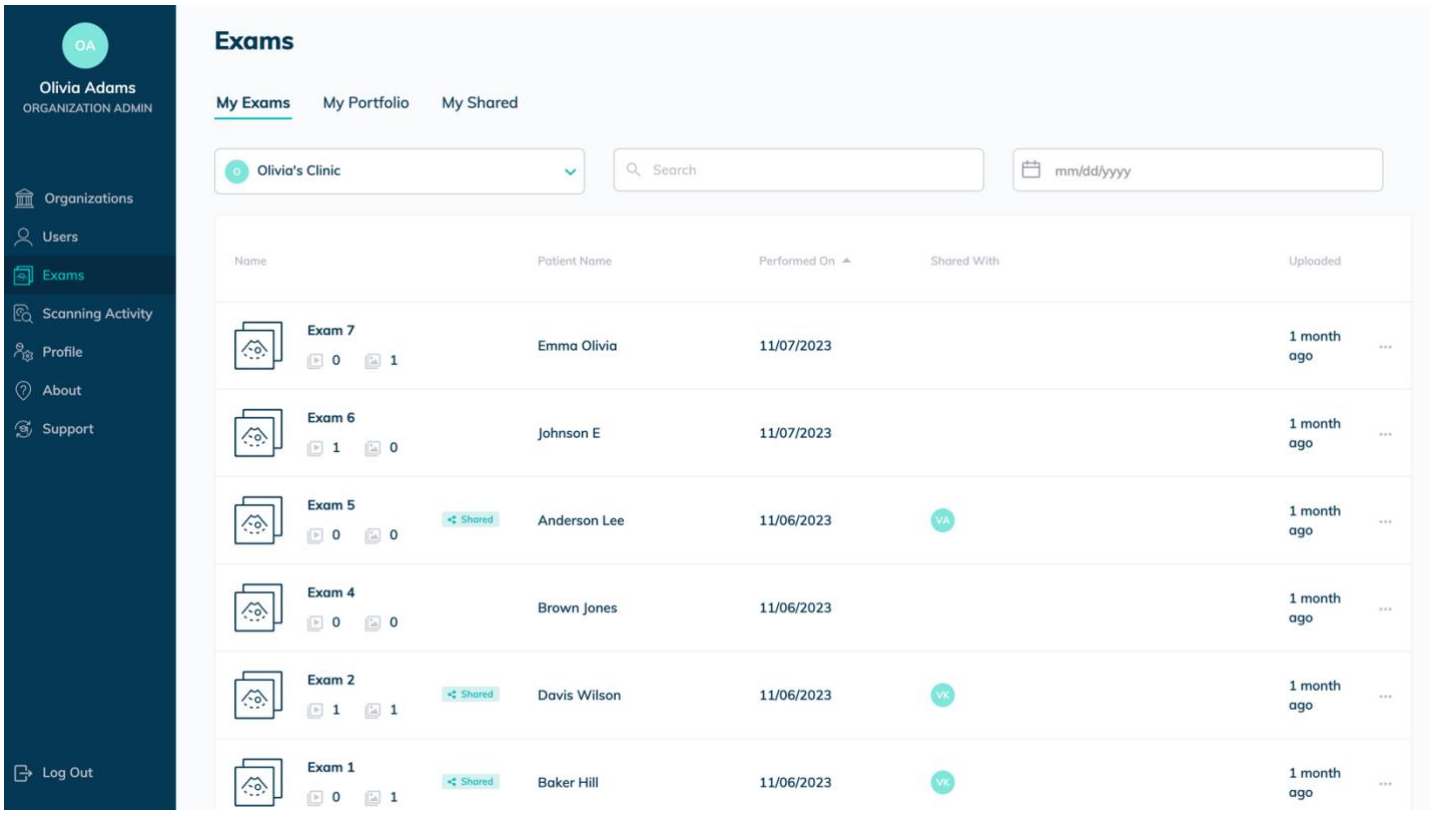
Exams

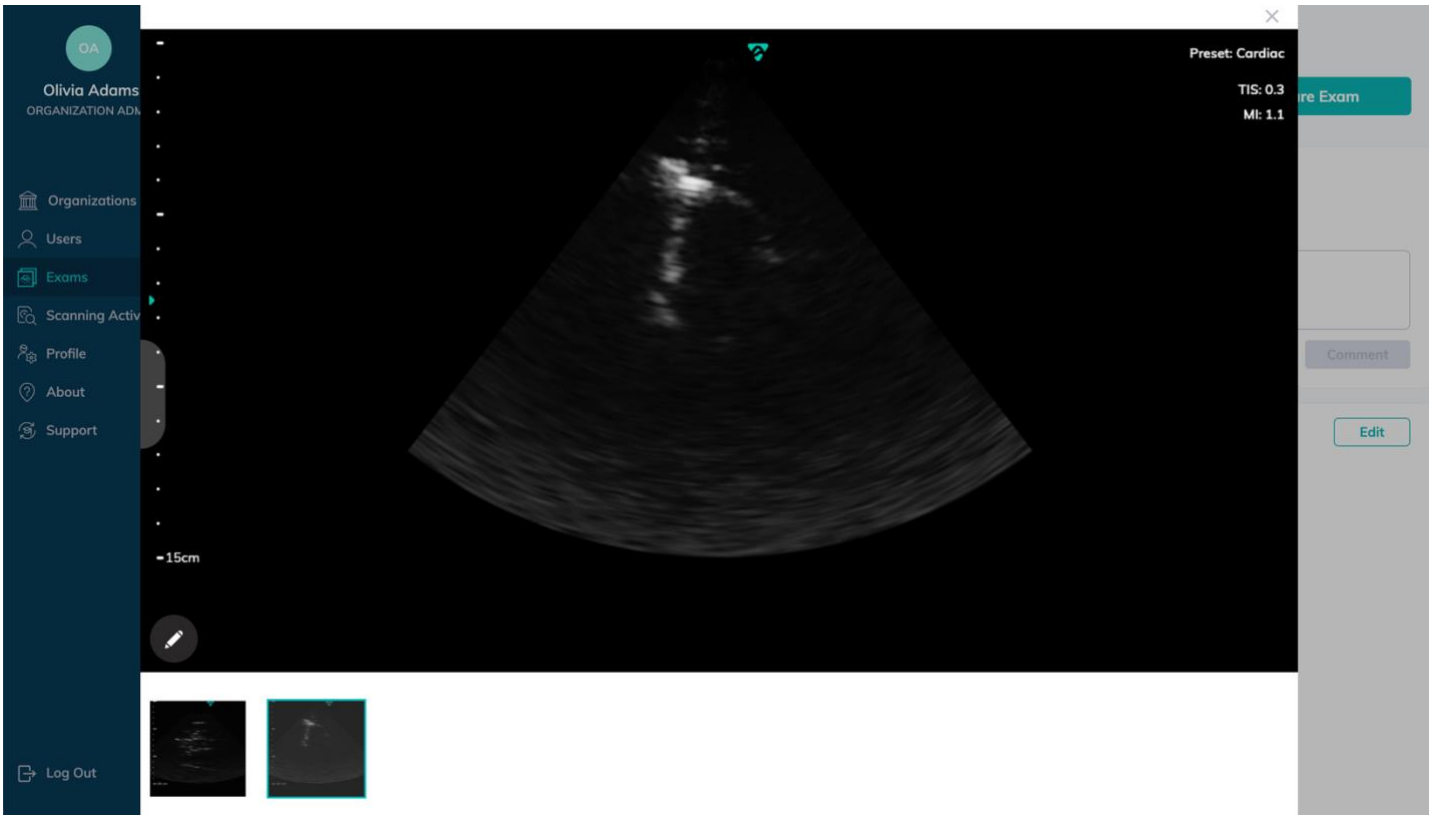
My Exams, My Portfolio, and My Shared. Click on the image you want to see for an expanded view.

My Exams

Shows all exams that you performed.

Figure 3.6: 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

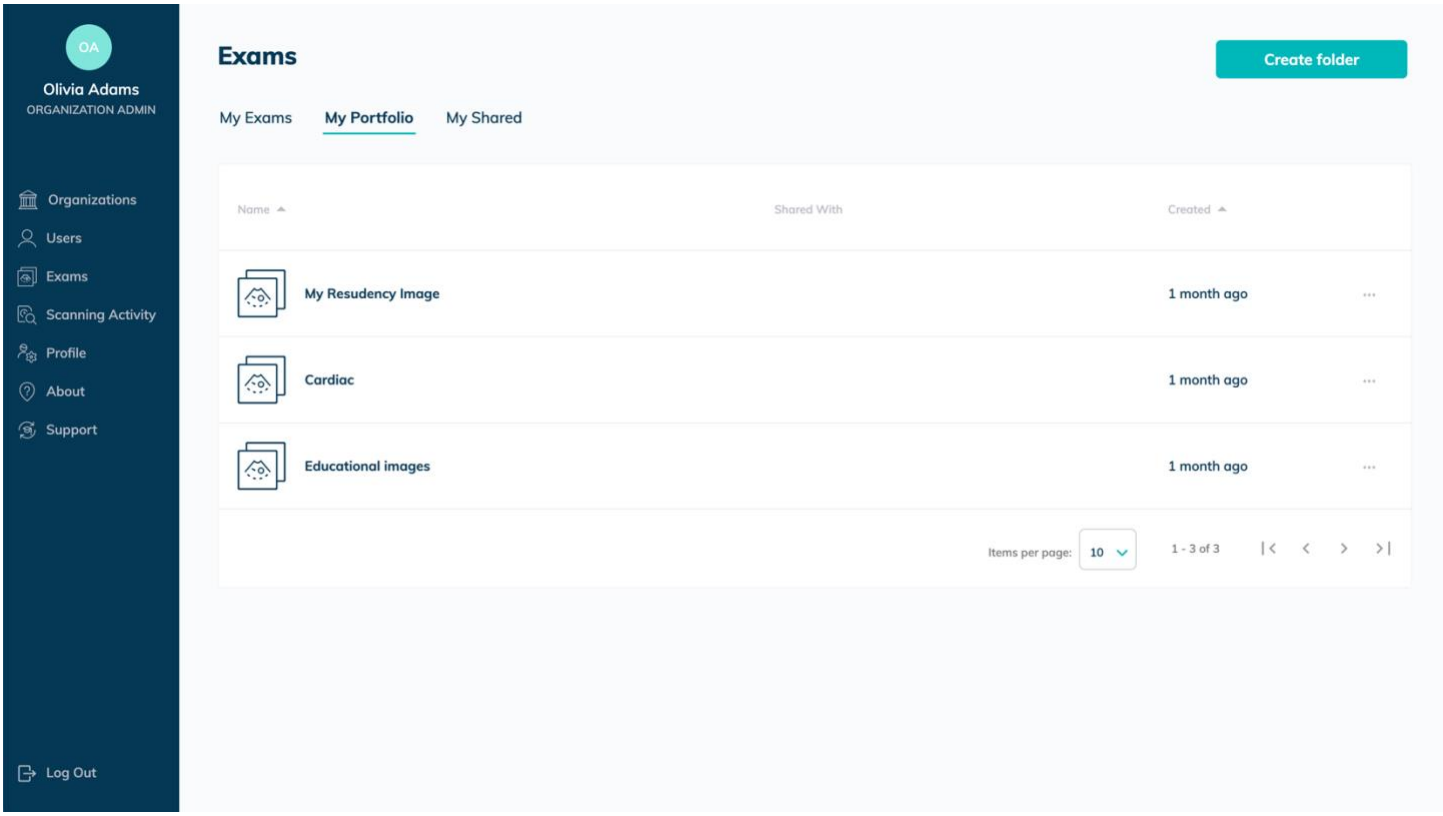
Note You can delete single exam files. Select each file you wish to delete – a checkmark appears on each thumbnail to be deleted.)

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.

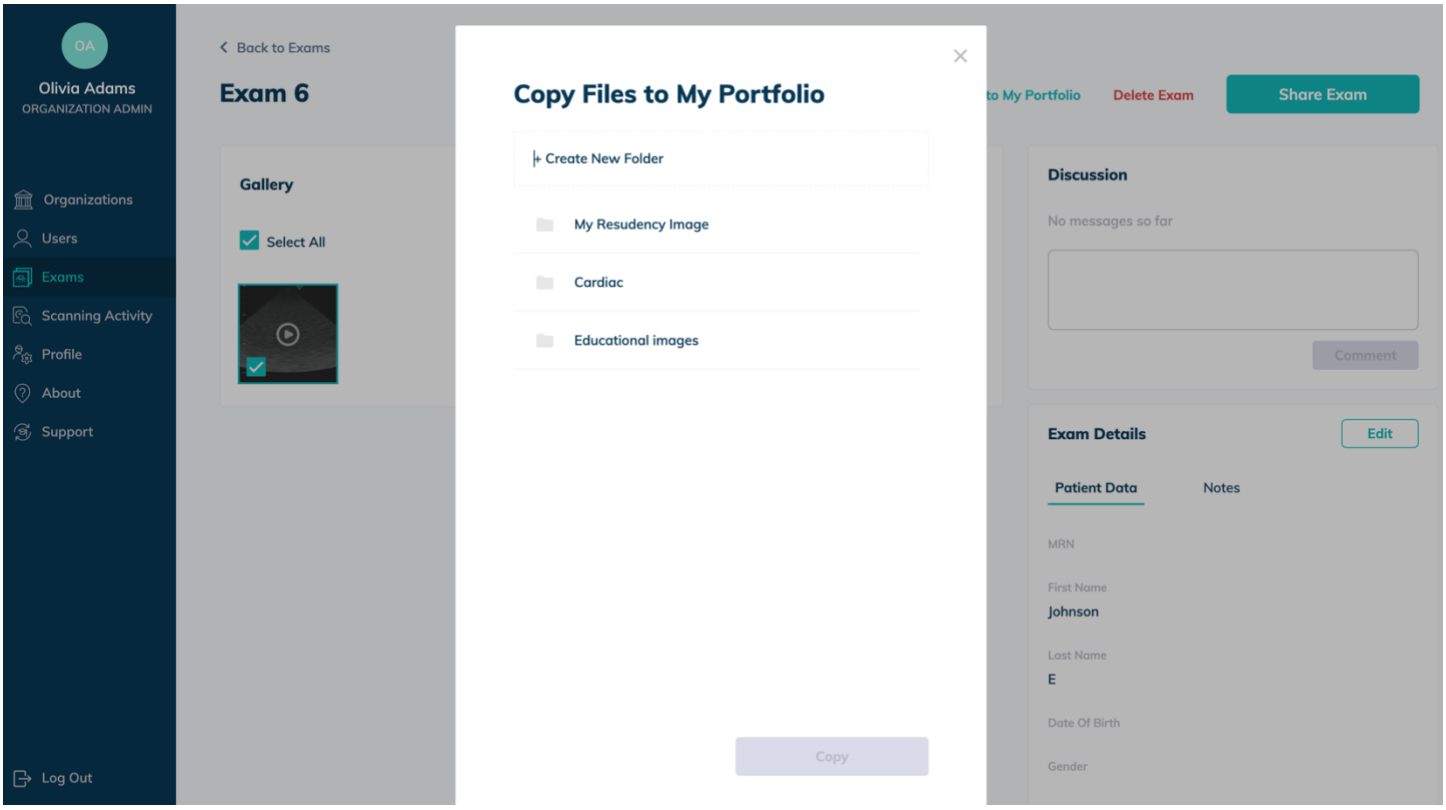
Figure 3.7: My Portfolio Page



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 3.8: Copying Exams to My Portfolio Example



My Shared

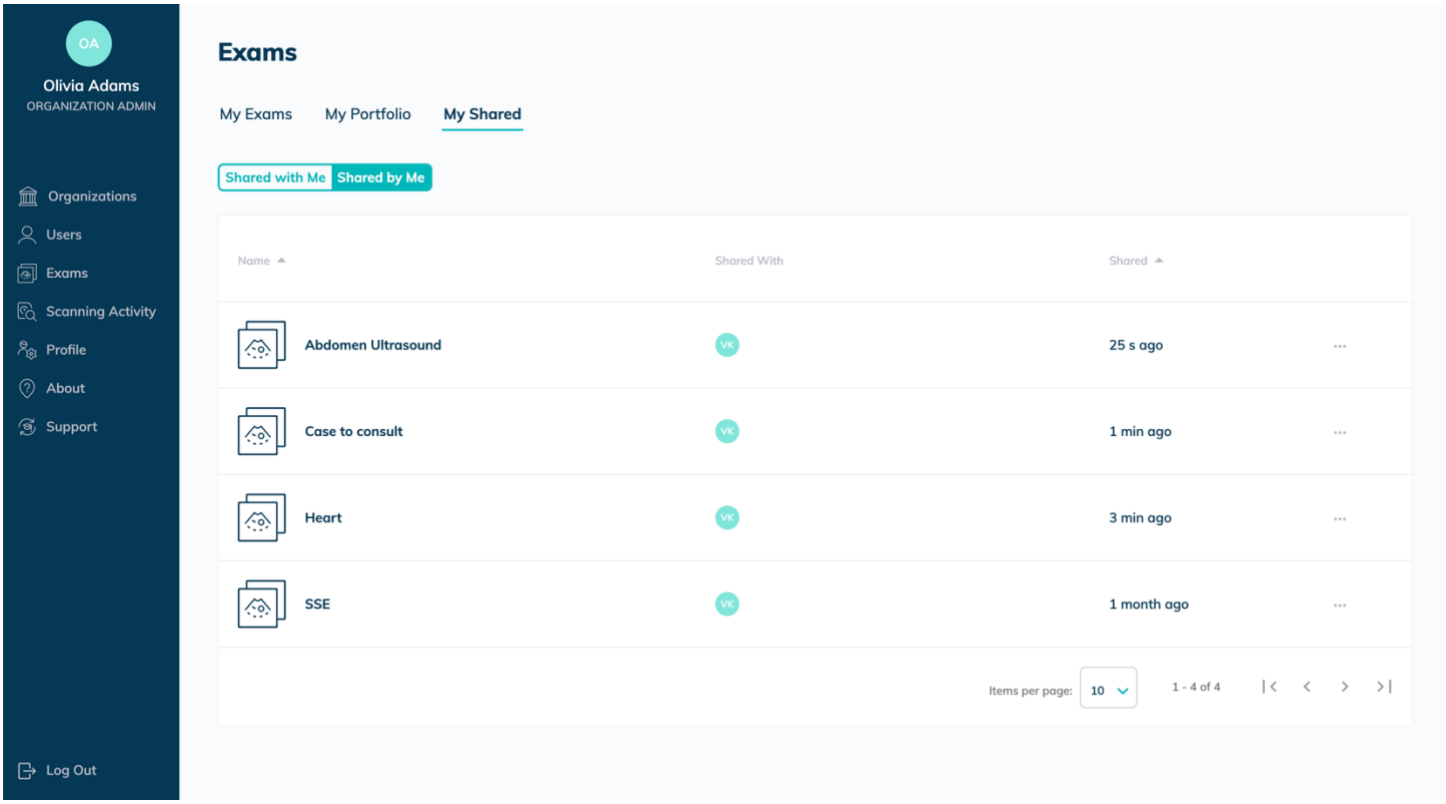
Shared by Me (Displays items you have shared with other Vave Health users.)

- 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 Patient Health Information (PHI). Please be certain you follow your organization's PHI protocols.

Figure 3.9: 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).

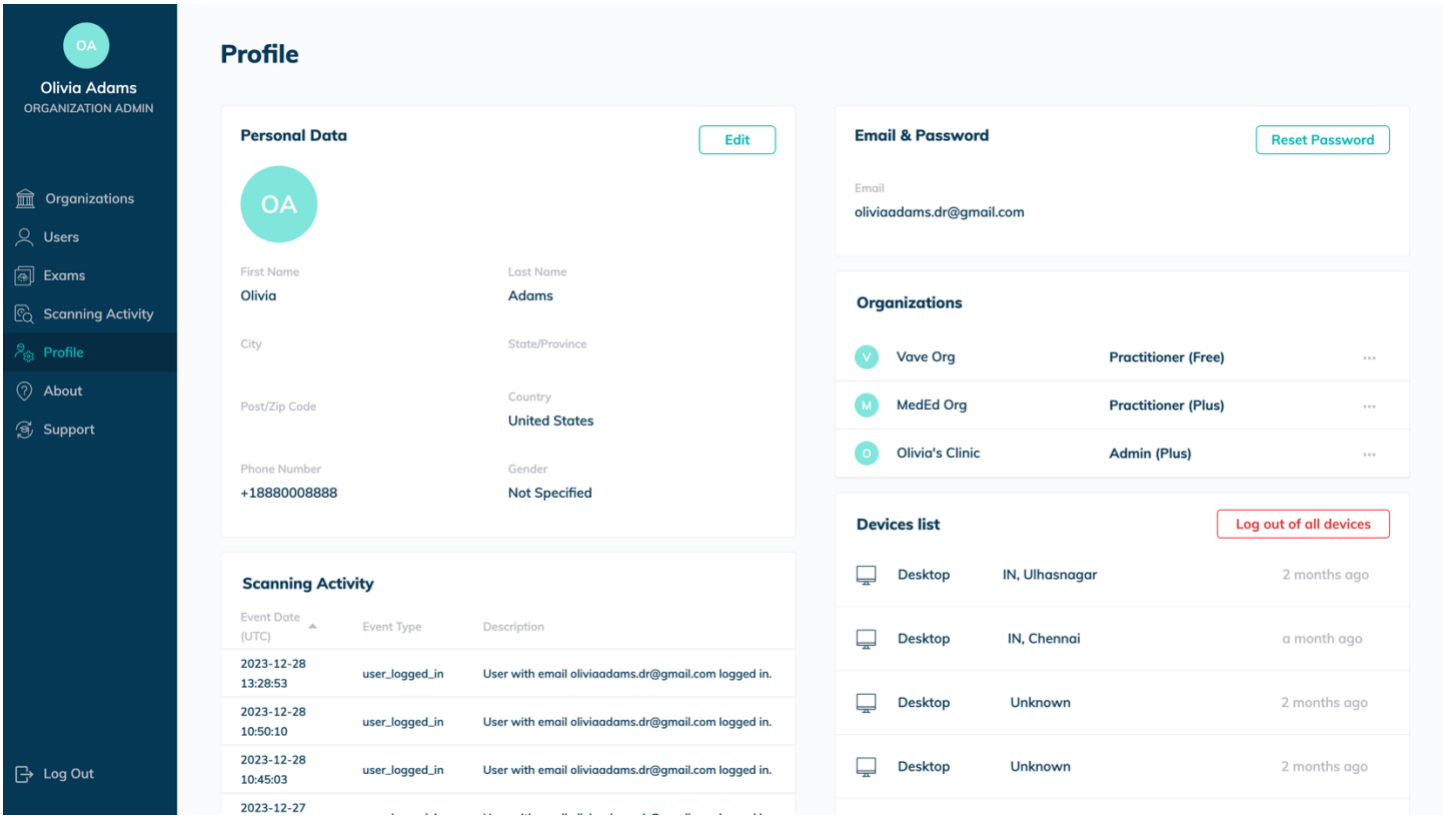
Note

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 3.10: Profile Page



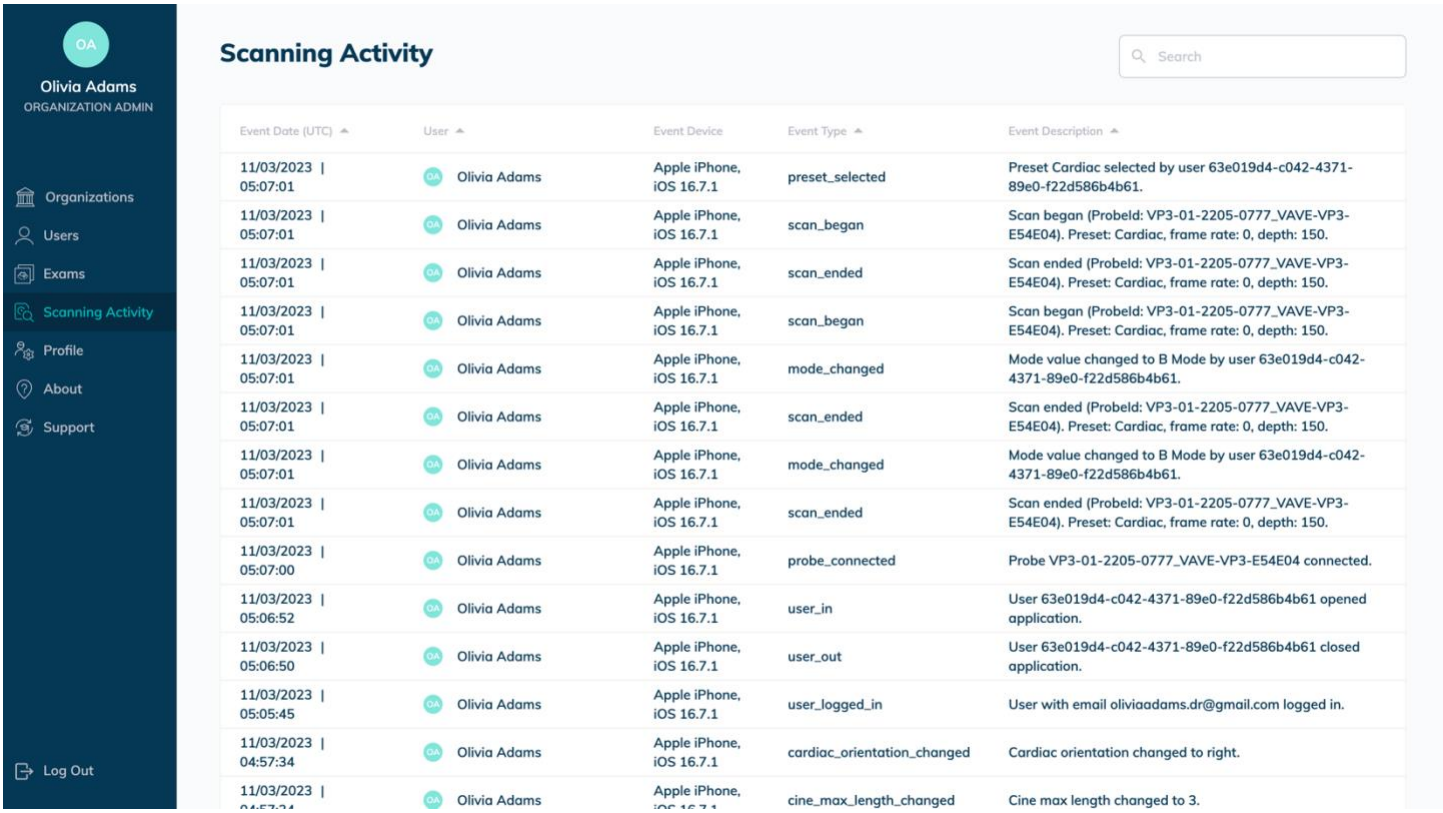
Available Actions:

- 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 3.11: Scanning Activity Page



Available Actions:

- View Activity (users and members of their organization)

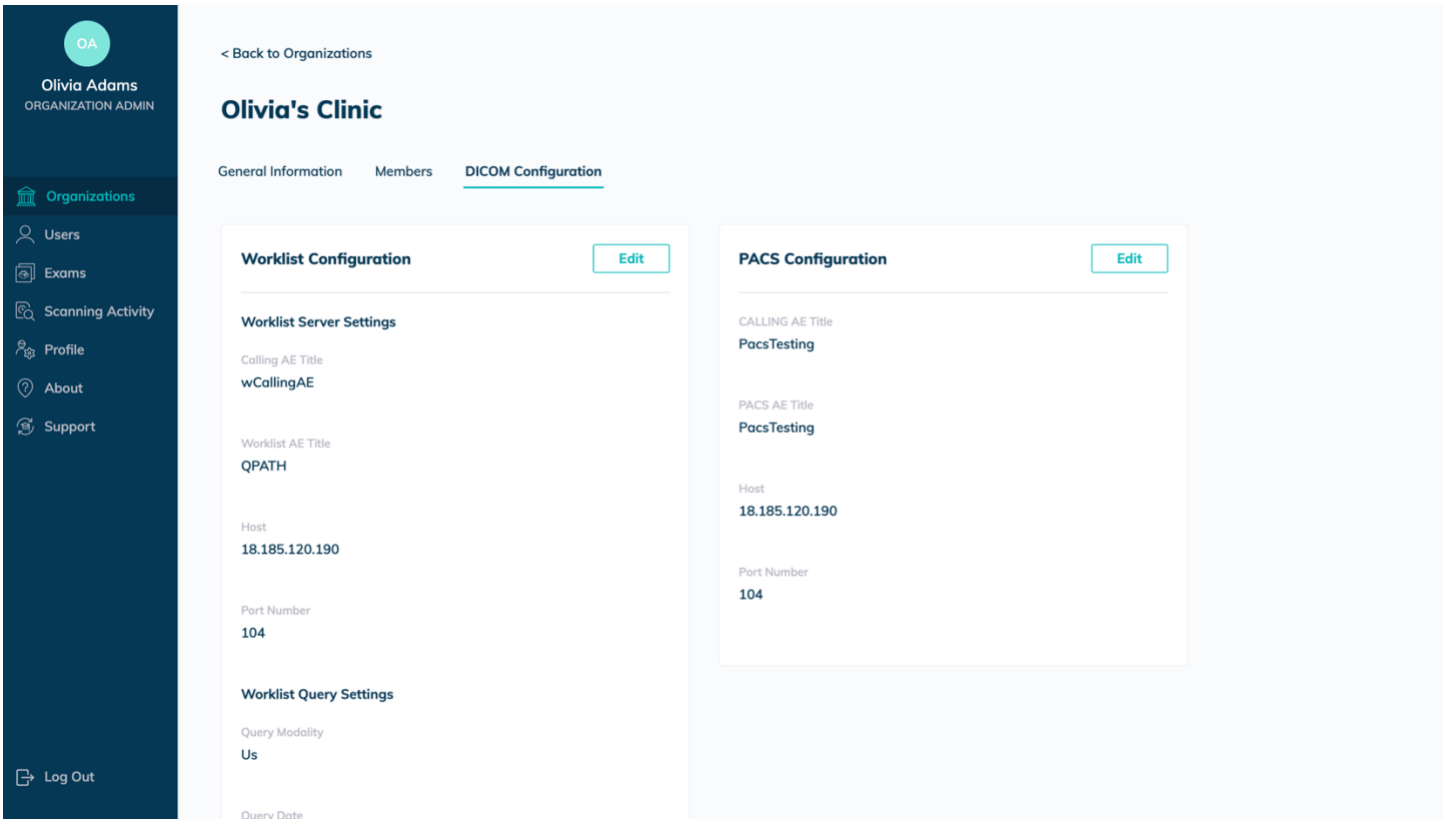
About and Support

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

Worklist and PACS Configuration

One can view the organization screen and click on any organization. You will find the worklist and PACS configuration.

Figure 3.12: Worklist and PACS configuration



Worksheet

The Worksheet Module enables structured oversight and QA processes. It involves three key roles:

- Performing: User who performs ultrasound.
- Attending: The attending physician reviews each POCUS scan and gives clinical feedback, but also formally signs off that the review was done.
- Clinical QA: A designated user or team of users responsible for conducting quality assurance reviews on exams that have been submitted.

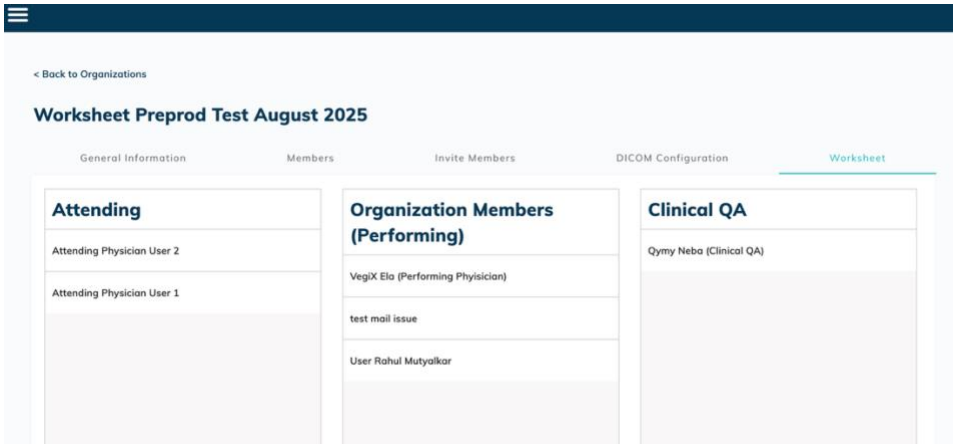
Worksheet supports two types of exams:

- Clinical Exams: Exams performed on patients for clinical purposes. These are eligible for billing.
- Educational Exams: Exams conducted for training or learning purposes. These are **not** eligible for billing.

Worksheet Administration at the Organization Level: Once enabled by Vave Admin, the worksheet functionality will generate a copy of the master data from Vave Health in the organization folder.
A new **"Worksheet" tab** will appear in the organization settings screen for Org Admins. Within this tab, admins can manage:

- **Performing List:** those users performing exams
- **Attending List**: those reviewing exams submitted by performing physicians
- **Clinical QA List**: users who conduct periodic QA of billed exams

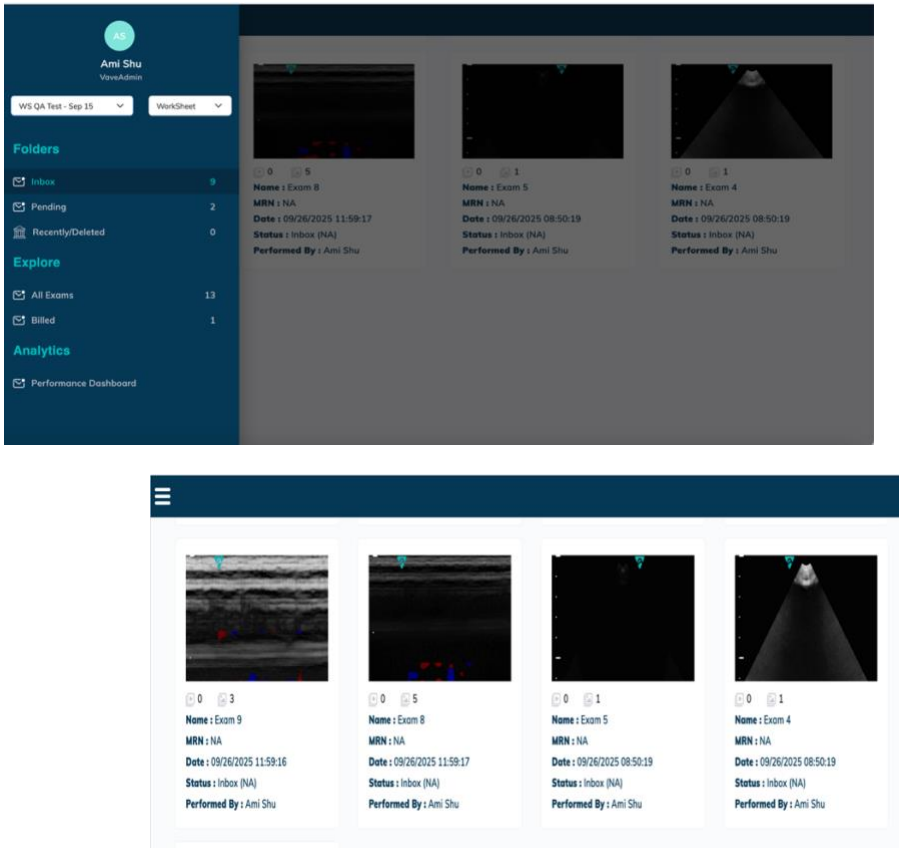
Figure 3.13: Worksheet



The organization admin can drag and drop users from any box to any other box. A user can have only one role.

Users belonging to an organization with worksheet functionality enabled will see the following page after logging into the Vave Web application:

Figure 3.14: Worksheet functionality enabled



A user will see two drop downs under their name:
Dropdown 1: Displays the list of organizations they are a member of.
Dropdown 2: Allows them to switch between the Worksheet view and the classic (default) view. By default, user will be shown the worksheet view.

Worksheet Navigation Elements:

- Folders:
  - Inbox: Displays the total count of exams performed by the logged in user.
  - Pending: Shows the number of exams that have been submitted for review by logged in user.

    - Recently Deleted: Contains exams that have been soft deleted. These exams do not appear in the Inbox.
- Explore
    - All Exams: Lists all exams available in the system.
    - Billed: Displays the count of exams for which billing has been completed.
- Analytics
    - Performance **Dashboard**: Presents key performance metrics. This is at organization level

Worksheet status flow: All exams that are part of worksheet can have one of the following statuses:

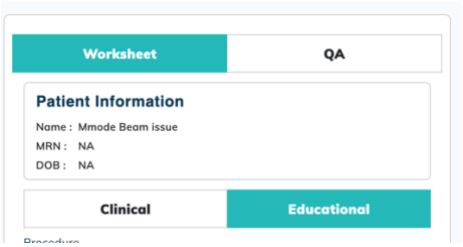
- Inbox: By default all exams get allocated Inbox status.
- PerformingReview: Exam has this status when performing physician is reviewing an exam
- PerformingSubmitted: Implies that exam has been submitted by performing physician for review
- AttendingReview: Exam has this status when attending physician is reviewing an exam
- AttendingSubmitted: Implies that exam has been submitted by attending physician. If an exam has CPT code and is clinical then it can be submitted to insurance company.
- Clinical QA Submitted: An exam that has been reviewed and submitted by Clinical QA role.

How to access workflow for worksheet and QA?

- A performing and clinical user can use the worksheet functionality
- A clinical QA user can use the QA functionality.

An exam can either be used for clinical purposes or educational purposes. Exam can't be part of both.
A clinical exam will have a CPT code associated with it whereas an educational exam will NOT have CPT code associated with it.

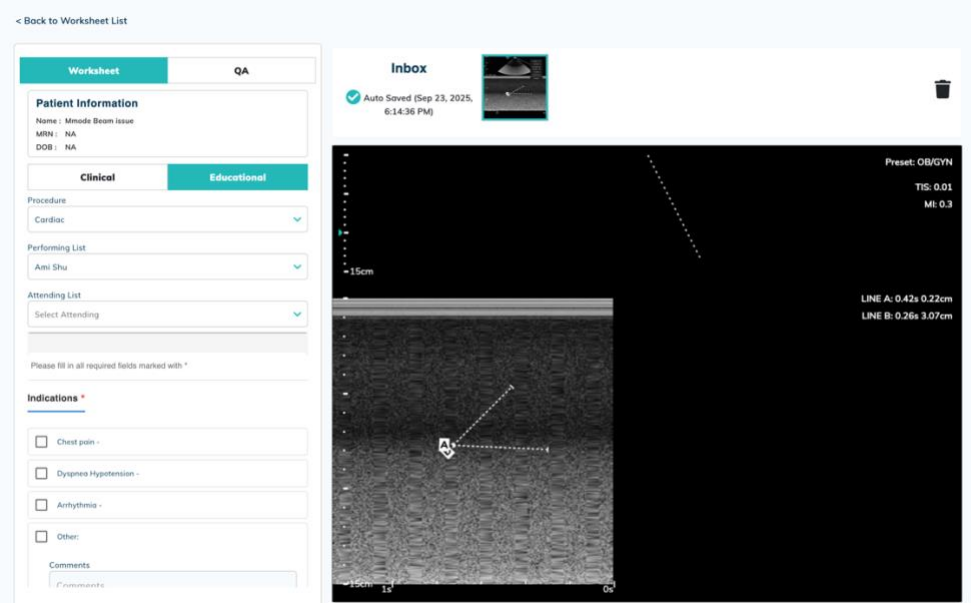
Figure 3.15: Worksheet, QA workflow



How to submit an exam for review?

Clicking on the exam with inbox status shows the following

Figure 3.16: Worksheet, Inbox status



A performing or attending physician first needs to select one of the listed procedures, assign attending in case the logged in user is performing.

Supported procedures:

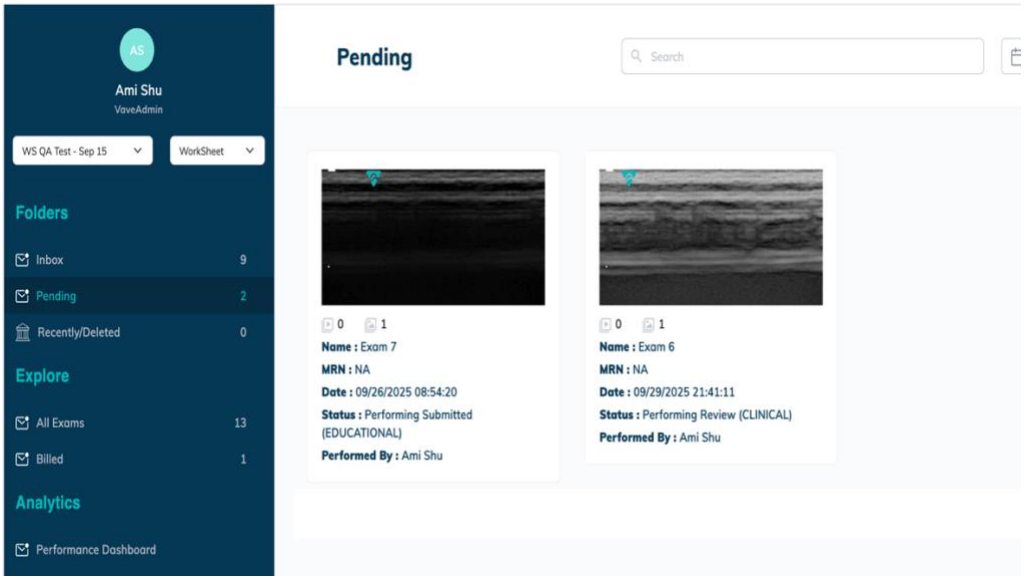
- Cardiac
- FAST Exam
- Hepatobiliary ultrasound
- Limited abdominal aorta ultrasound
- Limited vascular ultrasound: DVT
- OB
- Pleural Ultrasound
- Renal (limited retroperitoneal)
- Skin/Soft tissue

They will also have to fill in the following sections:

- Indications
- Finding
- Impressions
- CPT Codes: Only available to attending physicians

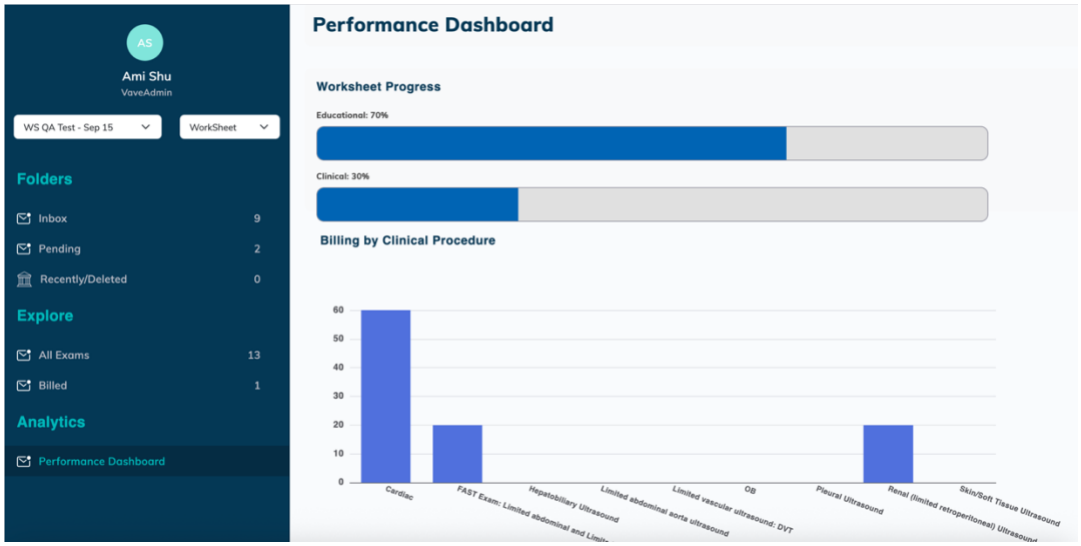
Pending folder:
The following figure shows exams with different submitted status and context in which the exam was used (Clinical and educational). All these exams will be in the inbox of the selected attending. In case the current user is attending, it will show up in billed folder.

Figure 3.17: Worksheet, Pending folder



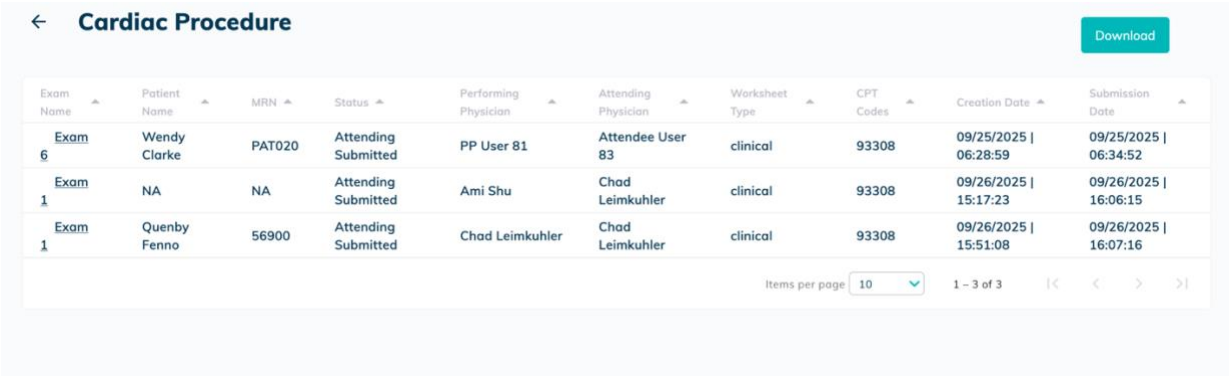
Performance Dashboard: This dashboard shows users progress on educational and clinical worksheet.
Horizontal graph: Shows number of exams that are part of clinical or educational worksheet.
Vertical graph: Percentage of exams that are associated with different observations.

Figure 3.18: Worksheet, Performance dashboard



Clicking on the vertical graph shows the detailed information about the exam and patient whose insurance can be billed.

Figure 3.19: Worksheet, Performance dashboard



Note

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

4 Product Safety

These instructions describe how to use the Vave Probe and App safely. These three safety levels note three 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 Benefits

Ultrasound imaging is widely used in clinical practice due to its well-established safety profile and recognized clinical benefits. Diagnostic ultrasound has been used for several decades, and when applied according to its intended use, no long-term adverse effects have been demonstrated.

Real-time ultrasound imaging enables visualization of anatomical structures at the point of care, supporting diagnostic assessment and clinical decision-making. As a non-ionizing imaging modality, ultrasound avoids exposure to ionizing radiation while providing immediate diagnostic information. The portability and cost-effectiveness of ultrasound systems allow their use across a broad range of clinical environments, facilitating timely patient evaluation and supporting efficient patient management. Ultrasound is widely accepted by patients and may complement or replace other imaging modalities when clinically appropriate.

Ultrasound Risks

Ultrasound imaging is considered safe, but ultrasound energy does have the potential to produce biological effects. During an ultrasound exam, the ultrasound waves may warm tissues in the body. In some cases, this warming may even produce pockets of gas in bodily fluids or tissues. The long-term consequences of these biological effects are 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

Caution

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.

Product Compatibility

Caution

- The Vave Ultrasound Solution 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.
- All parts of Vave wireless ultrasound system have been tested in accordance with current standards and are therefore suitable for use in the patient environment.
- This Vave ultrasound probe is intended to be used with a compatible display device (e.g., smartphone or tablet). The display device is considered part of the overall system. Ensure that any display device used complies with applicable IEC or ISO safety standards and is operated in accordance with the manufacturer's instructions. The combination of the probe and display device must be used in a manner that maintains compliance with IEC 60601-1 to reduce the risk of electrical hazards.

Using an improper gel type or combining gel types

Caution

- Using an improper gel type of 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

ALARA

Caution

- To avoid unintentional acoustic exposure, the operator must verify the control settings before and during equipment use. Ensure that the acoustic output parameters, including gain, acoustic power, depth, focus, and operating mode, are configured as needed for the clinical procedure. The user should continuously monitor the indices displayed on the screen, such as the Thermal Index (TI) and Mechanical Index (MI), and keep the levels as low as reasonably achievable, in accordance with the ALARA (As Low As Reasonably Achievable) principle. Avoid unintentional changes to the controls during the examination. Always confirm the settings after changing modes, presets, transducers, or restarting the system.

Notifications and alerts from third-party applications

Caution

- 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 Vave probe to malfunction during an exam.

Maximum Probe Temperature

Caution

- The Vave probe will shut down at 45°C (109°F) to prevent overheating. A warning message will appear 30 seconds before the shutdown.

Battery Safety

If the battery shows abnormal behavior (e.g., odor, heat, discoloration, or deformation) during use, charging, or storage, stop use immediately and contact Vave Health. Replace the battery if it does not fully charge.

Battery leaks may expose users or patients to hazardous chemicals. The battery enclosure is designed to prevent this risk. Do not open the battery enclosure.

Dispose of the battery in accordance with local regulations. Do not incinerate.

Caution

Caution:

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

Caution

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.

Caution

Defibrillation and MR Safety

- **Do not use the system during defibrillation**. Before defibrillation, remove all system components from contact with the patient. Defibrillation current may travel through conductive pathways, posing a risk of burns or injury to the patient or operator and potentially interfering with proper defibrillator pad contact.
- **MR Unsafe:** The Vave Probe poses unacceptable risks to patients, medical staff, and others in the MR (magnetic resonance) environment. Do not bring this device into the MR environment.

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.

Caution

- Do not use Vave probe 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.
- The Vave battery charger is powered by a double-insulated AC/DC adapter capable of providing adequate electronic separation between the mains power (AC) and the low-voltage output (DC), as well as providing mechanical separation through the corresponding AC plug.
- The AC/DC adapter serves as the primary means of disconnecting power to the Vave battery charger. Ensure that it remains easily accessible at all times. Do not position or obstruct the adapter in a way that makes it difficult to quickly unplug it from the power outlet.
- Do not use multiple sockets or extension cords to power the battery charger. Connecting additional equipment through a multi-outlet connection may increase leakage current beyond the limits specified in IEC 60601-1, creating a risk of electric shock to both the operator and the patient.

Electromagnetic safety

Caution

- 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.

Caution

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

Figure 4.1 Immunity to Fields near wireless RF communication equipment EN/IEC 61000-4-3

Test Frequency (Mhz)	V/m	Front		Rear		Left		Right	
		Vertical	Horizontal	Vertical	Horizontal	Vertical	Horizontal	Vertical	Horizontal
380-390	27	A	A	A	A	A	A	A	A
430-470	28	A	A	A	A	A	A	A	A
704-787	9	A	A	A	A	A	A	A	A
800-960	28	A	A	A	A	A	A	A	A

1700-1990	28	A	A	A	A	A	A	A	A
2400-2570	28	A	A	A	A	A	A	A	A
5100-5800	9	A	A	A	A	A	A	A	A

Note:
A – The equipment must continue to operate as intended without operator intervention. No performance degradation or loss of function is permitted below the minimum performance level when the equipment is used as intended.

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 degrade image quality. If interference is observed, use caution and relocate the system as necessary. EMI may appear as noise, artifacts, flickering, or distortion, potentially reducing diagnostic accuracy.

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.
Proximity magnetic field immunity per IEC 60601-1-2:2014+A1:2020 §8.11 is not applicable. Compliance is achieved via §8.11(b).

Figure 4.4 specifies a mandatory minimum separation distance of 0.15 m from magnetic field transmitting equipment during intended use, ensuring magnetically sensitive circuitry is not exposed to Table 11 field strengths.

Figure 4.4: Recommended Separation Distance from Magnetic Field Transmitting Equipment

Frequency Range	9 kHz to 13.56 MHz
Recommended Minimum Separation Distance	0.15 m

Biological Safety

Caution

- Follow the ALARA (As Low As Reasonably Achievable) principle during all ultrasound procedures.
- Clean and disinfect the Vave Ultrasound probe immediately after each use.
- Vave Ultrasound probes are intended for human use only and should not be used on animals.

Allergic Reactions to Latex

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

Thermal

Thermal bioeffects refer to tissue heating caused by ultrasound energy. The degree of heating depends on how different tissues absorb ultrasound. Fluids such as amniotic fluid, blood, and urine have very low absorption coefficients, allowing ultrasound to pass through with minimal energy loss or temperature increase. In contrast, bone has a high absorption coefficient and absorbs ultrasound energy rapidly, which can increase temperature. Adult bone absorbs nearly all acoustic energy, while fetal bone absorption may vary. Soft tissue absorption varies depending on the organ and tissue density, and attenuation within tissues occurs due to both absorption and scattering of the ultrasound beam.

Mechanical (Non-Thermal)

Mechanical bioeffects such as cavitation can occur when ultrasound output exceeds certain pressure thresholds, which vary depending on the tissue. Cavitation happens when ultrasound interacts with gas bubbles, causing them to change size. These changes can increase local temperature and pressure and place stress on nearby tissue. Tissues that contain gas, such as the lungs, are more susceptible. Cavitation is less likely at higher ultrasound frequencies because bubbles have less time to grow.

When cavitation occurs, gas bubbles may oscillate and create fluid motion that stresses nearby cell membranes, or they may expand and collapse, which can damage tissue, cause cell death, and produce reactive chemical species. In rare cases, small lung hemorrhages have been observed, but these typically heal without long-term effects.

Research shows that cavitation occurs only when specific pressure thresholds are exceeded; if ultrasound exposure remains below these thresholds, cavitation will not occur regardless of how long the exposure lasts.

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

Acoustic Output

As a Track 3 device, the Vave Ultrasound System acoustic output parameters comply with all applicable standards, including IEC 60601-2-37. The system displays the Thermal Index (TI) and Mechanical Index (MI) on the display device in accordance with industry standards.

The output display indicates the potential for bioeffects associated with the emitted ultrasound energy. This information helps users obtain the necessary diagnostic information while minimizing risk to the patient.

Although the system's acoustic output levels comply with established standards, users must be properly trained in ultrasound operation and aware of the potential for ultrasound-induced bioeffects. Users should minimize patient exposure and unnecessary risk by selecting appropriate output levels and exposure times and by following the ALARA principle while optimizing diagnostic information.

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 (Thermal Index):** This is continuously displayed based on the application and indicates the estimated potential for tissue heating. No fixed maximum limit is specified. TI consists of the following indices:
    - thermal index for soft tissue (TIS): Indicates the potential for heating within homogeneous soft tissue.
    - thermal index for bone (TIB): Indicates the potential for heating when the ultrasound beam passes through soft tissue and a focal region is at or near bone
- **MI (Mechanical Index):** This is continuously displayed based on the application and indicates the estimated likelihood of tissue effects due to cavitation. The maximum MI is typically limited to 1.9 in accordance with regulatory requirements and globally harmonized device design practices

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

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

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

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.

Accuracy of Displayed Acoustic Parameters
The equipment displays the acoustic indices TI and MI in increments of 0.1 over the range of 0 to maximum output according to the methods defined in IEC 60601-2-37. The displayed values are derived from laboratory measurements performed during the acoustic characterization of the system and represent estimates of the acoustic output under defined conditions.

The accuracy of the displayed indices TI and MI is ±0.1. The precision of the acoustic measurements is covered in the "Acoustic Measurement Precision and Uncertainty" section.

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.

	Precision	Uncertainty (Percentage, 95% Confidence Value)
Pr	<1%	+/- 8.4%
Wo	7.6%	+/- 16.8%
fc	<1%	< +/- 1%
PII.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)
PII.3 = the derated spatial-peak pulse intensity integral in joules per square centimeter (j/cm2)

Device Labels

These labels are included on the Vave probe, its accessories, or packaging, in compliance with ISO and IEC regulatory standards.

Universal Probe Kit Label	Universal Probe Label	Battery Label
		

Phased Probe Kit Label	Phased Probe Label	Battery Charger Label
		

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): United States FDA Class II and EU-MDR Class IIa
- Scanners: Type BF applied parts, IP67
- Battery: IP67
- Ordinary Equipment/Continuous Operation
- Non-AP/APG

Product Model Numbers

The model number for the Vave Wireless Ultrasound systems and components, including accessories, are provided in the following table.

Product Name / Description	Model Number
Vave Universal Probe Kit	**VA-0327**
Vave Universal Probe	**VA-0133**
Vave Phased Probe Kit	**VA-0182**
Vave Phased Probe	**VA-0116**
Vave Battery	**VA-0175**
Vave Battery Charger	**VA-0252**
Charger AC-DC Adaptor	**Mean Well GEM30I12-P1J**

Environmental operating, transient and storage conditions

The following are the acceptable environmental conditions for the operation, transport, and storage of the Vave ultrasound system, composed of the ultrasound probe and accessories.

Figure 5.1: 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 + 35°C (+95°F)	-20°C (-4°F) to + 50°C (+122°F)
(1) The conditions under which the Vave ultrasound system can operate, for at least 15 minutes, immediately after being removed from an environment of 20°C (60°F).			

Note: Display devices are not supplied by Vave Health and must be purchased separately. Follow the manufacturer's specified operating, transport, and storage conditions carefully.

If stored or transported in conditions outside what's stated above, the Vave ultrasound system 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 its temperature reaches 45°C (113°F). The patient contact area will not exceed 43°C (109°F) during operation.

The temperature icon:
- Blue: indicates that the scanner is cool.
- Orange: indicates that the scanner is warm.
- Red: it indicates that the scanner is hot.

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 Specifications

Figure 5.2: System Specifications

Product	System Specifications
Vave Phased Probe	**Dimensions**: 169 x 54 x 38 mm (including battery) **Weight**: 215 g (without battery) **Frequency Range**: 1 MHz to 5 MHz **Maximum Imaging Depth:** adjustable 5-24cm
Vave Universal Probe	**Dimensions**: 166 x 54 x 38 mm (including battery) **Weight**: 220 g (without battery) **Frequency Range**: 2 MHz to 8 MHz **Maximum Imaging Depth:** adjustable 5-24cm for Sector image and 2-8cm for Linear image
Vave Battery	**Dimensions**: 83.4 x 54 x 21.8 mm **Weight**: 130 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 5.3: Accessories Descriptions

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.

Mobile Display Device Specifications

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.

Caution

iOS Devices	Android Devices
Minimum Device Requirements: • Operating System: one version prior to the latest publicly released build • Hardware Specifications: Processor: A13, RAM: 3 GB **Recommended Requirements:** • Operating System: latest publicly released build • Hardware Specifications: Processor: A16+, RAM: 6 GB+	**Minimum Device Requirements:** • Operating System: one version prior to the latest publicly released build • Hardware Specifications: Processor: Quad-core, RAM: 3 GB **Recommended Requirements:** • Operating System: latest publicly released build • Hardware Specifications: Processor: Octa-core+, RAM: 6 GB+

Note: Please read the FAQ page on the Vave Health website for the list of mobile devices that have been specifically tested.

Battery and Charger Specifications

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

Battery Specifications	Description
Battery Manufacturer	Vave Health, Inc.
Battery Type/Chemistry	Lithium ion
Battery Model Number	VA-0175
Battery Management	Fuel gauge with protection circuitry and temperature monitoring
Battery Voltage / Capacity	3.6 V / 7000 mAh
Battery Life	The 1000th discharge capacity will have 80% of initial capacity
Charger AC Adaptor	Input: 100-240 Vac, 50/60 Hz, 1.0-0.6 A Output: 12 VDC, 2.5 A
Battery Charging Time	< 4 hours from an empty battery to full charge
Scan Time with Full Battery	Over 1 hour of continuous operation in B-Mode

Hardware Warranty and Disposal

Warranty/Disposal	Description
Warranty	Your Vave Probe includes a minimum one-year warranty. See https://www.vavehealth.com for current information.
Disposal	Vave Probe, Battery and Accessories can be environmentally hazardous if improperly disposed. Please follow all local, state, and federal regulations for electronic medical devices and Li-ion battery disposal.

Expected Service Life

The Vave Wireless Ultrasound system, including all accessories, is designed for an expected service life of 5 years under normal use conditions. The expected service life of the Vave Wireless Ultrasound System depends on multiple factors, including frequency of use, environmental conditions during operation, and adherence to recommended handling and maintenance practices. For optimal longevity, users must operate, store, and maintain the device in accordance with the instructions provided in this User Manual.

Standards

The Vave Wireless Ultrasound System has been evaluated, tested, and found to meet the applicable requirements of the following standards.

Standard	Description
EN ISO 13485:2016/A11:2021	Medical devices — Quality management systems — Requirements for regulatory purposes
EN ISO 14971:2019/A11:2021	Medical devices — Application of risk management to medical devices
EN IEC 60601-1:2006/A1:2013/A2:2021	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance
EN IEC 60601-1-2:2015/A1:2021	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic disturbances
EN IEC 60601-2-37:2024	Medical electrical equipment — Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
EN IEC 60601-1-6:2010/A1:2013/A2:2020	Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability
EN IEC 60601-1-11:2015/A1:2020	Medical electrical equipment — Part 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
EN IEC 60601-1-12:2014/A1:2020	Medical electrical equipment — Part 1-12: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment
EN IEC 62304:2006/A1:2015	Medical device software — Software life cycle processes
EN IEC 62366-1:2015/A1:2020	Medical devices — Part 1: Application of usability engineering to medical devices
EN ISO 10993-1:2020	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2021	Biological evaluation of medical devices — Part 10: Tests for skin sensitization
EN ISO 10993-23:2021	Biological evaluation of medical devices — Part 23: Tests for irritation
EN ISO 10993-12:2021	Biological evaluation of medical devices — Part 12: Sample preparation and reference materials
EN ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
EN ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
ISO 17664:2017	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices
EN IEC 62133-2:2017/A1:2021	Secondary cells and batteries containing alkaline or other non-acid electrolytes — Safety requirements for portable sealed secondary lithium cells and batteries

Specifications and main characteristics of wireless transmission systems

Tx Frequency Ranges (MHz)	Maximum Output Power (W)	Emission designation	Technologies	Modulation type	Maximum speed rate
2400 - 2483,5	0,0038	690KF7D	Bluetooth LE	GFSK	1 Mbit/s
	0,1659	15M1X9D	OFDM / 802.11n (20Mhz)	BPSK / QPSK / 16-QAM / 64-QAM	72,2 Mbit/s
	0,1230	35M1X9D	OFDM / 802.11n (40Mhz)	BPSK / QPSK / 16-QAM / 64-QAM	150 Mbit/s
5725 - 5850	0,1737	18M2X9D	OFDM / 802.11a	BPSK / QPSK / 16-QAM / 64-QAM	54 Mbit/s
	0,1230	17M8X9D	OFDM / 802.11n (20Mhz)	BPSK / QPSK / 16-QAM / 64-QAM	72,2 Mbit/s
	0,0851	36M0X9D	OFDM / 802.11n (40Mhz)	BPSK / QPSK / 16-QAM / 64-QAM	150 Mbit/s
5150 - 5350	0,0263	-	OFDM / 802.11a	BPSK / QPSK / 16-QAM / 64-QAM	54 Mbit/s
	0,0199	-	OFDM / 802.11n (20Mhz)	BPSK / QPSK / 16-QAM / 64-QAM	72,2 Mbit/s
	0,0123	-	OFDM / 802.11n (40Mhz)	BPSK / QPSK / 16-QAM / 64-QAM	54 Mbit/s
5470 - 5725	0,0257	-	OFDM / 802.11a	BPSK / QPSK / 16-QAM / 64-QAM	54 Mbit/s
	0,0195	-	OFDM / 802.11n (20Mhz)	BPSK / QPSK / 16-QAM / 64-QAM	72,2 Mbit/s
	0,0091	-	OFDM / 802.11n (40Mhz)	BPSK / QPSK / 16-QAM / 64-QAM	54 Mbit/s

Wireless Compliance with FCC and ISEDC

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

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

The FCC requires the user to be notified that any changes or modifications made to this device that are not expressly approved by Vave Health, Inc. may void the user's authority to operate the equipment. Per 47 CFR §15.19 This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This device complies with Innovation, Science and Economic Development Canada's 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.

ISEDC 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 – Phased Probe

Figure 5.4: B-Mode Fundamental Acoustic Output Table Phased Probe

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_{1x1} (mW)	-	33.1		33.1		
	z_s (cm)	-	-	n/a	-	-	-
	z_b (cm)	-	-	-	-	n/a	-
	z_{MI} (cm)	4.538	-	-	-	-	-
	$z_{PII,\alpha}$ (cm)	4.538	-	-	-	-	-
	f_{wf} (MHz)	2.719	2.719		2.719		n/a
Other Information	prr (Hz)	1720	-	-	-	-	-
	srr (hz)	20	-	-	-	-	-
	n_{pps}	1	-	-	-	-	-
	$I_{pa,\alpha}$ at $z_{PII,\alpha}$ (W/cm^2)	207.2	-	-	-	-	-
	$I_{spta,\alpha}$ at z_{PII} (mW/cm^2)	11.04	-	-	-	-	-
	I_{spta} at z_{PII} (mW/cm^2)	25.35	-	-	-	-	-
	p_r at z_{PII} (MPa)	2.54	-	-	-	-	-
Operating Conditions	Preset	Lung	Lung		Lung		-
	Focus (mm)	50	50		50		-

Tissue Harmonic B-Mode Operation – Phased Probe

Figure 5.5: Tissue Harmonic B-Mode Acoustic Output Table Phased Probe

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_{1x1} (mW)	-	34.3		34.3		
	z_s (cm)	-	-	n/a	-	-	-
	z_b (cm)	-	-	-	-	n/a	-
	z_{MI} (cm)	5.15	-	-	-	-	-
	$z_{PII,\alpha}$ (cm)	5.15	-	-	-	-	-
	f_{wf} (MHz)	1.694	1.694		1.694		n/a
Other Information	prr (Hz)	1320	-	-	-	-	-
	srr (hz)	30	-	-	-	-	-
	n_{pps}	1	-	-	-	-	-
	$I_{pa,\alpha}$ at $z_{PII,\alpha}$ (W/cm^2)	134.9	-	-	-	-	-
	$I_{spta,\alpha}$ at z_{PII} (mW/cm^2)	16.27	-	-	-	-	-
	I_{spta} at z_{PII} (mW/cm^2)	29.13	-	-	-	-	-
	p_r at z_{PII} (MPa)	1.96	-	-	-	-	-
Operating Conditions	Preset	Cardiac	Cardiac		Cardiac		-
	Focus (mm)	75	75		75		-

M-Mode Operation – Phased Probe

Figure 5.6: M-Mode Acoustic Output Table Phased Probe

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_{1x1} (mW)	-	34.3		34.3		
	z_s (cm)	-	-	2.504	-	-	-
	z_b (cm)	-	-	-	-	4.856	-
	z_{MI} (cm)	5.15	-	-	-	-	-
	$z_{PII,\alpha}$ (cm)	5.15	-	-	-	-	-
	f_{wf} (MHz)	1.694	1.694		1.694		n/a
Other Information	prr (Hz)	480	-	-	-	-	-
	srr (hz)	7.5	-	-	-	-	-
	n_{pps}	n/a	-	-	-	-	-
	$I_{pa,\alpha}$ at $z_{PII,\alpha}$ (W/cm^2)	134.9	-	-	-	-	-
	$I_{spta,\alpha}$ at z_{PII} (mW/cm^2)	27.65	-	-	-	-	-
	I_{spta} at z_{PII} (mW/cm^2)	51.28	-	-	-	-	-
	p_r at z_{PII} (MPa)	1.96	-	-	-	-	-
Operating Conditions	Preset	Cardiac	Cardiac		Cardiac		-
	Focus (mm)	75	75		75		-

Figure 5.7: Color Doppler Mode Acoustic Output Table Phased Probe

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_{1x1} (mW)	-	79.4		79.4		
	z_s (cm)	-	-	n/a	-	-	-
	z_b (cm)	-	-	-	-	n/a	-
	z_{MI} (cm)	4.74	-	-	-	-	-
	$z_{PII,\alpha}$ (cm)	4.74	-	-	-	-	-
	f_{wf} (MHz)	2.15	2.15		2.15		n/a
Other Information	prr (Hz)	2077	-	-	-	-	-
	srr (hz)	23.6	-	-	-	-	-
	n_{pps}	8	-	-	-	-	-
	$I_{pa,\alpha}$ at $z_{PII,\alpha}$ (W/cm^2)	305.4	-	-	-	-	-
	$I_{spta,\alpha}$ at z_{PII} (mW/cm^2)	180.83	-	-	-	-	-
	I_{spta} at z_{PII} (mW/cm^2)	364.22	-	-	-	-	-
	p_r at z_{PII} (MPa)	2.01	-	-	-	-	-
Operating Conditions	Preset	Cardiac	Cardiac		Cardiac		-
	Focus (mm)	50	50		50		-
	ROI Span (degrees)	18.8	56.2		56.2		-

B-Mode Operation – Universal Probe

Figure 5.8: B-Mode Acoustic Output Table Universal Probe

Index Label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value		0,84	0,21		0,38	0,21	0,38
Associated Acoustic Parameter	$p_{r,\alpha}$ at z_{MI} (MPa)	1,29	-	-	-	-	-
	P (mW)	-	22,77		22,77		22,77
	P_{1x1} (mW)	-	16,03		16,03		
	z_s (cm)	-	-	4,83	-	-	-
	z_b (cm)	-	-	-	-	4,83	-
	z_{MI} (cm)	4,83	-	-	-	-	-
	$z_{PII,\alpha}$ (cm)	4,83	-	-	-	-	-
	f_{wf} (MHz)	2,75	2,75	2,75	2,75	2,75	2,75
Other Information	prr (Hz)	1728	-	-	-	-	-
	srr (hz)	27	-	-	-	-	-
	n_{pps}	1	-	-	-	-	-
	$I_{pa,\alpha}$ at $z_{PII,\alpha}$ (W/cm^2)	1,14E+02	-	-	-	-	-
	$I_{spta,\alpha}$ at z_{PII} (mW/cm^2)	15,10	-	-	-	-	-
	I_{spta} at z_{PII} (mW/cm^2)	35,72	-	-	-	-	-
	p_r at z_{PII} (MPa)	2,04	-	-	-	-	-
Operating Conditions	Preset	Cardiac	Cardiac		Cardiac		-
	Focus (mm)	150	150		150		-

B-Mode Operation – Universal Probe – Vascular Preset

Figure 5.9: B-Mode Vascular Preset Acoustic Output Table Universal Probe

Index Label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value		0.29	0.15		0.07		0.07
Associated Acoustic Parameter	$p_{r,\alpha}$ at z_{MI} (MPa)	2.56	-	-	-	-	-
	P (mW)	-	1.60		1.60		1.60
	P_{1x1} (mW)	-	2.00		2.00		
	z_s (cm)	-	-	3.00	-	-	-
	z_b (cm)	-	-	-	-	3.00	-
	z_{MI} (cm)	3.00	-	-	-	-	-
	$z_{PII,\alpha}$ (cm)	3.00	-	-	-	-	-
	f_{wf} (MHz)	6.45	6.45		6.45		6.45
Other Information	prr (Hz)	1280.00	-	-	-	-	-
	srr (hz)	20.0	-	-	-	-	-
	n_{pps}	1.00	-	-	-	-	-
	$I_{pa,\alpha}$ at $z_{PII,\alpha}$ (W/cm^2)	22.67	-	-	-	-	-
	$I_{spta,\alpha}$ at z_{PII} (mW/cm^2)	0.43	-	-	-	-	-
	I_{spta} at z_{PII} (mW/cm^2)	1.62	-	-	-	-	-
	p_r at z_{PII} (MPa)	5.00	-	-	-	-	-
Operating Conditions	Preset	Vascular	Vascular		Vascular		-
	Focus (mm)	30	30		30		-

M-Mode Operation – Universal Probe

Figure 5.10: M-Mode Acoustic Output Table Universal Probe

Index Label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value		0.77	4.62E-02		0.08	0.69	0.08
Associated Acoustic Parameter	$p_{r,\alpha}$ at z_{MI} (MPa)	1.26	-	-	-	-	-
	P (mW)	-	4.80		4.80		4.80
	P_{1x1} (mW)	-	3.47		3.47		
	z_s (cm)	-	-	N/A	-	-	-
	z_b (cm)	-	-	-	-	N/A	-
	z_{MI} (cm)	5.30	-	-	-	-	-
	$z_{PII,\alpha}$ (cm)	5.30	-	-	-	-	-
	f_{wf} (MHz)	2.80	2.80	2.80	2.80	2.80	2.80
Other Information	prr (Hz)	200	-	-	-	-	-
	srr (hz)	N/A	-	-	-	-	-
	n_{pps}	1	-	-	-	-	-
	$I_{pa,\alpha}$ at $z_{PII,\alpha}$ (W/cm^2)	4.60E+01	-	-	-	-	-
	$I_{spta,\alpha}$ at z_{PII} (mW/cm^2)	5.61	-	-	-	-	-
	I_{spta} at z_{PII} (mW/cm^2)	14.70	-	-	-	-	-
	p_r at z_{PII} (MPa)	2.10	-	-	-	-	-
Operating Conditions	Preset	Cardiac	Cardiac		Cardiac		-
	Focus (mm)	150	150		150		-

M-Mode Operation – Universal Probe – Vascular Preset

Figure 5.11: M-Mode Vascular Preset Acoustic Output Table Universal Probe

Index Label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value		0.29	0.15		0.07		0.07
Associated Acoustic Parameter	$p_{r,\alpha}$ at z_{MI} (MPa)	2.56	-	-	-	-	-
	P (mW)	-	1.60		1.60		1.60
	P_{1x1} (mW)	-	2.00		2.00		
	z_s (cm)	-	-	N/A	-	-	-
	z_b (cm)	-	-	-	-	N/A	-
	z_{MI} (cm)	1: 3.00	-	-	-	-	-
	$z_{PII,\alpha}$ (cm)	1: 3.00	-	-	-	-	-
	f_{wf} (MHz)	1: 6.45 2: 6.45	1: 6.45 2: 6.45		1: 6.45 2: 6.45		1: 6.45 2: 6.45
Other Information	prr (Hz)	1: 384	-	-	-	-	-
	srr (hz)	1: 6.0	-	-	-	-	-
	n_{pps}	1: 1.00	-	-	-	-	-
	$I_{pa,\alpha}$ at $z_{PII,\alpha}$ (W/cm^2)	1: 22.67	-	-	-	-	-
	$I_{spta,\alpha}$ at z_{PII} (mW/cm^2)	0.13	-	-	-	-	-
	I_{spta} at z_{PII} (mW/cm^2)	0.49	-	-	-	-	-
	p_r at z_{PII} (MPa)	1: 5.00	-	-	-	-	-
Operating Conditions	Preset	Vascular	Vascular		Vascular		-
	Focus (mm)	30	30		30		-

Color Doppler Mode Operation – Universal Probe

Figure 5.12: Color Doppler Mode Acoustic Output Table Universal Probe

Index Label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value		1.42	0.90		1.82	0.90	1.82
Associated Acoustic Parameter	$p_{r,\alpha}$ at z_{MI} (MPa)	2.23	-	-	-	-	-
	P (mW)	-	108.93		108.93		108.93
	P_{1x1} (mW)	-	79.13		79.13		
	z_s (cm)	-	-	N/A	-	-	-
	z_b (cm)	-	-	-	-	N/A	-
	z_{MI} (cm)	4.72	-	-	-	-	-
	$z_{PII,\alpha}$ (cm)	4.72	-	-	-	-	-
	f_{wf} (MHz)	2.40	2.40	2.40	2.40	2.40	2.40
Other Information	prr (Hz)	2304	-	-	-	-	-
	srr (hz)	18	-	-	-	-	-
	n_{pps}	1	-	-	-	-	-
	$I_{pa,\alpha}$ at $z_{PII,\alpha}$ (W/cm^2)	3.87	-	-	-	-	-
	$I_{spta,\alpha}$ at z_{PII} (mW/cm^2)	0.07	-	-	-	-	-
	I_{spta} at z_{PII} (mW/cm^2)	0.12	-	-	-	-	-
	p_r at z_{PII} (MPa)	0.50	-	-	-	-	-
Operating Conditions	Preset	Cardiac	Cardiac		Cardiac		-
	Focus (mm)	100	100		100		-

Color Doppler Mode Operation – Universal Probe – Vascular Preset

Figure 5.13: Color Doppler Mode Vascular Preset Acoustic Output Table Universal Probe

Index Label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value		0.76	1.11		1.07		1.07
Index Component Value		-	1: 0.15 2: 0.96		1: 0.07 2: 1.0		1: 0.07 2: 1.0
Associated Acoustic Parameter	$p_{r,\alpha}$ at z_{MI} (MPa)	3.70	-	-	-	-	-
	P (mW)	-	1: 1.60 2: 38.50		1: 1.60 2: 38.50		1: 1.60 2: 38.50
	P_{1x1} (mW)	-	1: 2.00 2: 27.40		1: 2.00 2: 27.40		
	z_s (cm)	-	-	N/A	-	-	-
	z_b (cm)	-	-	-	-	N/A	-
	z_{MI} (cm)	3.00	-	-	-	-	-
	$z_{PII,\alpha}$ (cm)	3.00	-	-	-	-	-
	f_{wf} (MHz)	1: 6.45	1: 6.45 2: 4.20		1: 6.45 2: 4.20		1: 6.45 2: 4.20
Other Information	prr (Hz)	1: 2560.00	-	-	-	-	-
	srr (hz)	1: 20.0	-	-	-	-	-
	n_{pps}	1: 1.00	-	-	-	-	-
	$I_{pa,\alpha}$ at $z_{PII,\alpha}$ (W/cm^2)	1: 132.13	-	-	-	-	-
	$I_{spta,\alpha}$ at z_{PII} (mW/cm^2)	1: 26.95	-	-	-	-	-
	I_{spta} at z_{PII} (mW/cm^2)	1: 64.2	-	-	-	-	-
	p_r at z_{PII} (MPa)	1: 5.00	-	-	-	-	-
Operating Conditions	Preset	Vascular	Vascular		Vascular		-
	Focus (mm)	30	30		30		-

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/π)(Wo/ITA(z))]0.5, where ITA(z) is the temporal-average intensity as a function of z in centimeters.
- **deq@PIImax** Equivalent beam diameter at the point where the free-field, spatial-peak pulse intensity integral is a maximum in centimeters.
- **depth** Refers to the depth of the display. A constant speed of sound of 1538.5meters/second is assumed in the calculation of echo position in the image.
- **Dim. of Aaprt** Active aperture dimensions for the azimuthal (x) and elevational (y) planes in centimeters.
- **fc** The center frequency (MHz). For MI, fc is the center frequency associated with the transmit pattern giving rise to the global maximum reported value of MI. For TI, when using combined modes involving transmit patterns of unequal center frequency, fc is defined as the overall range of center frequencies of the respective transmit patterns.
- **in situ** In the natural or original position.
- **FL** Focal length, or azimuthal (x) and elevational (y) lengths if different, measured in centimeters.
- **Ipa.3@MImax** Derated pulse average intensity at the maximum MI in units of W/cm2.
- **ISPTA.3** Derated spatial peak, temporal average intensity in units of milliwatts/cm2.
- **ISPTA.3z1** Derated spatial-peak temporal-average intensity at axial distance z1 in units of milliwatts/cm2.
- **ITA.3(z1)** The derated spatial-peak temporal-average intensity at axial distance in units of milliwatts/cm2.
- **MI (mechanical index)** An indication of the likelihood of mechanical bioeffects occurring. The higher the MI, the greater the likelihood of mechanical bioeffects.
- **PD** Pulse duration 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) x 1 cm2)], where z ≥ _zbp in centimeters.
- **Zbp** 1.69 (Aaprt) in centimeters.
- **Zsp** For MI, the axial distance at which pr.3 is measured. For TIB, the axial distance at which TIB is a global maximum (for example, zsp = zb.3) in centimeters.
- **z@PII.3max** The axial distance corresponding to the maximum of the derated spatial-peak pulse intensity integral (megapascals).