GE HealthCare

Technical Publications

Vscan Air

Version 2.0

$C\,\epsilon_{0123}$

User Manual

H45621AA
GP092019-1EN - English

Rev 11

General User Documentation

Regulatory requirement

Vscan Air™

The Vscan Air R2 for iOS and Vscan Air R2 for Android product with their connected probes complies with regulatory requirements of the following European Directive 2017/745/EU Medical Device Regulation

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This manual is a reference for the following Vscan Air CL probe configurations: Vscan Air CL A1, Vscan Air CL A2, Vscan Air CL C1, Vscan Air CL I1 and Vscan Air CL G1.

This manual is a reference for the Vscan Air SL probe configurations: Vscan Air SL

This manual is a reference for all 2.X software versions of Vscan Air R2 for Android and all 2.X software versions of Vscan Air R2 for iOS.

GE HealthCare

Revision History

Reason for Change

REV	DATE DD Month YYYY	REASON FOR CHANGE
Rev 1 to 4	25 Apr 2023	Internal release
Rev 5	13 Jun 2023	Initial release
Rev 6	17 Aug 2023	Chapter 2: - Added Radio Frequency info under section - Interference Caution - Updated Table 2-2: Electromagnetic immunity (Part 1) Chapter 6: - Updated Step 2 in Table 6-5: Troubleshooting in pairing
Rev 7	20 Oct 2023	Chapter 3: - Updated Section Vscan Air - Compatible Display Devices Chapter 4: - Added Storage Mode information under Section Configuration - Updated Figure 4-67. Probe subscription details and Figure 4-68. Subscribed Digital tools available - Added Sections Subscription Auto renewal and Subscription Expiry Date Chapter 5: - Added Figure 5-7. Flat Linear Array (FLA) - Added Section Image crop and measurements - Added Angle measurement information - Added Figure 5-65. Select Angle measurement - Updated Section Storing devices in between uses Chapter 6: - Added Section Postpone update - Updated Section Upgrade software
Rev 8	27 Feb 2024	- Added Oman and South Africa Telecom Certification Information for Vscan Air CL - Added Oman, Korea, South Africa, Nigeria, and Morocco Telecom Certification Information for Vscan Air SL - Updated the 5GHz preferred bandwidth to 20MHz in the section 'Wireless description for Vscan Air probes'.
Rev 9	12 Mar 2024	- Included information on the End User License Agreement - Updated battery lifetime in Table 3-4 - Updated Sections: 'How to charge the Vscan Air probes', 'About', 'Zoom and pan', 'Supported Mobile Platforms' and 'Vscan Air - Compatible Display Devices' - Updated overall graphics to support new heading or banner change Chapter 5: - Added Section: AI tools Chapter 6: - Added Section: Troubleshoot subscriptions

REV	DATE DD Month YYYY	REASON FOR CHANGE
Rev 10	30 Apr 2024	- Added Canada IC information under Section 'Telecom Certification Information for Vscan Air SL' - Added Thailand label under Section 'Country Specific Approvals' Chapter 3: - Added Section: Vscan Air AC Adapter Type F - Updated Note related to password under Section 'Create a Vscan Air account' - Updated Sections: 'How to charge the Vscan Air probes', 'Supported Mobile Platforms' and 'Vscan Air - Compatible Display Devices' Chapter 6: - Updated Section: Password Guidelines
Rev 11	30 May 2024	Chapter 1: - Updated Section: 'Contact information' Chapter 3: - Updated Section: 'Vscan Air - Compatible Display Devices' - Added Section: 'Caption AI - Compatible Display Devices' - Added Section: 'Vscan Air app registration using a Enterprise Single Sign-On (SSO) user account' Chapter 4: - Added Section: 'Configure Modality Performed Procedure Step (MPPS) Server' Chapter 5: - Added Section: 'MPPS Server'

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Regulatory requirements

Conformance Standards

The GE HealthCare (GEHC) product families are tested to meet all applicable requirements in relevant EU Directives, EU regulations and European/International standards. Any changes to accessories, peripheral units or any other part of the device must be approved by the manufacturer. Ignoring this advice may compromise the regulatory approvals obtained for the product.

This product complies with the regulatory requirement of the following:

Table i-1:   Regulatory requirements

Standard/Directive	Scope
2017/745 Medical Device Regulation (MDR)	Medical Device Regulation (MDR). The CE label affixed to the product testifies compliance to this regulation. The location of the CE marking is shown in the Safety chapter of this manual. Year of first CE mark: 2023
93/42/EEC Medical Devices Directive (MDD)	Medical Devices Directive (MDD) The CE label affixed to the Vscan Air CL A1, Vscan Air CL A2, Vscan Air CL C1, Vscan Air CL I1 and Vscan Air CL G1 probes testifies compliance to the Directive. The location of the CE marking is shown in the safety chapter of this manual. Year of first CE mark: 2020
2014/53/EU	Radio Equipment Directive (RED)
2011/65/EU including 2015/863/EU Annex II	Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (ROHS)
2012/19/EU	Waste Electrical and Electronic Equipment (WEEE)
EN55011	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement
IEC* 60601-1 CAN/CSA-C22.2 No 601.1	Medical Electrical Equipment, Part 1; General Requirements for Safety

Table i-1: Regulatory requirements (Continued)

Standard/Directive	Scope
IEC* 60601-2-37	Medical electrical equipment - Part 2-37. Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
IEC* 60601-1-2	Medical Electrical Equipment - part 1-2. Collateral standard: Electromagnetic compatibility - Requirements and tests.
IEC* 60601-1-6	Medical Electrical Equipment - part 1-6. Collateral standard: Usability.
ISO10993-1	Biological evaluation of medical devices
EN 300 328	Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems
ISO 14971	Medical devices — Application of risk management to medical devices
IEC* 62304	Medical device software — Software life-cycle processes
IEC* 62366-1	Medical devices — Application of usability engineering to medical devices
IEC 60601-1-11	Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 60601-1-12	Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
EN13718-1	Medical vehicles and their equipment — Air ambulances, Part 1: Requirements for medical devices used in air ambulances
EN1789	Medical vehicles and their equipment — Road ambulances
ISO15223	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
EN1041	Information supplied by the manufacturer with medical devices
IEC 62209-2	Human exposure to radio frequency fields from hand-held and body-mounted wireless communication devices — Human models, instrumentation, and procedures — Part 2: Procedure to determine the specific absorption rate (SAR) for wireless communication devices used in close proximity to the human body (frequency range of 30 MHz to 6 GHz)

Table i-1: Regulatory requirements (Continued)

Standard/Directive	Scope
ISO 17664	Specifies requirements for the information to be provided by the medical device manufacturer for the processing of a medical device that requires cleaning followed by disinfection and/or sterilization to ensure that the device is safe and effective for its intended use. This includes information for processing prior to use or reuse of the medical device. The provisions of ISO 17664:2017 are applicable to medical devices that are intended for invasive or other direct or indirect patient contact.
2015/863/EU	Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances (RoHS 3).
* including national deviations	

NOTE: All references to standards/regulations and their revisions are valid at the time of publication of the user manual.

Authorized Swiss Representative:

CH | REP

GE Medical Systems (Schweiz) AG

Europa-Strasse 31

8152 Glattbrugg

Switzerland

Certifications

- GE Vingmed Ultrasound AS is ISO 13485 certified.

Classifications

The following classifications are in accordance with the IEC/EN 60601-1:

Type and degree of protection against electric shock:

- The Vscan Air CL and Vscan Air SL probes has an internal battery which allows the operation during AC power absence.
- The AC adapters available with Vscan Air are Class II devices.
- The AC adapters available with Vscan Air must be limited to indoor use only.

The Vscan Air CL and Vscan Air SL probes are labeled IP67 meaning that it can be submerged in 1m of water for 30 minutes.

The AC adapter is IP20 meaning it must be limited to indoor use.

Class II equipment

Equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conditions.

Type BF applied part

Type BF applied part providing a specified degree of protection against electric shock, with regard to allowable leakage current.

Table i-2:   Leakage current

	Normal condition	Single fault condition
Total Patient leakage current	<500 microA	<1000 microA

Original documentation

- The original document was written in English.
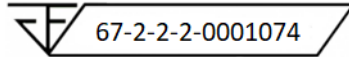
Country Specific Approval

Importer Information

• Türkiye

GE Medical Systems Türkiye Ltd. Şti. Esentepe Mah. Harman Sok. No: 8 34394 Şişli İstanbul Türkiye.

• Thailand

GE Medical Systems (Thailand) Ltd.

32nd Floor, Thanapoom Tower

1550 New Petchburi Road

Makkasan, Ratthewi, Bangkok 10400, Thailand

Tel: (+66) 2 624 8488

Vscan Air SL:

67-2-2-2-0001074

Telecom Certification Information for Vscan Air CL

- **Korea**

   R-C-GeH-GP000153

- **Nigeria**

  Connection and use of this communications equipment is permitted by the Nigerian Communications Commission.

- **Morocco**

AGREE PAR L'ANRT MAROC
Numéro d'agrément : MR00029825ANRT2021
Date d'agrément : 26/08/2021

- **USA**

  FCC ID: YOM-VSCANAIR

- **Canada**

  IC: 9136A-VSCANAIR

  Steps to access FCC ID and IC ID
  - To access FCC ID and IC ID information, select **Menu** icon on Vscan Air app.
  - Press **About** and select **Regulatory**.

- **Oman**

Oman - TRA
D172338
TRA/TA-R/12761/21

- **South Africa**

   TA-2021-0933 APPROVED

Telecom Certification Information for Vscan Air SL

• Korea

⟨ R-C-GeH-GP000180

• Nigeria

Connection and use of this communications equipment is permitted by the Nigerian Communications Commission.

• Morocco

AGREE PAR L'ANRT MAROC
Numéro d'agrément : MR00040176ANRT2023
Date d'agrément : 06/10/2023

• USA

FCC ID: YOM-VSCANAIRSL

• Canada

IC: 9136A-VSCANAIRSL

Steps to access FCC ID and IC ID
• To access FCC ID and IC ID information, select **Menu** icon on Vscan Air app.
• Press **About** and select **Regulatory**.

• Oman

OMAN - TRA
R/17215/23
D202897

• South Africa

I C·A·S·A   TA-2023-2728 APPROVED

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Chapter 1

Introduction

Contents:

Overview

Attention

This manual contains necessary and sufficient information to operate the ultrasound system safely. Read and understand all instructions in the User Manual before attempting to use the ultrasound system. Periodically review the procedures for operation and safety precautions. Disregarding information on safety is considered abnormal use. Not all features or products described in this document may be available or cleared for sale in all markets. Please contact your local GE representative to get the latest information.

NOTE: GE HealthCare reserves the right to make changes in specifications and features shown herein, or discontinue the product described at any time without notice or obligation. Contact your GE HealthCare representative for the most current information.

NOTE: All references to standards/regulations and their revisions are valid at the time of publication of the user manual.

Documentation

Vscan Air documentation consists of various manuals:

• The User Manual (TRANSLATED), the quick start guide and onboard app walkthrough provides information needed by the user to operate the system safely. It describes the basic functions of the system, safety features, operating modes, measurements/calculations, transducers, Acoustic Output and user care and maintenance.

Documentation (continued)

- The Privacy and Security Manual (TRANSLATED) describes privacy and security considerations, privacy and security capabilities, and how they are configured and used appropriately.

NOTE: *For Privacy and Security Manual, reach out to your GE HealthCare sales representative or GE HealthCare support team. Users can download the Privacy and Security Manual by registering and logging in to GE HealthCare's Product Security Portal.*

https://www.gehealthcare.com/productsecurity/products

- The Service Manual (ENGLISH ONLY) supplies block diagrams, lists of spare parts, descriptions, adjustment instructions, or similar information which helps qualified technical personnel in repairing those parts of the system which have been defined as repairable.

- Medical Ultrasound Safety publication from American Institute of Ultrasound in Medicine (AIUM) (ENGLISH ONLY). Provided as ALARA Educational Program, to comply with US FDA Track 3 - Not available in all countries.

NOTE: *The 'Electronic Instructions For Use' leaflet provided with the Vscan Air probe holds instructions on how to access user documentation available in electronic format. The Vscan Air user manual is written for users who are familiar with basic ultrasound principles and techniques and does not include sonographic training or detailed clinical procedures. The Vscan Air user documentation is available in English and translations are available.*

NOTE: *The screen graphics in this manual are only for illustration purposes and screen graphics text is replicated in English only. Actual screen output may differ with different software (SW) revisions.*

Documentation (continued)

NOTE: *The labels displayed in this manual are only for illustration purposes. The label content may be different for different regions.*

Please refer to the system product labels for the actual content.

This manual covers the following configurations of the Vscan Air:

1. Vscan Air software application (app):
    •   Vscan Air R2 for iOS
    •   Vscan Air R2 for Android
2. Vscan Air CL probe
3. Vscan Air SL probe

The table below lists the Vscan Air probe configurations covered by this manual:

Table 1-1:   Vscan Air probe configurations

Item	Vscan Air probe Part number	REF
1	GP000150	Vscan Air CL A1
2	GP000151	Vscan Air CL A2
3	GP000153	Vscan Air CL C1
4	GP000156	Vscan Air CL I1
5	GP000158	Vscan Air CL G1
6	GP000180	Vscan Air SL

NOTE: *The Vscan Air probes comes with different AC adapter configuration and different labeling depending on which country or region it is shipped.*

Naming conventions

The following naming conventions are used throughout the user manual:

- Vscan Air CL – refers to the Vscan Air curved/linear probe.
- Vscan Air SL – refers to the Vscan Air sector (phased array)/linear probe.
- Vscan Air probe – refers to the Vscan Air CL and/or the Vscan Air SL probes.
- Vscan Air for iOS – Vscan Air R2 app for iOS devices.
- Vscan Air for Android – Vscan Air R2 app for Android devices.

The term 'Vscan Air app' has been used to refer to the software (SW) application/app in a generic way.

The terms Vscan Air ultrasound system, Vscan Air ultrasound device or Vscan Air solution are used to refer to the Vscan Air product consisting of the probe and the app.

General description

Vscan Air is a battery-operated general-purpose diagnostic ultrasound imaging system for use by qualified and trained healthcare professionals enabling visualization and measurement of anatomical structures and fluid.

Vscan Air consists of a dual headed probe which integrates both curved and linear array transducers or sector and linear array transducers. It also includes an app which can be installed on Android or iOS mobile devices.

Its pocket-sized portability and simplified user interface enable integration into examination and training sessions indoors and in other environments. The information can be used for basic/focused assessments and adjunctively with other medical data for clinical diagnosis purposes during routine, periodic monitoring, and triage assessments for adult, pediatric and neonatal patients. Vscan Air can also be useful for procedural guidance.

The Vscan Air website is available for accessing supplementary product and clinical information.

Wireless description for Vscan Air probes

Wireless communication utilizes the 2.4GHz and 5GHz (UNII-1 and UNII-3) bands supporting the IEEE 802.11a, IEEE 802.11b, IEEE 802.11g and IEEE 802.11n protocols. The wireless module supports bandwidths of 20MHz and 40MHz. The preferred frequency is 5GHz, with bandwidth 20MHz.

Table 1-2:   Wireless description

Parameter	Vscan Air CL and Vscan Air SL
1. Wireless network protocols supported	IEEE 802.11a/b/g/n
2. Frequency bands of transmission / reception	2.4GHz and 5GHz (UNII-1 and UNII-3)
3. Preferred frequency or frequency band	5GHz
4. Bandwidth(s) supported	20MHz and 40MHz
5. FCC EIRP of 2.4GHz Wi-Fi	17.08 dBm
6. FCC EIRP of 5.0GHz Wi-Fi	17.07 dBm
7. FCC EIRP of Bluetooth Low-Energy	8.16 dBm
8. ETSI EIRP of 2.4GHz Wi-Fi	17.40 dBm
9. ETSI EIRP of 5.0GHz Wi-Fi	17.23 dBm
10. ETSI EIRP of Bluetooth Low-Energy	7.49 dBm
11. SAR	Vscan Air CL: FCC - 0.540 W/kg (SAR Limit = 1.6 W/kg - over 1g) ETSI - 0.295 W/kg (SAR Limit = 2.0 W/kg - over 10g) Vscan Air SL: FCC - 0.3265 W/kg (SAR Limit = 1.6 W/kg - over 1g) ETSI - 0.146 W/kg (SAR Limit = 2.0 W/kg - over 10g)
Federal Communications Commission (FCC), Effective Isotropic Radiated Power (EIRP), European Telecommunications Standards Institute (ETSI), Specific Absorption Rate (SAR)	

Principles of operation

Medical ultrasound images are created by computer and digital memory from the transmission and reception of mechanical high-frequency waves applied through a probe. The mechanical ultrasound waves spread through the body, producing an echo where density changes occur. The echoes return to the probe where they are converted back into electrical signals.

These echo signals are amplified and processed by several analog and digital circuits having filters with many frequency and time response options, transforming the high-frequency electrical signals into a series of digital image signals which are stored in memory. Once in memory, the image can be displayed in real-time on the display device.

A probe is an accurate, solid-state device, providing multiple image formats. The digital design and use of solid-state components provides highly stable and consistent imaging performance with minimal required maintenance.

Safety

Read and understand all instructions in the User's Manual before attempting to use the ultrasound unit. User Manual is available in electronic form and is easy to reach via the app or via web. Periodically review the procedures for operation and safety precautions.

Intended use

Vscan Air is a software application on a mobile phone or tablet to be used with a Vscan Air probe. The Vscan Air app is intended for diagnostic ultrasound examinations, image guidance and for measurements of anatomical structures and fluid.

Vscan Air CL is a battery-operated general-purpose ultrasound probe intended for diagnostic ultrasound examinations and image guidance that is to be used with a host SW and display device.

Vscan Air SL is a battery-operated general-purpose ultrasound probe intended for diagnostic ultrasound examinations and image guidance that is to be used with a host SW and display device.

Indications for use

Vscan Air is a battery-operated software-based general-purpose ultrasound imaging system for use 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 device is enabling visualization and measurement of anatomical structures and fluid including blood flow.

Vscan Air's pocket-sized portability and simplified user interface enables integration into training sessions and examinations in professional healthcare facilities (ex. Hospital, clinic, medical office), home environment, road/air ambulance and other environments as described in the user manual. The information can be used for basic/focused assessments and adjunctively with other medical data for clinical diagnosis purposes during routine, periodic follow-up, and triage.

Vscan Air supports black/white (B-mode), color flow (Color Doppler), Pulsed Wave Doppler mode, M-mode, combined (B + Color Doppler) and harmonic imaging modes with curved, linear and sector array transducers.

With the curved array transducer of the dual headed probe solution, the specific clinical applications and exam types include: abdominal, fetal/obstetrics, gynecological, urology, thoracic/lung, cardiac (adult and pediatric, 40 kg and above), vascular/peripheral vascular, musculoskeletal (conventional), pediatrics, interventional guidance (includes free hand needle/ catheter placement, fluid drainage, nerve block and biopsy).

Indications for use (continued)

With the linear array transducer of the dual headed probe solution, the specific clinical applications and exam types include: vascular/peripheral vascular, musculoskeletal (conventional and superficial), small organs, thoracic/lung, ophthalmic, pediatrics, neonatal cephalic, interventional guidance (includes free hand needle/catheter placement, fluid drainage, nerve block, vascular access and biopsy).

With the sector array transducer of the dual headed probe solution, the specific clinical applications and exam types include: cardiac (adult and pediatric, 40 kg and above), abdominal, fetal/obstetrics, gynecological, urology, thoracic/lung, pediatrics, adult cephalic, interventional guidance (includes free hand needle/catheter placement, fluid drainage, nerve block and biopsy).

Table 1-3:   Supported imaging modes

	Vscan Air		
Mode	Curved array transducer	Linear array transducer	Sector array transducer
Black/white imaging (B-mode)	X	X	X
Color flow (Color doppler)	X	X	X
Combined (B+ color doppler)	X	X	X
Harmonics	X	X	X
M-mode	X	X	X
Doppler/Spectral Doppler or Pulsed Wave (PW) Doppler	X	X	X

WARNING

- To avoid injury to the patient, select the Linear array Ophthalmic preset when performing an eye exam.
- The system will stay within the lower acoustic energy limits for ophthalmic use only when the Linear array Ophthalmic preset is selected.
- Select the Linear array Ophthalmic preset for any scan where the ultrasound beam will pass through the eye.

Clinical benefit

The clinical benefit of a diagnostic ultrasound device is to help healthcare professionals provide accurate diagnostic information (visualize human tissue/internal structure) that enhances the diagnostic and treatment care pathways of the patient for a variety of diseases and conditions.

Contraindications for use

⚠ **WARNING**   The Vscan Air diagnostic ultrasound system is not intended for use with contrast agents.

Clinical application not cleared for use in Japan

NOTE: *Vscan Air diagnostic ultrasound system does not hold regulatory clearance for Ophthalmic use.*

Clinical application not cleared for use in China

NOTE: *Vscan Air diagnostic ultrasound system is not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye.*

Reporting

In case of a serious incident occurrence in relation to any Vscan Air product, this should be reported to GE HealthCare and the competent Authority.

Intended users

The list of the potential users includes but is not limited to (based on title/geographical location): physicians, sonographers, medical healthcare technicians, paramedics, nurses, nurse practitioner, midwives, midwife practitioner, physiotherapists, physician assistants, medical students. The users may or may not be working under supervision or authority of a physician. Each user is expected to have a basic level of general ultrasound training that includes basic image acquisition techniques and interpretation (i.e. position the Vscan Air probe correctly on the patient and determine at least normal vs. abnormal anatomy views during scanning).

Each user is expected to have a basic knowledge relating to using, configuring and updating Android and/or iOS based phones and tablets.

Table 1-4:   User profile

User	Description
Primary care physicians (PCPs)	General practitioners and family physicians (generally in clinic, potentially during selected nursing home/retirement facility/ patient home visits or spending part time in pre-hospital emergency care) as well as physicians who serve patients at their home (part or full time) or non-physician healthcare professionals working under their supervision (e.g. residents).
Pre-hospital emergency care users	Physicians and supervised paramedics in providing medical ambulance or air-ambulance services.
Other point-of-care users	Healthcare professionals working in emergency care, intensive care units, or other hospital wards or clinics. It includes bedside physicians and other licensed medical providers like nurses, supervised nurses, nurse practitioners, physician assistants, sonographers, midwives, supervised midwives, residents, chiropractors and physical therapists.
Medical students	Guided by teaching experts at medical schools.
Service personnel	Biomedical engineers, service and IT specialists supporting product installation and maintenance.

⚠️ CAUTION   The operator must read and understand the user manual.

Contact GEHC sales representative for product training assistance and visit the Vscan Air website for reference materials.

Prescription Device

For USA only:

⚠ CAUTION	Federal law restricts this device to sale by or on the order of a physician or other authorized licensed healthcare practitioner.

SignalMax and XDclear

GE HealthCare continues to challenge expectations regarding the limits of ultrasound image quality. Once again, setting a new standard in handheld ultrasound by miniaturizing the power of XDclear transducers to deliver extraordinary image quality with our Sector/Linear probe. This combines the power of SignalMax, high intensity signal processing already in your Vscan Air device, with an industry leading transducer technology that is proven for its level of penetration, resolution, and sensitivity in imaging performance.

Warnings

Important safety considerations

To prevent damage of the equipment or injury to yourself or others, read the following safety warnings before using Vscan Air.

⚠ WARNING

- Vscan Air probe is a precision instrument. Handle Vscan Air probe and its accessories with care.
- Do not attempt to disassemble or alter any part of the unit including the Vscan Air probe, the battery, the AC adapter and accessories. Disassembly or modification may result in electrical shock.
- Stop using the unit if it emits smoke or noxious fumes. Failure to do so may result in electrical shock or fire.
- Stop using the unit if there is any damage to covers or transducer front faces. Failure to do so may result in electrical shock.
- Do not use the AC adapter if showing visible damages.
- Do not use the USB cable if showing visible damages.
- Do not use USB cables that are not certified.
- Use only the designated power accessories (wireless charger and USB cable). Failure to do so may result in electrical shock or fire.

Important safety considerations (continued)

⚠ WARNING

- Use the supplied wireless charger or use a Qi certified charger marked with the Qi logo and compliant to (marked with) applicable regional or country standards if the supplied charger is not available.
- Do not use the wireless charger if showing visible damages.
- To reduce risk for electrical shock, do not plug or unplug the AC adapter from mains socket with wet hands.
- Avoid dropping or subjecting the unit and accessories to severe impacts. This could result in electrical shock, corrosive liquid leakage and injury.
- Keep good hand contact with Vscan Air probe during scanning to avoid heating up of the unit and termination of scan due to built-in temperature limits.
- Disconnect the AC adapter and the wireless charger when not in use to avoid fire hazard.
- Keep the AC adapter and the wireless charger dry. Failure to observe this precaution may result in fire and electric shock.
- Before charging the Vscan Air probe it is important to be aware of the Environmental requirements for Vscan Air CL and Vscan Air SL (refer 'Environmental requirements' on *page 3-7*) and to read and understand information given in the Vscan Air Battery section (refer 'Vscan Air battery' on *page 3-20*).

Contact information

Contacting GEHC Ultrasound

For additional information or assistance, please contact your local distributor or the appropriate support resource listed on the following pages:

Internet   **Vscan web portal:**

https://vscanair-support.gehealthcare.com/

https://gehealthcare.com/usermanual

https://gehealthcare.com/probecare

https://www.gehealthcare.com

Clinical questions   For information in the United States, Canada, Mexico and parts of the Caribbean, call the Customer Answer Center.
TEL: (1) 800-682-5327 or (1) 262-524-5698

In other locations, contact your local Applications, Sales, or Service Representative.

Service questions   You can raise a service ticket in the United States via https://www.gehealthcare.com/support/home, or alternatively call GE CARES.

TEL: (1) 800-437-1171

In other locations, contact your local Service Representative.

Keep the serial number printed on your Vscan Air probe easily available when contacting service.

Contacting GEHC Ultrasound (continued)

Information requests	To request technical product information in the United States, call GEHC. TEL: (1) 800-643-6439 In other locations, contact your local Applications, Sales, or Service Representative.
Placing an order	To order accessories, supplies, or service parts in the United States, call the GEHC Contact Center. TEL: (1) 800-558-5102 In other locations, contact your local Applications, Sales, or Service Representative.

NOTE: *Electronic ordering will be up running in some regions.*

Global ultrasound support center phone numbers

For countries not listed in the tables below, please contact the local distributor.

Table 1-5:   Americas

ARGENTINA		TEL: 0800-222-4342
BRAZIL	GE Healthcare do Brasil Comércio e Serviços para Equipamentos Médicos - Hospitalares Ltda. CNPJ: 00.029.372/0001-40 Av. Magalhães de Castro, 4800 - Andar 10 Conj. 101 e 102, Torre 3 - Cidade Jardim - CEP: 05676-120 - São Paulo/SP - Brasil Responsável Técnico: Aline Pereira Cezar Conselho de Classe Profissional: CREA – Conselho Regional de Engenharia e Agronomia Número do Conselho / UF: 5069116937/SP	TEL: 3004-2525 (Capitais e Regiões Metropolitanas) TEL: 08000 165 799 (Demais Localidades)
CANADA	GE Ultrasound 9900 Innovation Drive Wauwatosa, WI 53226 When contacting GEHC CARES for your Vscan Air, you will need to provide the serial number printed on your Vscan Air probe.	TEL: (1) 800-668-0732 Customer Answer Center TEL: (1) 905-412-3213
LATIN & SOUTH AMERICA	GE Ultrasound 9900 Innovation Drive Wauwatosa, WI 53226	TEL: (1) 262-524-5300 Customer Answer Center TEL: (1) 262-524-5698
MEXICO		TEL: 8002000111
COLOMBIA	#417 for Movistar, Claro & Tigo telecom operators	TEL: 01 800 018 1350 or #417

Table 1-5:   Americas (Continued)

PUERTO RICO		TEL: 1-855-964-0639
PERU		TEL: 0800-5-4342
CHILE		TEL: 1888-0020-4342, 800204302
USA	GE Ultrasound 9900 Innovation Drive Wauwatosa, WI 53226 When contacting GEHC CARES for your Vscan Air, you will need to provide the serial number printed on your Vscan Air probe.	TEL: (1) 800-437-1171 FAX: (1) 414-721-3865

Table 1-6:   Asia

ASIA PACIFIC JAPAN	GE Healthcare Asia Pacific 4-7-127, Asahigaoka Hinoshi, Tokyo 191-8503, Japan	TEL: +81 42 585 5111
AUSTRALIA	GE Healthcare Level 8, 241 O'Riordan Street HC, Mascot NSW 2020 Australia	TEL: 1800 659 465
CHINA	GE Healthcare – Asia No. 1, Yongchang North Road Beijing Economic & Technology Development Area Beijing 100176, China	TEL: (8610) 5806 8888 FAX: (8610) 6787 1162 Service: 4008128188 (24h)
INDIA	Wipro GE Healthcare Pvt Ltd No. 4, Kadugodi Industrial Area Sadaramangala, Whitefield Bangalore, 560067	TEL: 1-800-425-8025
KOREA	15F, 416 Hangang Dae ro, Chung-gu Seoul 04637, Korea	TEL: +82 2 6201 3114
NEW ZEALAND	Level 7 Vero Centre 48 Shortland St, Auckland, 1010 New Zealand	TEL: 0800 65 94 65
SINGAPORE	GE Healthcare ASEAN (Singapore) 11 North Buona Vista Drive #11-07 The Metropolis Tower 2 Singapore 138589	TEL: +65 6291 8528

Table 1-7:   Europe, Middle East & Africa

AUSTRIA	GE Healthcare Austria GmbH & Co OG EURO PLAZA, Gebäude E Technologiestrasse 10 A-1120 Vienna Solingen (Germany) ServiceCenterAustria@ge.com	TEL: (+43) 1 97272 0 FAX: (+43) 1 97272 2222 TEL: 0800 244 260 FAX: (+41) 44 809 9231
BELGIUM & LUXEMBURG	GE Healthcare BVBA/SPRL Kouterveldstraat 20 1831 DIEGEM	TEL: (+32) 2 719 7204 FAX: (+32) 2 719 7205
CZECH REPUBLIC (e-commerce only)	GE Healthcare Repair Center EE Inpark Ipari Park, Building H Csonka Janos ut 1-3, Paty H-2071 Hungary repaircenter.ee@gehealthcare.com	TEL: + 36 70 512 6056
SLOVAKIA (e-commerce only)	GE Healthcare Repair Center EE Inpark Ipari Park, Building H Csonka Janos ut 1-3, Paty H-2071 Hungary repaircenter.ee@gehealthcare.com	TEL: + 36 70 512 6056
ROMANIA (e-commerce only)	GE Healthcare Repair Center EE Inpark Ipari Park, Building H Csonka Janos ut 1-3, Paty H-2071 Hungary repaircenter.ee@gehealthcare.com	TEL: + 36 70 512 6056
BULGARIA	GE Healthcare Bulgaria 36, Dragan Tsankov blvd. Interpred - WTC Office 407B 1040 Sofia Bulgaria gehc.bg.servicecall@ge.com	TEL: 00359 2 971 2040 - Office 00359 080018170 - Call Center FAX- +359 2 8704002
SERBIA (e-commerce only)	GE Healthcare Repair Center EE Inpark Ipari Park, Building H Csonka Janos ut 1-3, Paty H-2071 Hungary repaircenter.ee@gehealthcare.com	TEL: + 36 70 512 6056
DENMARK	GE Healthcare Park Allè 295 DK-2605 Brøndby, Denmark	TEL: (+45) 43 295 400 0045 80 400 247
ESTONIA & FINLAND	GE Healthcare Finland Oy Kuortaneenkatu 2, 000510 Helsinki P.O.Box 330, 00031 GE Finland	TEL: (+358) 10 39 48 220 00358 800 528 474

Table 1-7:   Europe, Middle East & Africa

FRANCE	GE Medical Systems SCS Division Ultrasound 24 Avenue de l'Europe - CS20529 78457 Vélizy Villacoublay Cedex Buc (FR) healthfranceSERVICECENTERULS@ge.com	TEL: (+33) 1 34 49 52 70 FAX: (+33) 13 44 95 202 TEL: 0800 139 140 FAX: + 33 1 39 26 85 62
GERMANY	GE Healthcare Gmbh Beethovenstrasse 239 42655 Soligen ServiceCenterDeutschland@ge.com	TEL: (+49) 0800 4373 784 FAX: (+49) 212-38327-590
GREECE	GE Healthcare 8-10 Sorou Str. Marousi Athens 15125 Hellas GREECESERVICECENTER@ge.com	TEL: (+30) 210 89 30 660 0030 210 8930660
HUNGARY	GE Hungary Zft. Bence utca 3 Budapest BU 1138 HU ge.szerviz@ge.com	TEL: (+36)-1-465-9100/1 or (+36) 80 20 54 80 0036 802 05480
IRELAND	NORTHERN IRELAND GE Healthcare Victoria Business Park 9, Westbank Road Belfast BT3 9JL. REPUBLIC OF IRELAND GE Healthcare 3050 Lake Drive Citywest Business Campus Dublin 24	TEL: 0044 800 072 0248 TEL: 1800 992 557 FAX: (+353) 1 686 5327
ITALY North Centre South	GE Medical Systems Italia spa Via Galeno, 36, 20126 Milano front.office@ge.com; service@ge.com	TEL: (+39) 02 2600 1111 FAX: (+39) 02 2600 1417 TEL: 0039 800 827 164 TEL: 800827168: FAX: 800917293 TEL: 0039 800 827 168
ISRAEL	Haifa revital.sassu@ge.com	TEL: 00972-4-858-2929 FAX: 00972-4-858-0969
KAZAKHSTAN	«Дженерал Электрик Қазақстан» ЖШС Қазақстан, Алматы қаласы 050040, Тимирязев көшесі, 28В ү., 307 кеңсе. Alma-Aty 88000700770@ge.com	TEL: +7 727 3560020 TEL: 88000700770 FAX: +77273568544

Table 1-7:   Europe, Middle East & Africa

NETHERLANDS	GE Healthcare De Wel 18 B, 3871 MV Hoevelaken PO Box 22, 3870 CA Hoevelaken Diegem (BEL) ServiceCenterBenelux@ge.com	TEL: (+31) 33 254 1290 FAX: (+31) 33 254 1292 TEL: 0800 099 4442 FAX: +32 2 719 73 36
LIECHTENSTEIN	Diegem (BEL) ServiceCenterCESwitzerland@ge.com	TEL: 0041-44 809 9293 FAX: 0041-44 809 9231
NORWAY	GE Vingmed Ultrasound AS Sandakerveien 100C 0484 Oslo, Norway GE Vingmed Ultrasound Strandpromenaden 45 P.O. Box 141, 3191 Horten	TEL: (+47) 23 18 50 50 TEL: 0047 800 627 89 TEL: (+47) 33 02 11 16
POLAND	GE Medical Systems Polska Sp. z o.o., ul. Woloska 9 02-583 Warszawa, Poland usg.serwis@gehealthcare.com	TEL: (+48) 22 330 83 99
PORTUGAL	General Electric Portuguesa SA Avenida do Forte 6 - 6A Edifício Ramazzotti 2790-072 CARNAXIDE Madrid GEHealthcareServiceCenterIberia@ge.com	TEL: (+351) 21 425 1300 FAX: (+351) 21 425 1343 TEL: 0035 800834004 FAX: 34916632715
RUSSIA	GE Healthcare Presnenskaya nab. 10 Block C, 12 floor 123317 Moscow, Russia 88003336967@ge.com	TEL: 88003336967 TEL: 007 8 800 333 69 67
SPAIN	GE Healthcare España C/ Gobelas 35-37 28023 Madrid GEHealthcareServiceCenterIberia@ge.com	TEL: 902400246 TEL: 0034 902 400 246
SWEDEN	GE Healthcare Sverige AB FE 314, 182 82 Stockholm Besöksadr: Vendevagen 89 Danderyd, Sverige	TEL: (+46) 08 559 500 10 FAX: (+46) 08 559 500 15 Service Center 0046 201201436
SWITZERLAND	GE Medical Systems (Schweiz) AG Europastrasse 31 8152 Glattbrugg ce.switzerland.sc@ge.com	TEL: 0800 556 958 FAX: (+41)-44 809 9231

Table 1-7: Europe, Middle East & Africa

TÜRKIYE	GE Healthcare Türkiye Istanbul Office Levent Sekoya Plaza Esentepe Mah. Harman Sok. No:8 Sisli-Istanbul	TEL: +90 212 398 07 00 FAX: +90 212 284 67 00
EGYPT	Cairo-Plot 44 Tesseen, El Shamaly Street Al Salam Axis HC First Sector, City Centre, 5th settlement - zip code 11835	19434
SAUDI	GE Healthcare office - Riyadh - Square 1 Business Center third floor Zip code 11564	8001243002
NIGERIA	Mansard Place Plot 927/928, Bishop Aboyade Cole Street Victoria Island P.O Box 54255, Falomo, Ikoyi Lagos, Nigeria	TEL: +234 (1) 4607101 TEL: +234 (1) 4607102
GHANA		233501555066
KENYA	The Courtyard Building General Mathenge Drive-Westlands P.O Box 41608-00100. Nairobi, Kenya	TEL: +254 (20) 421 5000 TEL: +254 (20) 421 5044 TEL: +254 719093044 TEL: +254 719 093000
UNITED ARAB EMIRATES (UAE)	GE Healthcare Dubai Internet City, Building No. 18 First Floor, Dubai – UAE	TEL: (+971) 4 429 6101 or 4 429 6161 TEL: 8003646
UNITED KINGDOM	GE Medical Systems Ltd Pollards Wood Nightingales Lane Chalfont St Giles Buckinghamshire HP8 4SP Pollards Woods (UK) ultrasoundandbmdsdc@ge.com	TEL: (+44) 1494 544000 FAX: (+44) 1707 289742 TEL: 0845 850 3392 FAX: 01707 289660
For all other European countries not listed, please contact your local GEHC distributor or the appropriate support resource listed on www.gehealthcare.com.		

Manufacturer

GE VINGMED ULTRASOUND AS
Strandpromenaden 45
3191 Horten, Norway
TEL: (+47) 3302 1100

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Chapter 2

Safety

Contents:

Introduction

Overview

This chapter describes the important safety measures which should be taken before operating the Vscan Air ultrasound system. Procedures for simple care and maintenance of the Vscan Air probe are also described.

Various levels of safety precautions may be found on the equipment, and different levels of severity are identified by one of the following icons that precede precautionary statements in the text.

The following icons are used to indicate precautions:

⚠ DANGER   Indicates that a specific hazard is known to exist which through inappropriate conditions or actions will cause:

- Severe or fatal personal injury
- Substantial property damage.

⚠ WARNING   Indicates that a specific hazard is known to exist which through inappropriate conditions or actions may cause:

- Severe personal injury
- Substantial property damage.

Overview (continued)

 CAUTION   Indicates that a potential hazard may exist which through inappropriate conditions or actions will or can cause:

- Minor injury
- Property damage.

NOTE: *Indicates precautions or recommendations that should be used in the operation of the ultrasound system, specifically:*

- *Maintaining an optimum system environment*
- *Using this Manual*
- *Notes to emphasize or clarify a point.*

Owner responsibility

Overview

It is the responsibility of the owner to ensure that anyone operating Vscan Air reads and understands this section of the manual. However, there is no representation that the act of reading this manual renders the reader qualified to operate, inspect or troubleshoot the system. There are no user serviceable parts in the system or accessories. If servicing is required, contact GEHC.

The owner of Vscan Air should ensure that only properly trained, fully qualified personnel are authorized to operate the system. Before authorizing anyone to operate the system, it should be verified that the person has read, and fully understands, the operating instructions contained in this manual. It is advisable to maintain a list of authorized operators.

Should the system fail to operate correctly, or if Vscan Air does not respond to the commands described in this manual, the operator should contact the nearest GEHC ultrasound service office.

For information about specific requirements and regulations applicable to the use of electronic medical equipment, consult the local, state and federal agencies.

The owner of Vscan Air must be aware of applicable data protection policies. GEHC is not responsible for data being shared.

⚠ CAUTION   Vscan Air should be used in compliance with law. Some jurisdictions restrict certain uses, such as gender determination.

Notice against user modification

Never modify this product, including system components, cables, and so on. User modification may cause safety hazards and degradation in system performance. All modification must be done by a GEHC qualified person.

Software upgrade following GEHC recommendations can be done by the user.

Important safety considerations

Overview

This section includes considerations for the following:

- Patient safety
- Personnel and equipment safety

The information contained in this section is intended to familiarize the user with the hazards associated with the use of Vscan Air, and to alert them to the extent to which injury and damage may occur if the precautions are not observed.

Users are obligated to familiarize themselves with these safety considerations and to avoid conditions that could result in injury or damage.

NOTE: *It is user responsibility to safeguard data exported from the Vscan Air app and used outside the Vscan Air app.*

NOTE: *As a safety precaution, scanning is not possible when charging the Vscan Air probes.*

NOTE: *Please be aware that if using a long press in a Vscan Air text field including the patient data fields, to select and possibly then copy data to the display device image gallery will make the copied text accessible by all display device active apps. Take care to not share any privacy related data inadvertently via the above display device 'select and copy' feature.*

⚠️ CAUTION   The wireless charger and the AC adapter supplied as accessories with the product, are verified for use with the Vscan Air probes. The wireless charger and the AC adapter are considered being information technology equipment that does not affect basic safety or essential performance of the Vscan Air probes.

⚠️ CAUTION   The wireless charger and the AC adapter are compliant to the IEC/EN 62368-1 standard which applies to audio/video, information and communication technology equipment.

Patient safety

⚠ WARNING — The concerns listed in this section can seriously affect the safety of the patient undergoing a diagnostic ultrasound examination.

Whenever required include proper identification with all patient data and verify the accuracy of the patient's name and/or identity number when entering such data. Ensure that the correct patient ID is provided on all recorded data. Identification errors could result in an incorrect diagnosis.

Diagnostic information

The images provided and the measurement results offered are intended for use by competent users, as a diagnostic tool. They are not to be explicitly regarded as the sole, irrefutable basis for clinical diagnosis. Users are encouraged to study the literature and reach their own professional conclusions regarding the clinical use of the device.

⚠ CAUTION — The system provides calculations (e.g. estimated fetal weight) based on published scientific literature. The selection of the appropriate tables and clinical interpretation of calculations is the sole responsibility of the user.
The user must consider contraindications for the use of a calculation as described in the scientific literature. The diagnosis, decision for further examinations, and medical treatment must be performed by qualified personnel following good clinical practice.

Diagnostic information (continued)

The user should be aware of the product specifications and of the device accuracy and stability limitations. These limitations must be considered before making any decision based on quantitative values. If in doubt, the nearest GEHC ultrasound service office should be consulted.

Equipment malfunction or incorrect settings can result in measurement errors or failure to detect details in the image. The user must become thoroughly familiar with the operation of the Vscan Air to optimize its performance and to recognize possible malfunctions.

NOTE: Be certain to ensure the privacy of patient information.

⚠ CAUTION Avoid reflections from windows/lamps/direct sunlight on the display. Avoid analyzing data from small viewing angles.

Personnel and equipment safety

⚠ DANGER The hazards listed below can seriously affect the safety of personnel and equipment during a diagnostic ultrasound examination.

Explosion hazard

Never operate the Vscan Air probe, the wireless charger, the AC adapter or the personal mobile device in the presence of flammable or explosive liquids, vapors or gases. A malfunction of any of these devices can electrically ignite such substances. Operators should be aware of the following points to prevent such explosion hazards.

- If flammable substances are detected in the environment, do not plug in or turn on any of the devices.
- If flammable substances are detected after the any of the devices has been turned on or are in use, do not attempt to turn them off or unplug them.
- If flammable substances are detected, evacuate and ventilate the area before continuing working with the devices.

Electrical hazard

WARNING The internal circuits of the AC adapter use high voltages, capable of causing serious injury or death by electrical shock.

NOTE: *Any rest energy within the Vscan Air CL or Vscan Air SL probes or their components will be below 60 V DC or 2 mJ.*

## Electrical safety

Device classifications

The Vscan Air CL and the Vscan Air SL probes are internally powered devices, type BF. The AC adapters available with Vscan Air are Class II devices.

External connection

CAUTION Charging of Vscan Air probes via the AC adapter and the wireless charger must be kept outside the patient environment (refer to local regulation and EN/ES/IEC 60601-1).
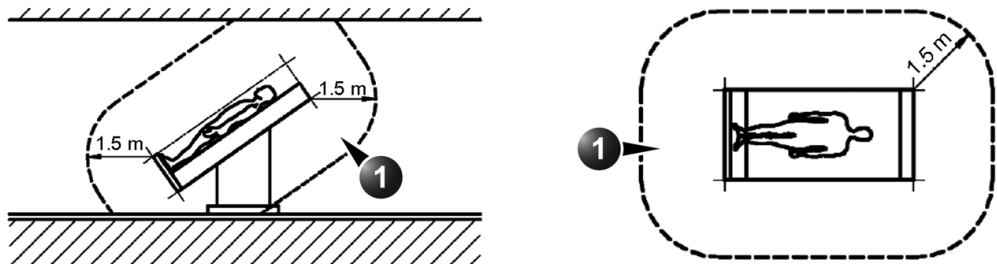
1. Patient environment

Figure 2-1.   Patient environment

Allergic reactions to latex-containing medical devices

Due to reports of severe allergic reactions to medical devices containing latex (natural rubber), the FDA advises healthcare professionals to identify latex-sensitive patients and be prepared to treat allergic reactions promptly. Latex is a component of many medical devices, including surgical and examination gloves, catheters, intubation tubes, anesthesia masks, and dental dams. Patient reaction to latex has ranged from contact urticaria to systemic anaphylaxis.

For more details regarding allergic reaction to latex, refer to *FDA Medical Alert MDA91-1, March 29 1991*.

The Vscan Air probes do not contain latex.

⚠ CAUTION — Contact with natural rubber latex may cause a severe anaphylactic reaction in persons sensitive to the natural latex protein. Sensitive users and patients must avoid contact with these items. Refer to package labeling to determine latex content.

Electromagnetic Compatibility (EMC)

NOTE: *This unit carries the CE mark. It complies with regulatory requirements of the Regulation (EU) 2017/745 concerning medical devices. It also complies with emission limits for a Group 1, Class B Medical Device as stated in EN/IEC 60601-1-2. It complies with emission limits in RTCA DO-160G, Section 21, Category M and ETSI EN 301489-1 and ETSI EN 301489-17.*

NOTE: *The ultrasound unit is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.*

Electrical medical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

Electromagnetic Compatibility (EMC) (continued)

All types of electronic equipment may characteristically cause electromagnetic interference with other equipment, transmitted either through air or connecting cables. The term Electromagnetic Compatibility (EMC) indicates the capability of the equipment to curb electromagnetic influence from other equipment, while at the same time not affecting other equipment with similar electromagnetic radiation.

Radiated or conducted electromagnetic signals can cause distortion, degradation, or artifacts in the ultrasound image which may impair the ultrasound unit's essential performance (see 'Electrical safety' on *page 2-8*).

There is no guarantee that interference will not occur in a particular installation. If this equipment is found to cause or respond to interference, attempt to correct the problem by one or more of the following measures:

- Re-orient or re-locate the affected device.
- Increase the separation between the unit and the affected device.
- Power the equipment from a source other than that of the affected device.

Consult the service representative for further suggestions. Unauthorized changes or modifications could void the user's authority to operate the equipment.

To comply with the regulations on electromagnetic interference, all interconnecting cables to peripheral devices must be shielded and properly grounded. Use of cables not properly shielded and grounded may result in the equipment causing or responding to radio frequency interference, in violation of the FCC regulation, European Union Medical Device Directive and Medical Device Regulations.

Interference Caution

⚠ CAUTION Use of devices that transmit radio waves near the system could cause it to malfunction.

Devices which intrinsically transmit radio waves such as radio transceivers, mobile radio transmitters, radio-controlled toys, and so on, should preferably not be operated near the unit. Medical staff in charge of the device are required to instruct technicians, patients, and other people who may be around the device to fully comply with the above recommendations.

Any electrical device can unintentionally emit electromagnetic waves. However, minimum device separation distances cannot be calculated for such unspecified electromagnetic radiation. When the ultrasound unit is used adjacent to or in close proximity to other equipment the user should be attentive to unexpected device behavior which may be caused by such electromagnetic radiation.

Before using the system, be aware of the proximity of known Radio Frequency (RF) sources, such as:

• Radio and TV stations

• Two-way radios

• Fixed RF communication devices including security systems (electromagnetic anti-theft systems (EAS), metal detectors, etc.)

• High-frequency surgical units, such as diathermy, electrocautery, argon beam coagulators, etc.

• X-ray, CT, or MRI devices

    These devices are also possible sources of interference as they may emit higher levels of electromagnetic radiation.

The ultrasound unit is intended for use in the electromagnetic environment specified in the tables below 'Electromagnetic emissions' on *page 2-15*.

Electromagnetic Compatibility (EMC) (continued)

The user of the ultrasound unit should assure that the device is used in such an environment.

⚠️ **WARNING** The use of accessories and cables other than those specified, may result in increased electromagnetic emissions or decreased electromagnetic immunity of the Vscan Air probes.

⚠️ **WARNING** The Vscan Air probes should not be used adjacent or very close to other equipment. The Vscan Air should be observed to verify normal device behavior in the configuration in which it will be used.

⚠️ **WARNING** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Vscan Air device. Otherwise, it may degrade the performance of this equipment.

NOTE: *It is advised to keep a 30 cm separation distance in between the Vscan Air probe and the display device running the Vscan Air app.*

FCC compliance statements

CAUTION — Any changes or modifications not expressly approved by the party Responsible for compliance could void the user's authority to operate this Equipment.

Part 15B compliance statements for digital devices:

NOTE: *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:

- 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.

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.

Canadian regulatory statement

This Class B digital apparatus complies with Canadian ICES-003.

This device complies with Industry Canada license-exempt RSS standard(s). 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.

Operation in the band 5150-5250 MHz is only for indoor use to reduce the potential for harmful interference to co-channel mobile satellite systems.

Users are advised that high-power radars are allocated as primary users (i.e., priority users) of the band 5725-5850 MHz and that these radars could cause interference and/or damage to LE-LAN devices.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence.

L'exploitation est autorisée aux deux conditions suivantes: (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement. La bande 5 150-5 250 MHz est réservés uniquement pour une utilisation à l'intérieur afin de réduire les risques de brouillage préjudiciable aux systèmes de satellites mobiles utilisant les mêmes canaux.

NOTE: *Vscan Air CL is a handheld ultrasound wireless probe with dual transducer. Convex and Linear side of the probe is intended to be placed on human body for ultrasound scanning. Other faces of the probe (front, rear, left side and right side) are intended to be used by hand.*

NOTE: *Vscan Air SL is a handheld ultrasound wireless probe with dual transducer. Sector and Linear side of the probe is intended to be placed on human body for ultrasound scanning. Other faces of the probe (front, rear, left side and right side) are intended to be used by hand.*

Thailand compliance statements

This telecommunication equipment conforms to NTC/NBTC technical requirement.

This radio communication equipment has the specific absorption rate (SAR) of 0.295 W/kg for Vscan Air CL and 0.146 W/kg for Vscan Air SL as related to the equipment, which is in compliance with the Safety Standard for the Use of Radio communication Equipment on Human Health announced by the National Telecommunications Commission.

Electromagnetic emissions

Table 2-1:   Electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions.		
The Vscan Air probes are intended for use in the electromagnetic environment below. The customer or the user of the Vscan Air probe should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emission EN55011	Group 1	The Vscan Air probe uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission EN55011	Class B	The Vscan Air probes are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emission EN/IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions EN/IEC 61000-3-3	Complies	

Electromagnetic immunity

Table 2-2: Electromagnetic immunity (Part 1)

Guidance and manufacturer's declaration – electromagnetic immunity.			
The Vscan Air probes are intended for use in the electromagnetic environment below. The customer or the user of the Vscan Air probe should assure that it is used in such an environment.			
Immunity test	**EN/IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) EN/IEC 61000-4-2	+/-8 kV contact +/-15 kV air	+/-8 kV contact +/-15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst EN/IEC 61000-4-4	+/-2 kV for power-supply lines +/-1 kV for input/output lines	+/-2 kV for power-supply lines +/-1 kV for input/ output lines	Mains power quality should be that of a typical commercial, hospital, or home environment.
Surge EN/IEC 61000-4-5	+/-1 kV line(s) to line(s)	+/-1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial, hospital, or home environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN/IEC 61000-4-11	0% U_T; 0,5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U_T; 1 cycle 70% U_T; 25/30 cycles Single phase: at 0° 0% U_T; 250/300 cycles	Compliance for all test levels. Controlled shutdown with return to pre-disturbance condition after operator's intervention. (Power-on switch)	Mains power quality should be that of a typical commercial, hospital, or home environment.
Power frequency (50/ 60 Hz) magnetic field EN/IEC 61000-4-8	30 A/m 50 and 60 Hz	30 A/m 50 and 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial, hospital, or home environment.
NOTE: U_T is the a. c. mains voltage prior to application of the test level.			

Electromagnetic immunity (continued)

Table 2-3:   Electromagnetic immunity (Part 2)

Guidance and manufacturer's declaration – electromagnetic immunity – for all medical electrical equipment and medical electrical systems that not life-supporting		
The Vscan Air probes are intended for use in the electromagnetic environment below. The customer or the user of the Vscan Air probe should assure that it is used in such an environment.		
Immunity test	**IEC 60601 test level**	**Compliance level**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms
Radiated RF and Proximity fields from RF wireless communications equipment IEC 61000-4-3	10 V/m; 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m; 80 MHz to 2.7 GHz 80% AM at 1 kHz
	385 MHz (18 Hz Pulse Modulation)	27 V/m
	450 MHz (FM +/ -5 kHz deviation1 kHz sine or 18 Hz Pulse Modulation)	28 V/m
	710 MHz (217 Hz PM)	9 V/m
	745 MHz (217 Hz PM)	9 V/m
	780 MHz (217 Hz PM)	9 V/m
	810 MHz (18 Hz PM)	28 V/m
	870 MHz (18 Hz PM)	28 V/m
	930 MHz (18 Hz PM)	28 V/m
	1720 MHz (217 Hz PM)	28 V/m
	1845 MHz (217 Hz PM)	28 V/m
	1970 MHz (217 Hz PM)	28 V/m
	2450 MHz (217 Hz PM)	28 V/m
	5240 MHz (217 Hz PM)	9 V/m
	5500 MHz (217 Hz PM)	9 V/m
	5785 MHz (217 Hz PM)	9 V/m
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

Essential Performance

The essential performance of the Vscan Air are:

- The ability to display physiological images as input for diagnosis by qualified and trained healthcare professionals.
- The ability to display quantified data as input for diagnosis by qualified and trained healthcare professionals.
- The display of ultrasound indices as aid for safe use of the Vscan Air probes.

Acoustic output

Definition of the acoustic output parameters

Thermal Index

TI is an estimate of the temperature increase of soft tissue or bone. There are three thermal index categories:

- TIS: Soft tissue thermal index. The main TI category. Used for applications that do not image bone.
- TIB: Bone thermal index (bone located in a focal region). Used for fetal application.
- TIC: Cranial bone thermal index (bone located close to the surface). Used for transcranial application.

Reference to calculation of TI can be found in:

- EN/IEC 60601-2-37. Medical electrical equipment. Part 2-37: Requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
- EN/IEC 62359: Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasound fields.

Mechanical Index

MI is the estimated likelihood of tissue damage due to cavitation. The absolute maximum limit of the MI is 1.9 as set by the FDA guidance of June 27, 2019 for diagnostic ultrasound systems and transducers.

Ispta

The Ispta is the Spatial Peak Temporal Average Intensity. The absolute maximum limit of Ispta is 720 mW/cm^2 as set by the FDA guidance of June 27, 2019 for diagnostic ultrasound systems and transducers.

Acoustic output and display on Vscan Air

MI and TI values are displayed on the scanning screen.

The display resolution of MI and TI is 0.1.

The maximum possible MI and Ispta on the Vscan Air probes are within the limits set in Track 3 in the FDA guidance of June 27, 2019 for diagnostic ultrasound systems and transducers, MI <1.9 and Ispta <720 mW/cm^2. The Vscan Air provides the ability to select the display of any of the TI categories independent of the category set as the factory default setting. The TI category display changes when 'tapping' the TI value displayed in the lower left corner of the screen while scanning, refer 'Black/white imaging mode (B-mode)' on *page 3-15*.

Accuracy of the displayed acoustic output and acoustic measurement uncertainties

The accuracy of the displayed acoustic output and the acoustic measurements uncertainty is summarized in the table below. Accuracy of the output display (TI, MI) parameters depends on the measurement system uncertainty, the acoustic model used to calculate the parameters and variation in the acoustic output of probes and systems. The overall measurement uncertainty has been assessed by determining Type A and Type B uncertainties following the ISO Guide to the Expression of Uncertainty in Measurement (GUM) at a 95% confidence level for MI and TI from and above the 0.4 limit given by IEC/EN60601-2-37 Ed2, Amd1.

Table 2-4:   Accuracy of the displayed acoustic output

Parameter	Displayed acoustic output accuracy	Measurement uncertainty Black/ white (B-mode), Color flow (Color doppler), M-mode and Pulsed wave doppler (PW doppler)
Pressure, MI	+/-25%	+/-15%
Power, TI	+/-50%	+/-30%

Accuracy of the displayed acoustic output = (Measured value -Acoustic output display value)/Acoustic output display value * 100%.

System controls affecting acoustic output

The operator controls that directly affect the acoustic output are discussed in the Acoustic Output Data Tables. These tables show the highest possible acoustic intensity for a given mode, obtainable only when the maximum combination of control settings is selected. Most settings result in a lower output.

Key principles for the safe use of ultrasound

The British Medical Ultrasound Society (BMUS) has given the following guidance related to the safe use of ultrasound

- Medical ultrasound imaging should only be used for medical diagnosis.
- Ultrasound equipment should only be used by people who are fully trained in its safe and proper operation.

    This requires:

    - an appreciation of the potential thermal and mechanical bio-effects of ultrasound,

    - a full awareness of equipment settings

    - an understanding of the effects of machine settings on power levels.
- Examination times should be kept as short as is necessary to produce a useful diagnostic result.
- Output levels should be kept as low as is reasonably achievable whilst producing a useful diagnostic result.
- The operator should aim to stay within the BMUS recommended scan times (especially for obstetric examinations).
- Scans in pregnancy should not be carried out for the sole purpose of producing souvenir videos or photographs.

Sensitive tissues

Particular care should be taken to reduce the risk of thermal hazard when exposing the following to diagnostic ultrasound:

- an embryo less than eight weeks after conception;

- the head, brain or spine of any fetus or neonate;

- an eye (in a subject of any age).

The British Medical Ultrasound Society has suggested some maximum scanning times relative to displayed TI as follows:

Table 2-5:   Recommended maximum scanning times

Obstetric scanning		General Abdominal, Peripheral Vascular, Musculoskeletal, Cardiac and other not listed applications		
TI	Time	TI	Time	Note
0.0–0.7	Unlimited	0.0–1.0	Unlimited	Monitor TI
0.7–1.0	< 60 min	1.0–1.5	< 120 min	
1.0–1.5	< 30 min	1.5–2.0	< 60 min	
1.5–2.0	< 15 min	2.0–2.5	< 15 min	
2.0–2.5	< 4 min	2.5–3.0	< 4 min	
2.5–3.0	< 1 min	3.0–4.0	< 1 min	
References • The British Medical Ultrasound Society. Guidelines for the safe use of diagnostic ultrasound equipment. • American Institute of Ultrasound in Medicine Consensus Report on Potential Bioeffects of Diagnostic Ultrasound.				

Further guidance on the safe use of obstetric ultrasound can be found in the official statements of the American Institute of Ultrasound in Medicine (AIUM) – "Prudent Use and Safety of Diagnostic Ultrasound in Pregnancy."

Sensitive tissues (continued)

Table 2-6:   Recommended maximum scanning times (Neonatal scanning)

Neonatal- Transcranial and Spinal scanning		Neonatal - General and Cardiac imaging		
TI	**Time**	**TI**	**Time**	**Note**
0.0–0.7	Unlimited	0.0–0.7	Unlimited	Monitor TI
0.7–1.0	< 60 min	0.7–1.0	Unlimited	
1.0–1.5	< 30 min	1.0-1.5	120 min	
1.5–2.0	< 15 min	1.5-2.0	60 min	
2.0–2.5	< 4 min	2.0-2.5	15 min	
2.5–3.0	< 1 min	2.5-3.0	4 min	
3.0-4.0	Scanning of the central nervous system is not recommended	3.0-4.0	1 min	
References • The British Medical Ultrasound Society. Guidelines for the safe use of diagnostic ultrasound equipment. • American Institute of Ultrasound in Medicine Consensus Report on Potential Bioeffects of Diagnostic Ultrasound.				

In eye scanning applications, it is recommended that TI is monitored. TI values should be limited to a maximum of 1.0.

International Society of Ultrasound in Obstetrics and Gynecology (ISUOG) safety guidelines

The below referenced ISUOG statement of safe use tells that doppler ultrasound should not be used routinely in the embryonic period, GA(LMP)<11 weeks. The scan operator should also take care to keep the exposure time as short as possible with the displayed thermal index TI=1.0 if utilizing doppler ultrasound in the fetal period, GA(LMP)>=11 weeks.

Salvesen K, Abramowicz J, Ter Haar G, Miloro P, Sinkovskaya E, Dall'Asta A,Maršál K, Lees C; Board of the International Society of Ultrasound in Obstetrics and Gynecology (ISUOG). ISUOG statement on the safe use of Doppler for fetal ultrasound examination in the first 13+6weeks of pregnancy (updated). Ultrasound Obstet Gynecol 2021; 57: 1020.

Selecting preset

Selecting the appropriate preset for a particular ultrasound examination automatically provides acoustic output limits within FDA guidance for that examination. Other parameters which optimize performance for the selected examination are also set automatically and should help reducing the patient exposure time.

Changing imaging modes

Acoustic output depends on the imaging mode selected. This greatly affects the energy absorbed by the tissue, as described in 'Black/white imaging (B-mode)' on *page 5-20*, 'Color flow (Color Doppler)' on *page 5-28*, 'Pulsed wave (PW) spectral doppler' on *page 5-35* and 'M-mode (Motion mode)' on *page 5-50*

ALARA

Ultrasound procedures should be performed using output levels and exposure times **A**s **L**ow **A**s **R**easonably **A**chievable (ALARA) while acquiring clinical information.

During a diagnostic ultrasound examination, high frequency sound penetrates and interacts with tissue in and around the area of anatomy to be imaged. Only a small portion of the sound energy is reflected back to the probe for use in constructing the image while the remainder is dissipated within the tissue. The interaction of sound energy with tissue at sufficiently high levels can produce biological effects (aka bioeffects) of either a mechanical or thermal nature. Bioeffect is generally undesired in diagnostic application and may be harmful in some conditions.

ALARA training is provided in the Medical Ultrasound Safety booklet, published by AIUM (American Institute of Ultrasound in Medicine). This booklet is provided with the Vscan Air CL and the Vscan Air SL to customers in USA. The ALARA education program for the clinical end-user covers basic ultrasound principles, possible biological effects, the derivation and meaning of the indices, ALARA principles, and examples of specific applications of the ALARA principle. This document is acceptable to FDA as meeting the content of the ALARA educational program.

ALARA (continued)

To contact the AIUM concerning their publications:

- In the USA, by telephone at 1-800-638-5352
- To write them, use the following address:

  AIUM

  14750 Sweitzer Lane

  Suite 100

  Laurel, MD, USA 20707-5906

In addition to the AIUM document, the sections 'The real-time display of acoustic output indices' on *page 7-3* and 'Controls affecting acoustic output' on *page 7-5* should be studied carefully in order to implement ALARA.

Training

During each ultrasound examination the user is expected to weigh the medical benefit of the diagnostic information that would be obtained against the risk of potential harmful effects. Once a diagnostic image is achieved, prolonging the exposure cannot be justified. It is recommended that all users receive proper training in applications before performing them in a clinical setting.

Environmental protection

System disposal

The equipment must not be disposed as unsorted municipal waste nor be destroyed by incineration.

It must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

Maximum probe temperature

Maximum probe temperature

The table below indicates the maximum probe temperature.

Table 2-7:   Maximum probe temperature

Probe	Max Temp (°C) (Simulated use)	Max Temp (°C) (Still air)
Vscan Air CL – Curved array transducer (for deep scanning)	39.4	48.7
Vscan Air CL – Linear array transducer (for shallow scanning)	40.8	45.8
Vscan Air SL – Sector array transducer (for deep scanning)	39.7	46.7
Vscan Air SL – Linear array transducer (for shallow scanning)	40.8	45.2

NOTE: Measurement uncertainty and probe variation: 2.0 °C.

NOTE: The probe will stop scanning, if exceeding an applied part surface temperature of 43°C

NOTE: Lens temperature is measured under conditions per IEC 60601-2-37, Ed2.1.

- Thermocouple was placed at the geometric center of the lens.
- Thermal phantom at not less than 33°C or in the range 20-33°C for external probes. Maximum Vscan Air probe temperature rise is measured and added to 33°C. Maximum Vscan Air probe temperature (Simulated use) is <43°C.
- With the Vscan Air probe transmitting in air, temperature rise is measured and added to 23°C. Maximum Vscan Air probe temperature (Still air) is <50°C. Lens temperature is monitored for 20 minutes.

Device labels and symbols

Vscan Air labels
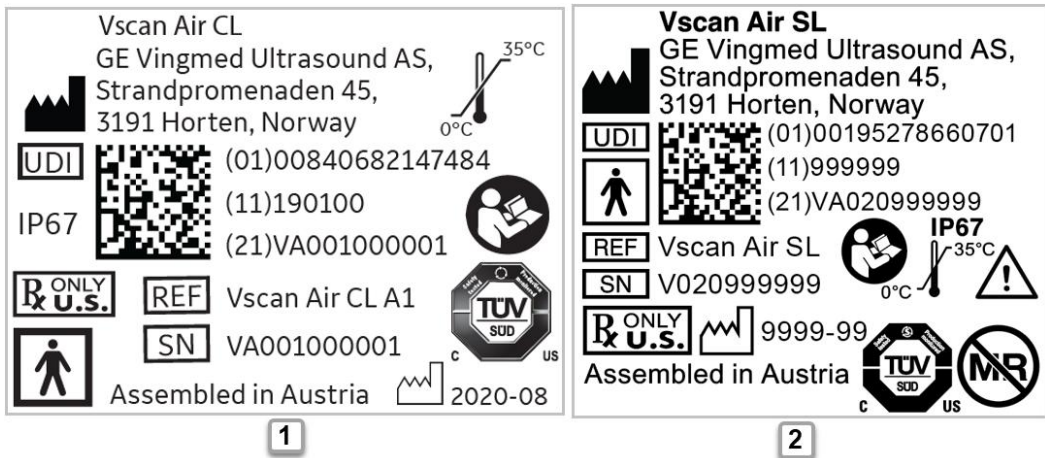
1. Laser printed label for Vscan Air CL probe – US Version
2. Laser printed label for Vscan Air SL probe – North America Version

Figure 2-2.   Vscan Air probe rating label versions

Vscan Air labels (continued)
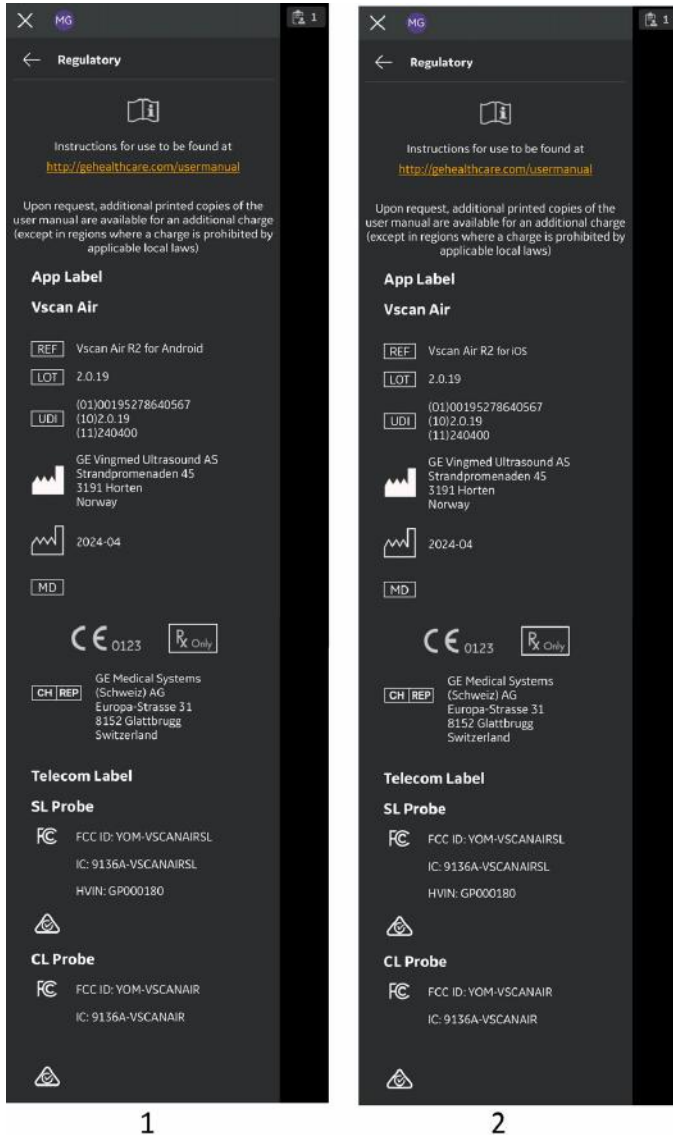
1. Vscan Air for Android rating label
2. Vscan Air for iOS rating label

Figure 2-3.   Vscan Air app rating label versions

Vscan Air labels (continued)

Figure 2-4.   Adapter label
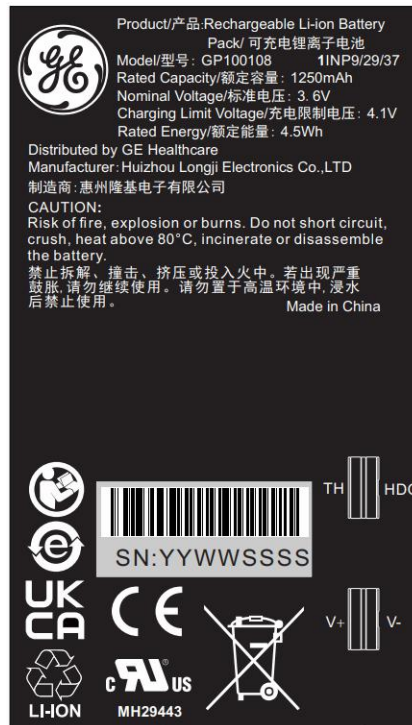
Figure 2-5.   Battery label

NOTE: The adapters and labels shown in Figure 2-2, Figure 2-3, Figure 2-4 and Figure 2-5 are included for illustration purposes only. The adapter color may be different and the label content may vary based on country requirements and product configuration.

Vscan Air labels (continued)

The following table describes the purpose of safety labels and other important information provided on the equipment.

Table 2-8:   Label Icons
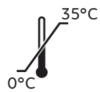
Label	Purpose	Location	Standard
CE_{0123}	Indicates that the product is in compliance with all relevant European Directives and Regulations, under surveillance by Notified Body 0123.	- Vscan Air app - Vscan Air probe	N/A - by certification body
(crossed-out wheelie bin symbol)	This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact the manufacturer or other authorized disposal company to decommission your equipment.	- Vscan Air probe - Vscan Air probe battery	EN 50419
(read instructions symbol)	Follow instructions for use. Read and understand all instructions in the User's Manual before attempting to use the ultrasound unit.	- Vscan Air probe - Vscan Air probe battery	ISO 7010-M002
(TÜV SUD C US mark)	TUV SUD NRTL Certification Mark	Vscan Air probe	N/A - by certification body
(thermometer 35°C / 0°C)	Indicates the temperature limits to which the medical device can be safely exposed. For Vscan Air the temperature range is relating to continuous environmental operating conditions.	Vscan Air probe	ISO 7000-0632
(caution triangle)	Caution is needed relating to probe operating temperature range.	Vscan Air probe	ISO 7000-0434
R ONLY U.S.	Prescription device statement for the USA only: Caution: Federal law restricts this device to sale by or on the order of a physician or other authorized licensed healthcare practitioner.	- Vscan Air app - Vscan Air probe	FDA guidance

Table 2-8: Label Icons

Label	Purpose	Location	Standard
	Type BF Applied Part symbol (see 'Classifications' on *page i-7*)	Vscan Air probe	IEC 60417-5333
	Manufacturer name and address	- Vscan Air probe - Vscan Air app	ISO 7000-3082
	Manufacturing date (year-month)	- Vscan Air probe - Vscan Air app	ISO 7000-2497
REF	Brand and model identifier.	- Vscan Air probe - Vscan Air app	ISO 7000-2493
SN	Serial number	Vscan Air probe	ISO 7000-2498
UDI	Unique Device Identification (UDI). Every system has a unique marking for identification. Scan or enter the UDI information into the patient health record according to governing laws.	- Vscan Air probe - Vscan Air app	21 CFR 830 Unique Device Identification MDR Regulation (EU) 2017/745
Assembled in Austria (Austria is a country name)	Identify the customs country of origin of the materials.	Vscan Air probe	N/A- by GEHC
IP67	Vscan Air can be completely submerged upto 1m in water.	Vscan Air probe	IEC 60529
LOT	Batch or lot code	Vscan Air app	ISO 7000-2492
CAUTION: For use with Vscan Air only.	Guidance to user to use the AC adapter and wireless charger only with Vscan Air.	Accessories and Service probe shipment box.	N/A- by GEHC
MD	This symbol indicates the item is a medical device	- Vscan Air probe - Vscan Air app	ISO15223-1
(MR)	Indicates that the device poses unacceptable risks to the patient, medical staff or other persons within the MR environment	Vscan Air probe	FDA guidance: Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment.
Assembled in Mexico (Mexico is a country name)	Identify the customs country of origin of the materials.	Vscan Air probe	N/A- by GEHC

Table 2-8:   Label Icons

Label	Purpose	Location	Standard
CH REP	Authorized Swiss Representative	Vscan Air app	The Swiss Federal Council, Medical Devices Ordinance art 16 para.1 in conjunction with MDR Annex I 23.2.d

Table 2-9:   Telecom-, radio and wireless marking

Label	Purpose	Location	Standard
FCC ID:	Federal Communications Commission Identification number	Vscan Air app	FCC Part 15 Subpart C 15.247, 15.207, FCC Part 15 Subpart E 15.407,15.207, FCC Part 18 Subpart C 18.307 ,18.305 / FCC 47 CFR Part 2 Subpart 2.1093, IEEE Std 1528-2013
IC ID:	The Canadian certification ID number relating to radio apparatus and broadcasting equipment	Vscan Air app	RSS 247 Issue 2 and RSS GEN Issue 5 RSS 247 Issue 2 and RSS GEN Issue 5 RSS-102 Issue 5, ICES-001 Issue 5 IEEE Std 1528-2013
R 005-102655 Indoor use only	Compliance to the Japan Radio Law. "Indoor Use Only" applies when utilizing 5 GHz WiFi.	Vscan Air probe	Japanese Radio Law
	Ensures the safety and performance of telecoms, electrical, and wireless devices for Australia and New Zealand	Vscan Air probe	Regulatory Compliance Marking (RCM) Australia / New Zealand

NOTE: The label content for the Vscan Air probe, the Vscan Air app and the Vscan Air packaging will vary based on country requirements and configuration. Symbols or icons available for a recently manufactured device might differ if comparing to an earlier manufactured device of the same model.

For China only

Explanation of the Pollution control label

The following product pollution control information is provided according to SJ/T11364-2014 Marking for Restriction of Hazardous Substances caused by electrical and electronic products.

Label	Description
	This symbol indicates the product contains hazardous materials in excess of the limits established by the Chinese standard GB/T 26572 Requirements of concentration limits for certain restricted substances in electrical and electronic products. The number in the symbol is the Environment-friendly Use Period (EFUP), which indicates the period during which the hazardous substances contained in electrical and electronic products will not result in any severe environmental pollution, any bodily injury or damage to any assets. The unit of the period is "Year". In order to maintain the declared EFUP, the product shall be operated normally according to the instructions and environmental conditions as defined in the product manual, and periodic maintenance schedules specified in Product Maintenance Procedures shall be followed strictly. Consumables or certain parts may have their own label with an EFUP value less than the product. Periodic replacement of those consumables or parts to maintain the declared EFUP shall be done in accordance with the Product Maintenance Procedures. This product must not be disposed of as unsorted municipal waste, and must be collected separately and handled properly after decommissioning.

Explanation of the Pollution control label for China

The following product pollution control information is provided according to SJ/T11364-2014 Marking for Restriction of Hazardous Substances caused by electrical and electronic products.

Table 2-10:   Hazardous substances

Component Name	Hazardous Substances' Name					
	Pb	Hg	Cd	Cr^{6+}	PBB	PBDE
Probe	X	O	O	O	O	O

O: Indicates that hazardous substance contained in all of the homogeneous materials for this part is below the limit requirement in GB/T 26572.
X: Indicates that hazardous substance contained in at least one of the homogeneous materials used for this part is above the limit requirement in GB/T 26572.
• Data listed in the table represents best information available at the time of publication.
• Applications of hazardous substances in this medical device are required to achieve its intended clinical uses, and/or to provide better protection to human beings and/or to environment, due to lack of reasonably (economically or technically) available substitutes.

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Chapter 3

Preparing Vscan Air for Use

Contents:

Package contents

Vscan Air shipment box contents

Vscan Air SL product box contents

1. Vscan Air Quick Start Guide
2. Vscan Air wireless charger with USB cable
3. Protective case
4. Vscan Air SL probe
5. SL probe with Protective Case
6. AC adapter (plug type varies based on region and model)

Figure 3-1. Vscan Air SL product box contents

Vscan Air CL product box contents

1. Vscan Air Quick Start Guide
2. Protective case
3. CL probe with Protective Case
4. Vscan Air CL probe
5. AC adapter (plug type varies based on region and model)

Figure 3-2.   Vscan Air CL product box contents

NOTE: The Protective case will protect the Vscan Air probe from scratches if probe is stored within it when not being used.

How to charge the Vscan Air probes

1. Plug one end of the USB cable into the wireless charger and the other into the AC adapter.

1. Vscan Air wireless charger
2. Anker wireless charger

Figure 3-3.   Vscan Wireless charger

2. Connect the AC adapter into the wall outlet.
3. Place the Vscan Air probe on the wireless charger with the GE logo up.

NOTE: *The Vscan Air wireless charger LED light will be solid blue for 3 seconds and then turn off when connecting the charger to power.*

NOTE: *The Vscan Air wireless charger LED light will be solid blue when actively charging a device.*

How to charge the Vscan Air probes (continued)

4. The Vscan Air probe LEDs lights up and the probe starts charging.

5. Vscan Air probe gets wirelessly charged. The LEDs will light in an orange/red toned yellow color whenever charge is less than 8% and probe needs a higher charge level to allow starting. Yellow light on both LEDs indicates the Vscan Air CL is charging with capacity in the range 8-90%. Green light on both LEDs indicates the Vscan Air probe is fully charged 90-100% (see 'Vscan Air CL/ Vscan Air SL LED indication' on *page 3-24*).

How to charge the Vscan Air probes (continued)

NOTE: The Smart Connect feature allows the Vscan Air probe to stay powered, connected and charging when on the wireless charger. The battery icon will indicate the battery charge level. Be aware that charging time (when charging from 10-90%) will increase by approximately 5 minutes from the times specified in Table 3-4 when utilizing the Smart Connect feature.

NOTE: If the Vscan Air probe is powered off when the probe is placed onto the wireless charger it will start charging. Charging time is listed in Table 3-4.

NOTE: Both LEDs will blink in case of any kind of charging issue. This is most likely caused by the probe and battery being too warm to start charging. Please let the probe cool off and check that the probe starts charging as indicated by steady LED light in both LEDs.

NOTE: The probe charge status will be monitored at regular intervals if probe is left fully charged on the wireless charger. Charging will restart as required to keep the probe fully charged while it is placed on the wireless charger.

Environmental requirements

Environmental requirements for Vscan Air probe

Table 3-1:   Environmental requirements

Description	Operational	Non-operational	Storage and transport
Temperature	0°C to + 35°C	- 40°C to + 70°C	- 40°C to + 70°C
Humidity	10–90%	10–95%	10–95%
Air pressure	54 kPa to 106 kPa	50 kPa to 106 kPa	50 kPa to 106 kPa

Transient operating conditions

NOTE: *Permissible transient environmental operating conditions:*

- Temperatures ranging from -20°C to 0°C or from +35°C to +50°C.
- Device will function for a minimum of 20 minutes when placed in an environment with temperatures ranging from -20°C to 0°C or from +35°C to +50°C after storage at room temperature (20 +/- 2°C).
- Following storage at temperatures ranging from -20°C to 0°C or from +35°C to +50°C, the device will within 10 minutes after being returned to room temperature (20 +/- 2°C), function for a minimum of 20 minutes.

NOTE: *Avoid exposing the unit to saline moisture. In case of exposure to saline moisture, clean the unit as described in 'Cleaning and disinfection' on page 6-6.*

Image on the display device hosting the Vscan Air app is dependent on ambient light; avoid direct sunlight or reflections from other light sources on the display when scanning and reviewing images. The display viewing angle should be as small as possible.

If you are having difficulty seeing the image due to the lighting conditions, try to change brightness of the display device or change your position/location of use.

Acclimatization time

Allow the Vscan Air probe to acclimate for approximately 10 minutes prior to use, if stored at temperatures ranging from -20°C to 0°C or in temperatures ranging from +35°C to +50°C.

Allow the Vscan Air probe to acclimate for approximately 30 minutes prior to use, if stored at temperatures ranging from -40°C to -20°C or in temperatures ranging from +50°C to +70°C.

Other environment: Aircraft Ambulance/Road Ambulance

The Vscan Air ultrasound system can be used in an emergency medical services environment, including road** and air ambulances*.

• The Vscan Air probes are not certified for being mounted or fixed inside a road- or air ambulance.

• The Vscan Air probes can be used in emergency medical services environments. See 'Environmental requirements for Vscan Air probe' on *page 3-7 for more information.*

• The Vscan Air probes are not certified for being charged inside a road- or air ambulance.

• The AC Adapters must NOT be operated above 5000m.

* The Vscan Air ultrasound system is compliant to IEC 60601-1-12 and EN13718 as stated in 'Regulatory requirements' on *page i-4*. Additional regulations might apply

** The Vscan Air ultrasound system is compliant to IEC 60601-1-12 and EN1789 as stated in 'Regulatory requirements' on *page i-4*. Additional regulations might apply.

System description

System overview

The Vscan Air probes are dual headed battery-operated ultrasound devices. The Vscan Air probe has a linear array on one side, and a curved or sector/phased array on the opposite side. It generates a beam of ultrasound that is transmitted into the subject's body. The reflection of this beam is transformed into an image that is wirelessly transmitted to a phone or a tablet and displayed via the Vscan Air app.

The Vscan Air app provides the user interface and the needed software functionality for using a generic mobile device as a display and control unit for ultrasound imaging. The generic mobile device must be operating with either Android OS or iOS. The Vscan Air app is available for installation via the Google Play store and the Apple App store.

Figure 3-4.   Vscan Air probe

1.	Power/Probe button	4.	LED indicator
2.	Directional marker	5.	Linear array
3.	Curved array	6.	Sector array
		7.	Battery door

NOTE: *To charge Vscan Air probe refer 'How to charge the Vscan Air probes' on page 3-4*

Display screens

Connection and probe battery status

- **Not connected to probe** - No outline of the battery and no battery charge indicator

- A Vscan Air probe connecting is indicated by a blue battery outline displaying in varying intensity.

- When the Vscan Air probe has connected to the display device a steady blue battery outline is displayed.

- **Connected to probe** - When the Vscan Air probe is connected and the probe battery status is available for the following icon with battery status and white battery outline is displayed.

1. White outline of the battery
2. Battery charge indicator

Wireless connection quality indicator
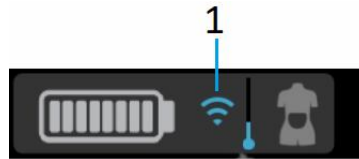
1. Wireless connection quality indicator

A wireless probe has a limited inherent risk of a disrupted connection due to various factors that could lead to loss of real time imaging.

The 'Wireless connection quality indicator' provides a visual indication of the connection quality between the probe and the app during scanning. An unstable connection may result in loss of image quality or slow image update during real time imaging.

1. Stable connection
2. Unstable connection

Probe temperature indicator and thermal management

1. Thermal indicator

The 'Probe temperature indicator' tracks and displays changes in the operating temperature of the probe during scanning. Factors affecting probe temperature are:

• Transducer: Curved array transducer gets warm more quickly than linear array due to higher power consumption.

• Preset: Certain presets like Abdominal and cardiac have higher power requirements depending on the image settings causing the probe to warm up faster than other presets.

• Mode: Operating in Color or PW doppler modes warms up probe faster than the Black and white mode.

• Length of scan: Duration of continuous scanning.

• Ambient temperature: Higher ambient temperatures can cause the probe to reach the thermal management levels faster.

The thermal management system of Vscan Air probes automatically reduces some parameters such as frame rates or image width to keep the probe temperature within optimal functional levels to support continuous scans up to 50 minutes.

NOTE: *Image acquisition and the corresponding on-screen live display will pause and quickly resume whenever the thermal management system changes the scan setup.*

Probe temperature indicator and thermal management (continued)

There are 5 thermal management levels (0-4). Level 0 is the initial state when starting with a cool probe as indicated in the Figure 3-5 below. The probe temperature changes during a scan based on the factors described above. The temperature indicator reflects these changes as shown in Fig 3-4 as the different thermal levels are activated. A user notification on the screen accompanies these changes (refer 'Thermal indicator toast message' on *page 3-14*).

NOTE: *Probe temperature and related user notifications are independent of the probe battery status.*

1. Level 0   4. Level 3
2. Level 1   5. Level 4
3. Level 2
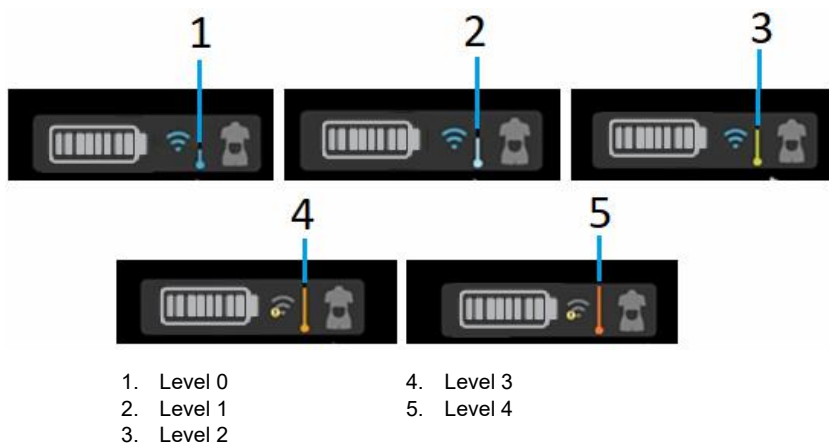
Figure 3-5.   Thermal indicator levels

Probe temperature indicator and thermal management (continued)
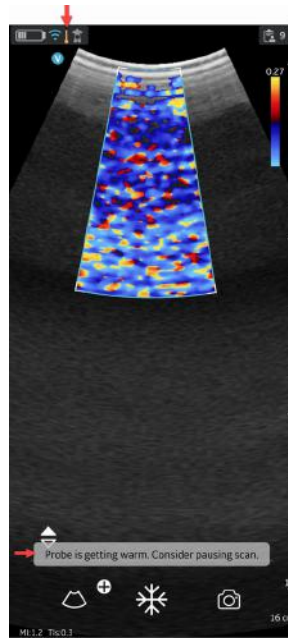
Figure 3-6.   Thermal indicator toast message
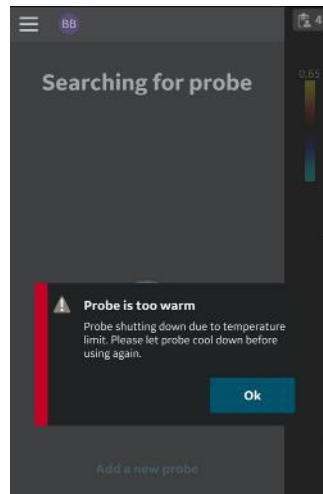
Figure 3-7.   Thermal warning message

Black/white imaging mode (B-mode)
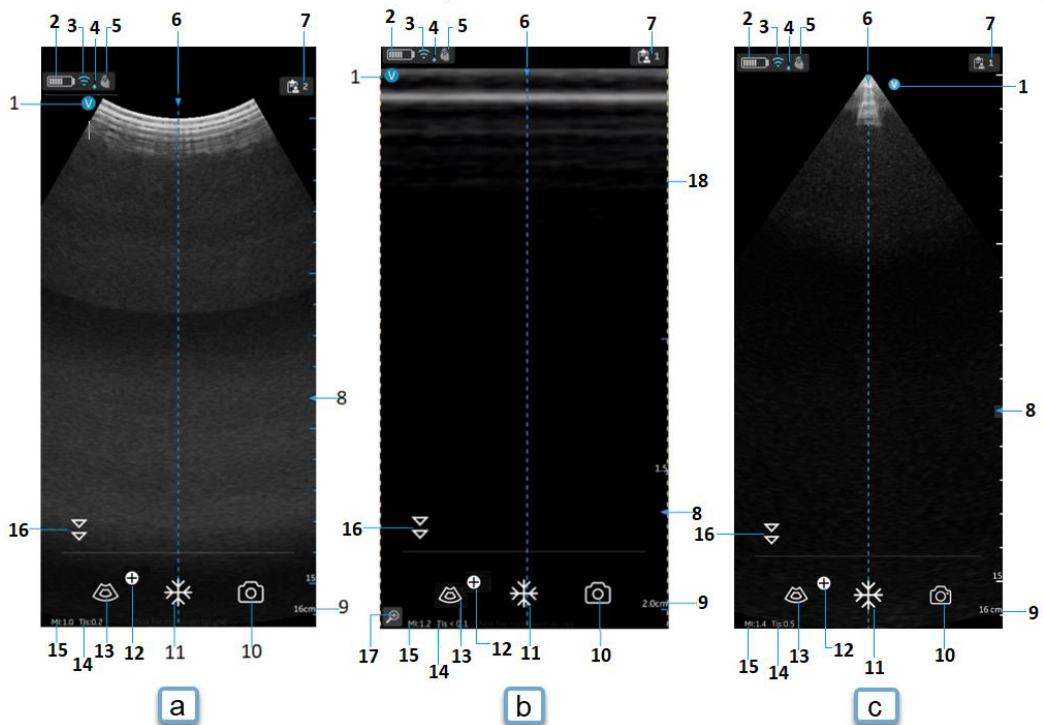
Figure 3-8.   Black/white imaging mode (B-mode)

a. Curved array (deep scanning) transducer
b. Linear array (shallow scanning) transducer
c. Sector array (deep scanning) transducer

1.	Image orientation marker	10.	Store
2.	Vscan Air battery level indicator	11.	Freeze
3.	Wireless connection quality indicator	12.	Additional modes menu button
4.	Thermal indicator	13.	Color flow
5.	Selected preset	14.	Thermal Index (TI)
6.	Center line marker	15.	Mechanical Index (MI)
7.	Exam number	16.	Resolution/Penetration toggle button
8.	Focus marker	17.	Zoom indicator
9.	Depth	18.	Image crop indicator

Accessories

Optional accessories

Vscan Air AC Adapters

The AC adapter power plug requirement for the country or region is shipped together with the Vscan Air probe according to purchase order.

Figure 3-9.   International AC Adapter

1. Type C - Europe, Türkiye, Korea, Indonesia, Philippines, Thailand, Vietnam, Israel, Russia, Brazil, Chile, Egypt
2. Type A - USA, Canada, Japan, Taiwan, Mexico
3. Type G - United Kingdom, Hong Kong, Ireland, Malta, Cyprus, Malaysia, Singapore, UAE, Saudi Arabia
4. Type I - Australia, New Zealand, China, Argentina

Vscan Air AC Adapter Type F

Figure 3-10.   AC Adapter Type F Korea

Vscan Air AC Adapter - multiplug

Figure 3-11.   Vscan Air AC Multiplug Adapter

NOTE: *The multiplug adapter shown in Figure 3-11 is included for illustration purposes only. The colors may be different and the label content may not represent the current version being used.*

Optional accessories (continued)

Table 3-2:   Other accessories

Accessory	Figure
Anker PowerWave charging pad	
trophon® Wireless Ultrasound Probe Holder	

Table 3-2:   Other accessories

Accessory	Figure
Vscan Air Charger	
Roll Stand	

Vscan Air battery

Battery

The Vscan Air probes are powered by a Li-ion battery. The battery is not fully charged prior to shipment. To maximize time of use, it is recommended to recharge the battery before use for at least 1.5 hours. Establish a routine for charging the battery to maximize device availability.

The battery will be charged when charging the Vscan Air probe as described in the section 'How to charge the Vscan Air probes' on *page 3-4*.

Battery specification

The battery specification is shown in the below table.

Table 3-3:   Basic Battery specification

Items		Unit	Value	Description
Basic	Nominal voltage	mV	3600	MAX
	Current	mA	889	Avg 0.71C

WARNING | Use only AC adapter that are compliant to (marked with) applicable regional or country standards.

WARNING | The Vscan Air probes are not certified for being charged inside a road- or air ambulance.

CAUTION | The AC adapter and the wireless charger must be kept outside the patient environment (refer to local regulation and EN 60601-1). The user should perform charging of the Vscan Air probes outside the patient area.

Battery specification (continued)

Table 3-4:   Battery specification

Item	Specification
Charging time starting at 10%, charging to 90% capacity. Conditions: Probe powered off, new probe or battery, room temperature (20 to 25 deg C).	75 minutes
Capacity	50 minutes continuous scan (see Note)
Lifetime	At least 850 charges

In order to get maximum charging capacity of your Vscan Air battery, you should initially allow the battery to be fully charged and then fully discharged at least three times. Perform normal operation during these cycles. Once the initial charging/ discharging cycles are performed, the following is applicable without reducing the lifetime of the battery:

• It is not necessary to completely discharge the battery before re-charging.

• It is possible to stop charging the battery before it is fully charged, but the battery will then be discharged more rapidly.

• It is possible to charge the battery several times each day, if needed.

To minimize battery performance degradation, avoid prolonged storage of the Vscan Air probe outside the specified temperature range.

NOTE: *To maximize battery life it is recommended to store the Vscan Air probe inside a temperature range of - 20°C to + 50°C.*

Batteries generally degrade by aging and number of recharging cycles and will have reduced capacity over time.

NOTE: *The 50 minutes continuous scanning time is valid for a fully charged new battery using 80% B-mode and 20% color during scanning. Scanning is taking place at normal room temperature (22°C) and the factory default for the curved array Abdominal preset is utilized.*

Voltage requirements

The AC adapter will function on voltage from 100 to 240 VAC and 50/60 Hz.

⚠ CAUTION   Only use mains power of 100 – 240 VAC. Voltage outside this range can cause a malfunction or destroy the AC adapter.
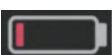
Charging the battery

Place the Vscan Air probe on the wireless charger as shown in 'How to charge the Vscan Air probes' on *page 3-4*

Battery level indicator

The Vscan Air battery level indicator icon is displayed on the screen when Vscan Air probe is connected to the Vscan Air app. The following icons are displayed.

Table 3-5:   Battery level indicator

Icon	Description
	Battery charged 90-100%
	Battery charged 80-90%
	Battery charged 65-80%
	Battery charged 50-65%
	Battery charged 35-50%
	Battery charged 25-35%
	Battery charged 15-25%. Prepare to recharge the battery.
	Battery charged 8-15%. Prepare to recharge the battery.

Vscan Air CL/ Vscan Air SL LED indication

Turning the probe ON/OFF

To turn **ON** the Vscan Air probe, press and hold the power button for 1 second.

To turn **OFF** the Vscan Air probe, press and hold the power button for 3 seconds.

1. Powering up	5. Connected
2. Booting	6. Active array
3. Searching	7. Powering OFF/Occupied
4. Display found	8. Error

Figure 3-12.   LED states when Vscan Air probe is ON

- A **blinking white light** switching between Vscan Air probe ends indicates that the Vscan Air probe is ON and booting.

- A **blinking white light** on both LEDs indicates the Vscan Air probe is ON and searching for Vscan Air App.

- A **steady white light** on both LEDs indicates that the Vscan Air probe is ON and a display device with the Vscan Air App is found.

- A **steady blue light** on both LEDs indicates that the Vscan Air probe is ON and connected.

- A **steady blue** LED on one Vscan Air probe side indicates which transducer is active and selected. Vscan Air probe is powered ON.

- A **steady purple light** on both LEDs indicates the Vscan Air probe is ON, is occupied and shall not be interrupted. E.g. when running test or upgrading software.

- A **steady red** on both LEDs indicates the Vscan Air probe is ON and an error has been detected.

NOTE: *The steady blue LED will light up in a brighter blue color when scanning compared to when scanning is halted. i.e. in Freeze. Indicating that probe now saves power while not scanning. The Vscan Air probe will switch itself off when the battery capacity drops 17% from the charge level probe had when it was left connected to the app in Freeze.*

Vscan Air probe is OFF

A short press (<1 sec) on the power button while the Vscan Air probe is off will show the battery charge status via the LED lights.
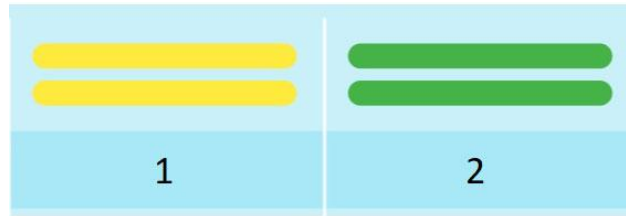
1. Battery level 8-90%
2. Fully charged

Figure 3-13.   LED states when Vscan Air probe is OFF

No light indicates that the Vscan Air probe Storage mode is enabled for one of the below reasons:

- A new not yet used Vscan Air probe arrives with Storage mode enabled. Before starting to use the probe it has to be activated as described in the section 'How to charge the Vscan Air probes' on *page 3-4*.
- The Vscan Air probe will automatically enter Storage mode when the probe charge level is <8%. The probe will need to charge to a level above 8% to accept being powered on.
- The probe can also have been put into Storage mode as described in the 'Storing devices in between uses' on *page 5-135*.

NOTE: To re-activate the probe, the probe needs to be placed onto the wireless charger. When the probe has been re-activated it can be turned ON and battery status can be checked via the short press (<1 sec) as described in this section.

A **steady yellow light** on both LEDs indicates a Vscan Air probe charge level in the range 8-90%.

A **steady green light** on both LEDs indicates a Vscan Air probe charge level in the range 90-100%.

Vscan Air probe is charging

Please refer 'How to charge the Vscan Air probes' on *page 3-4*'.
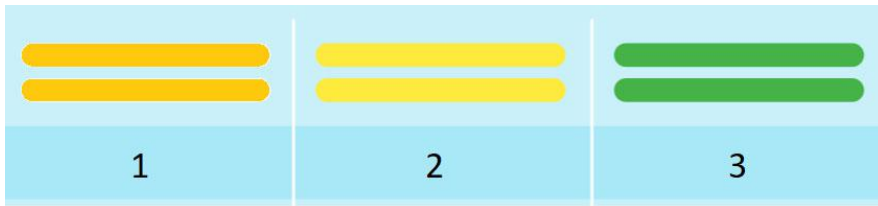
1. Battery level <8%
2. Battery level 8-90%
3. Fully charged

Figure 3-14.   LED states when Vscan Air probe is charging

- A **blinking light** on both LEDs indicates a Vscan Air probe charging issue.

- A **steady orange/red toned yellow** on both LEDs indicates the Vscan Air probe is charging. Charge level is less than 8%, and probe will need to charge above this level to be powered on.

- A **steady yellow light** on both LEDs indicates the Vscan Air probe is charging. Charge level in the range 8-90%.

- A **steady green light** on both LEDs indicates the Vscan Air probe is charging. Charge level 90-100%.

Initial use

Pre-requisites

Vscan Air app requires the display device to have at least 700MB of free storage space on the mobile device when starting.

Supported Mobile Platforms

- Operating system options

  - Android phones and tablets with OS version 12, 13, or 14 device with 0x64 ARM based CPU architecture and 64-bit Kernel, Android open GL ES 3.0, and compatibility with Google Play store

  - iPad and iPhone devices with iOS 15, 16 or 17

- Screen requirements

  - Size: from 5 to 20 inches

  - 960 x 640 (or 640 x 960) pixel or more

- Internal storage requirement: 8GB or more

- Internal RAM requirement: 4GB or more

- Connectivity requirements

  - IEEE 802.11n

  - Peer-to-peer connectivity (Android only)

  - Bluetooth Low-Energy 4.0

- Security requirements

  - WPA2

  - Data on device must be encrypted and authentication enabled

NOTE: *Using the Vscan Air app with a mobile device which does not meet the minimum requirements may result in low-quality images, unexpected results, and possible misdiagnosis. The Vscan Air app may not work on all devices.*

NOTE: *Data communication between probe and app are encrypted using WPA2 during scan.*

Vscan Air - Compatible Display Devices

Please visit the Vscan Air support center to access the most recent list of validated display devices.

http://vscanair-support.gehealthcare.com/

Vscan Air App iOS has been validated for the following display devices:

Apple iPhones	Operating system
iPhone 11	iOS 17.3.1
iPhone 11 Pro	iOS 15.0.1 iOS 17.2 iOS 17.2.1
iPhone 11 Pro Max	iOS 16.6
iPhone 12	iOS 15 iOS 15.3.1
iPhone 12 Mini	iOS 15
iPhone 12 Pro	iOS 15.0.1 iOS 16.3.1
iPhone 12 Pro Max	iOS 15.4 iOS 16.1 iOS 16.0.3
iPhone X	iOS 16.4.1
iPhone 13 Mini	iOS 15.0.1
iPhone 13	iOS 15.0.1
iPhone 13 Pro	iOS 15.0.1 iOS 16.0.2 iOS 16.5 iOS 16.5.1
iPhone 13 Pro Max	iOS 15.1.1 iOS 15.4
iPhone 14	iOS 16.0.3 iOS 16.6.1
iPhone 14 Plus	iOS 16.0.3
iPhone 14 Pro	iOS 16.0.3 iOS 16.3 iOS 16.4
iPhone 14 Pro Max	iOS 16.0.3 iOS 17.0.2 iOS 17.1
iPhone 15	iOS 17.0.3

Apple iPhones	Operating system
iPhone 15 Plus	iOS 17.0.3 iOS 17.2.1 iOS 17.3
iPhone 15 Pro	iOS 17.0.3 iOS 17.3 iOS 17.3.1
iPhone 15 Pro Max	iOS 17.0.3 iOS 17.2

Vscan Air - Compatible Display Devices (continued)

Apple iPads	Operating system
iPad 7th Gen	iPadOS 15.7 iPadOS 16.5.1 iPadOS 17.0.3 iPadOS 17.2 iPadOS 17.3 iPadOS 17.3.1 iPadOS 17.4
iPad Pro 4th Gen	iPadOS 16.5
iPad 8th Gen	iPadOS 15 iPadOS 15.4
iPad Air 4th Gen	iPadOS 15.0.1 iPadOS 15.4 iPadOS 16.1 iPadOS 16.2 iPadOS 16.6 iPadOS 17.2
iPad Mini 5	iPadOS 15.0.1
iPad Mini 6th Gen	iPadOS 15.1
iPad 9th Gen	iPadOS 15.1 iPadOS 17.0.1
iPad Pro 5th Gen	iPadOS 15
iPad Air 5th Gen	iPadOS 16.2 iPadOS 16.4.1 iPadOS 16.5.1 iPadOS 16.7 iPadOS 17.3.1
iPad Air 6th Gen	iPadOS 15.5
iPad Air 10th Gen	iPadOS 17.1.1
iPad 4th Gen	iPadOS 16.6
iPad 9th Gen	iPadOS 17.3 iPadOS 17.3.1 iPadOS 17.4
iPad 10th Gen	iPadOS 16.3 iPadOS 16.4 iPadOS 16.5 iPadOS 17.1.1 iPadOS 17.4

Vscan Air - Compatible Display Devices (continued)

The Vscan Air app for Android has been validated for the following display devices:

Samsung Mobiles	Operating system
Samsung Galaxy S20 Ultra (Intl.)	Android 13
Samsung Galaxy A72	Android 12 Android 14
Samsung Galaxy S23 Ultra	Android 13 Android 14
Samsung Galaxy S23+	Android 13 Android 14
Samsung Galaxy S23	Android 13 Android 14
Samsung Galaxy S21+5G	Android 14
Samsung Galaxy S21 5G	Android 14
Samsung Galaxy A33	Android 13
Samsung Galaxy A73	Android 13
Samsung Galaxy S22+	Android 12 Android 14
Samsung Galaxy S22	Android 12 Android 14
Samsung Galaxy S22 Ultra	Android 12 Android 13 Android 14
Samsung Xcover 6 Pro	Android 13
Samsung Galaxy S24	Android 14
Samsung Galaxy S24+	Android 14
Samsung Galaxy S24 Ultra	Android 14

Vscan Air - Compatible Display Devices (continued)

Samsung Tablets	Operating system
Samsung Tab A8	Android 13
Samsung Galaxy Tab Active 3	Android 13 Android 14
Samsung Galaxy Tab Active 4 Pro	Android 13
Samsung Galaxy Tab S8+	Android 12 Android 13 Android 14
Samsung Galaxy Tab S8+ 5G	Android 12 Android 14
Samsung Galaxy Tab S8 wifi	Android 13
Samsung Galaxy Tab S8 5G	Android 12 Android 13 Android 14
Samsung Galaxy Tab S8 Ultra 5G	Android 12 Android 14
Samsung Tab S9	Android 13
Samsung Tab S9 5G	Android 14
Samsung Tab S9+	Android 13
Samsung Tab S9 Ultra	Android 13 Android 14
Samsung Tab A9	Android 13
Samsung Tab A9+	Android 13
Samsung Tab Active 5	Android 14

Vscan Air - Compatible Display Devices (continued)

Google Mobiles	Operating system
Google Pixel 5	Android 12 Android 13
Google Pixel 6	Android 12 Android 14
Google Pixel 6a	Android 13
Google Pixel 6 Pro	Android 13
Google Pixel 7	Android 13 Android 14
Google Pixel 7 Pro	Android 13 Android 14
Google Pixel 8	Android 14
Google Pixel 8 Pro	Android 14

NOTE: *Device and OS combinations not listed have not been verified for compatibility with Vscan Air. OS point releases higher than the release listed for your device (also known as maintenance releases) are compatible but have not been explicitly verified for the device. It is recommended to upgrade your device to the latest OS version verified to be compatible with the device. It is not recommended to upgrade your device OS to a major release not listed for your device.*

Please visit the Vscan Air support center for the latest information on compatible OS versions.

https://vscanair-support.gehealthcare.com/support/solutions/ articles/47001169561-vscan-air-compatible-display-devices

NOTE: *The Vscan Air app is kept compatible with OS versions as long as these are supported by the device manufacturers. A rule thumb is that the three latest OS versions are supported.*

Caption AI - Compatible Display Devices

Please visit the Vscan Air support center to access the most recent list of validated display devices.

http://vscanair-support.gehealthcare.com/

Caption AI Tool has been validated for the following display devices:

Apple iPads	Operating system
iPad Air 4th Gen	iPadOS 16

Samsung Tablets	Operating system
Samsung Galaxy Tab Active 4 Pro	Android 13
Samsung Galaxy Tab S8+ 5G	Android 13

Please visit the Vscan Air support center for the latest information on compatible OS versions.

https://vscanair-support.gehealthcare.com/support/solutions/articles/47001169561-vscan-air-compatible-display-devices

NOTE: *Caption AI is only visible in the presets and tools menu if purchased and is supported by the Vscan Air SL only.*

NOTE: *Caption AI may be subject to government regulation and may not be available in all countries. Please check with your local GEHC representative for details.*

Display device image quality verification

Adjusting the display brightness is one of the most important factors for optimal image quality visualization. A proper setup displays a complete grey scale.The lowest levels should just disappear into the black background and the highest white should be bright, but not saturated.

The following can be done to adjust the display brightness of the device for adequate visualization. Open the **Display calibration** screen and follow the instructions to make sure that the different shades of gray are discernible.
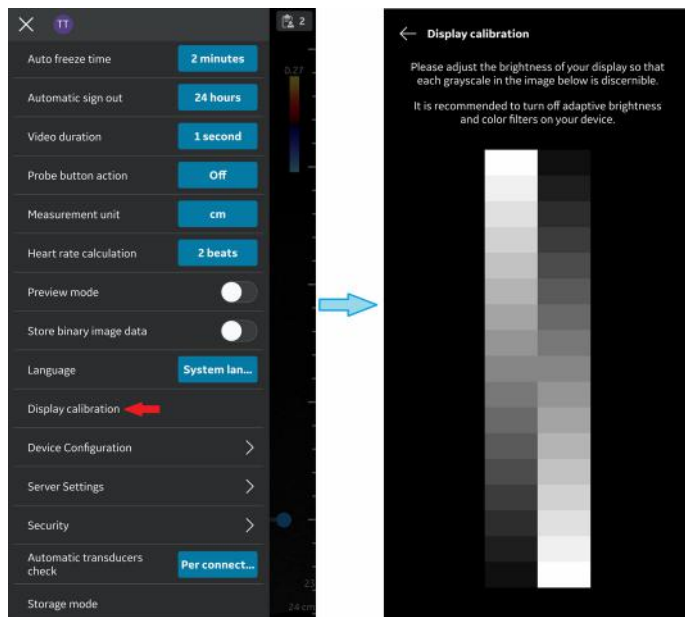
Figure 3-15.   Display calibration

NOTE: *Reference images are available in 'Preview mode'. These images can be used to check that the full range of grays are visible in the images.*

Display device image quality verification (continued)

Recommended example images: Abdominal preset on Curved and MSK preset on Linear transducer.
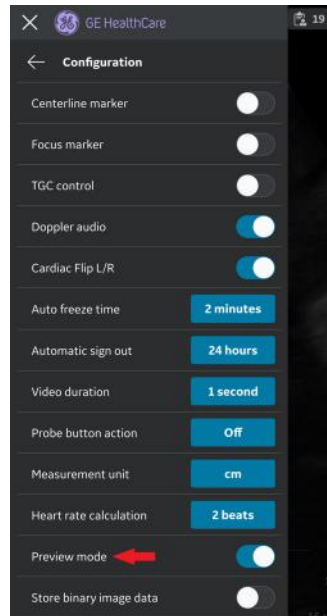
Figure 3-16.   Screen with preview mode
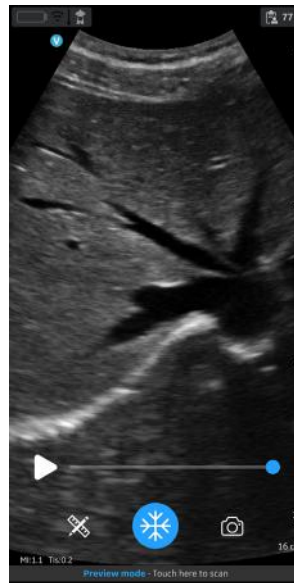
Figure 3-17.   Abdominal preset with curved

Display device image quality verification (continued)
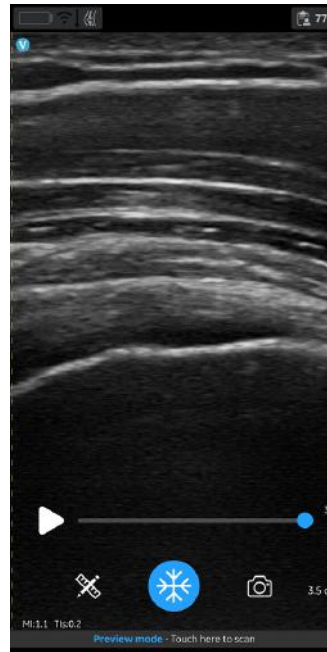
Figure 3-18.   MSK preset with linear

It is recommended to turn off adaptive brightness and display filters.

Power ON/OFF

To power ON the Vscan Air probe

To power on the Vscan Air the first time the first step is to start a charging cycle. Place the Vscan Air probe on the wireless charger as shown in 'How to charge the Vscan Air probes' on *page 3-4*.

To turn **ON** the Vscan Air probe, press and hold the power button for 1 second.

The LEDs start blinking white light when the Vscan Air probe is switched ON and searching for Vscan Air app.

Figure 3-19.   LED blinking white light

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To power ON the Vscan Air probe (continued)

NOTE: A Vscan Air probe will search for a Vscan Air app for 5 minutes after being started. If not successfully paired within those 5 minutes it will power OFF except if placed onto the wireless changer while still being powered.

NOTE: A powered Vscan Air probe will search for a Vscan Air app for 20 seconds after it is put onto the wireless charger and it continues its search when removed from the charger. User can manually trigger a search for the Vscan Air app by clicking the probe power button when a powered probe is charging.

To power OFF the Vscan Air probe

To turn **OFF** the Vscan Air probe, press and hold the power button for 3 seconds.

The LEDs color change to steady magenta when shutdown has been initiated.

Figure 3-20.   LED steady magenta light

To power OFF the Vscan Air probe (continued)

NOTE: *When the button is pressed to power off, wait for 1 minute for the device to shut down completely.*

NOTE: *The system will not save any live image that is not stored when switching off the device. To save the current image on screen, press* **Save***.*

Vscan Air App Version

App Version/Revision	
Version	2.0
Revision	2.0.15.19394

NOTE: *This is an example of the display format for App Version/ Revision.*

Activation and Registration

Each Vscan Air device needs to be registered to an account on the Vscan Air product registration server to be activated and ready for use. This account will hold the medical device owner contact information in addition to information on devices registered to this account.

NOTE: *A user registering a Vscan Air device is regarded being the Vscan Air medical device owner.*

NOTE: *Make sure to unregister and re-register the medical device if relocating to a country different from the country where the app and/or the probe was originally registered.*

First time registration

Vscan Air app installation

1. Power **ON** the display device.
2. Download the Vscan Air app via Google Play Store or Apple App Store depending on your display device OS.
3. Install the Vscan Air app on your device.
4. Select **Allow** to let the Vscan Air App access photos, media and files on the display device.

NOTE: *Screen capture functionality in general is allowed when Vscan Air application is on the foreground/in-use.*

NOTE: *The device (android and iOS) date and time settings need to be set automatic. This is required to ensure successful authentication of device.*

⚠ WARNING   Do not download the Vscan Air app from 3rd party app stores. Use only trusted apps downloaded and installed from the Google Play Store or the Apple App Store.

Create a Vscan Air account

1. Click on the Vscan Air app icon on the display device to start the app.

2. Review the End User License Agreement. If accepting check the box to Continue.
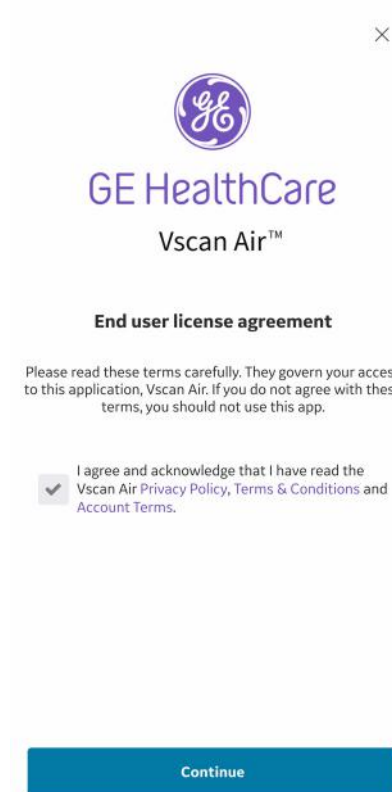
Figure 3-21.   End User License Agreement

Create a Vscan Air account (continued)

3.   Press **Register** to start registration.
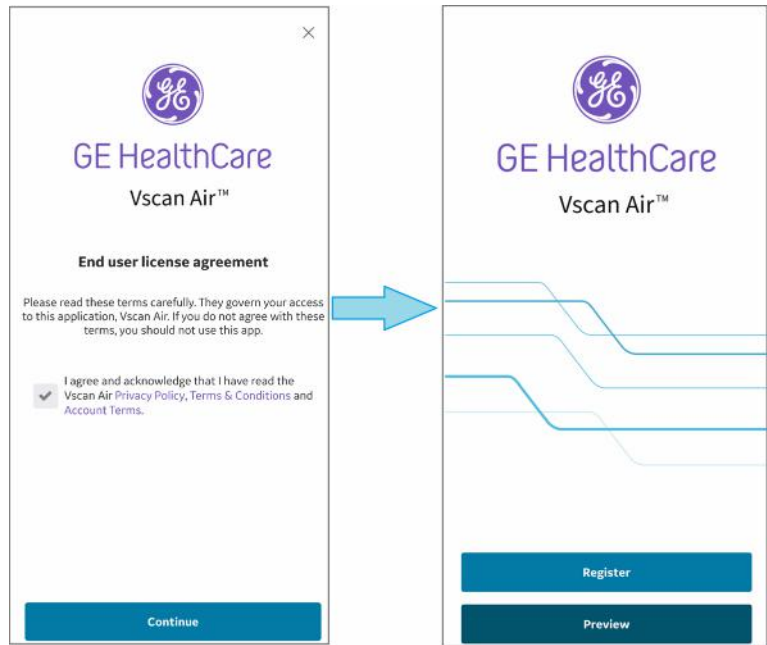
Figure 3-22.   Start registration

NOTE: *The app can be explored by selecting "Preview". Scanning is disabled while in Preview.*

Create a Vscan Air account (continued)

4. Select "**Create New Account**" available for selection when the End User License Agreement check-box is checked.
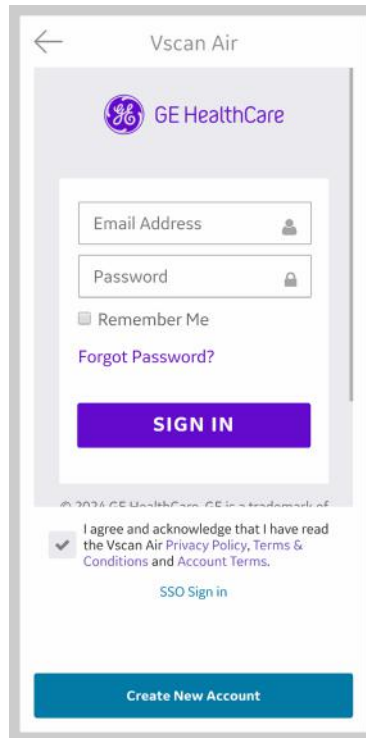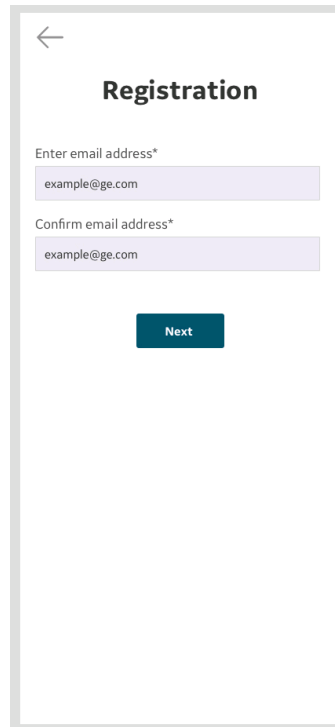
Figure 3-23.   Register the Vscan Air app

NOTE: *For security reasons, if the sign in screen is kept open for more than 30 minutes, user is expected to close and open the app again.*

Create a Vscan Air account (continued)

If a registered account is already found for the email entered, the app will return to the previous screen to sign in using the existing credentials. If an existing account is not found for the entered email, you will be taken to the next step.

Figure 3-24.   Confirm email address

Create a Vscan Air account (continued)

5.   **Turn on** Vscan Air probe.
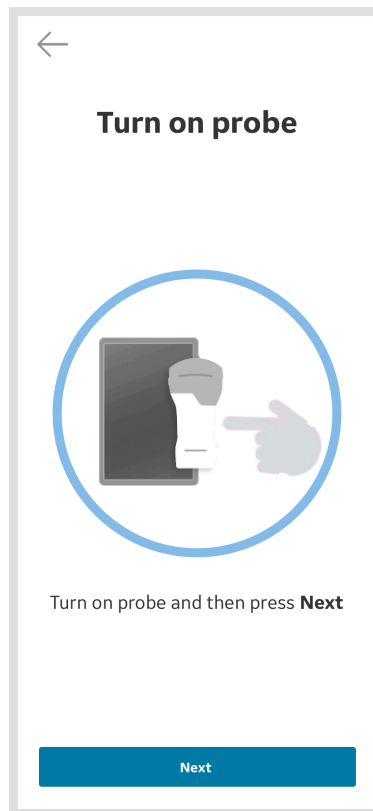
Figure 3-25.   Search for Vscan Air probe

NOTE: *The Vscan Air probe will not be able to connect to the Vscan Air app if the Android or iOS mobile device is in 'Flight mode'.*

Create a Vscan Air account (continued)

6.   Wait for initialization of Vscan Air probe.
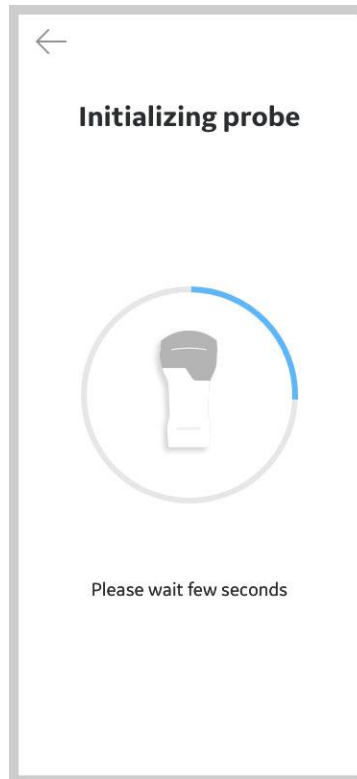
Figure 3-26.   Initialization of Vscan Air probe

Create a Vscan Air account (continued)

7. Press the power button on Vscan Air probe to connect to the Vscan Air app.
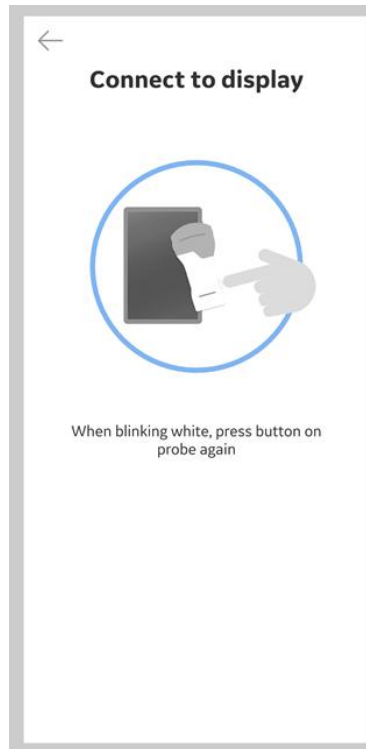
Figure 3-27.   Connect to display

Create a Vscan Air account (continued)

8. Once Vscan Air probe is found, select "**Continue registration**".

Figure 3-28.   Vscan Air probe detected

9. Enter the required information.
10. Confirm that given information is correct.

Create a Vscan Air account (continued)

11. Acknowledge Terms and Conditions related to user accounts and check desired options to either participate in collaborative GEHC activities or to receive special offers and promotions.

12. Press **Submit**.

Figure 3-29.   Registration submission

NOTE: *The password must have at least 8 characters and contain at least one number, one uppercase letter, one lowercase letter, and one of the following special characters: ! " # $ % & ' ( ) * + , - . / : ; < = > ?@ [\ ] ^ _ ` { | } ~*

NOTE: *Fields marked with an asterisk * are required fields.*

Create a Vscan Air account (continued)

13. An email is sent to your email address to validate the Vscan Air user account.

User Registration Complete

An email has been sent to
example@ge.com

Please click the link in your email
to validate your account

If the email address has been entered correctly,
you should receive a confirmation email. Please
remember to check your email spam folder
before selecting resend

Sign in
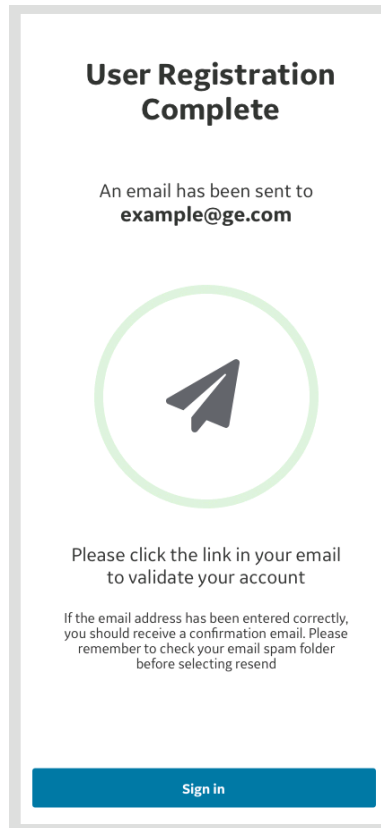
Figure 3-30.   Confirm email

NOTE: *Please check your spam folder if you do not receive the email to validate your account.*

Create a Vscan Air account (continued)

14. The following activation email will be sent to the registered email.
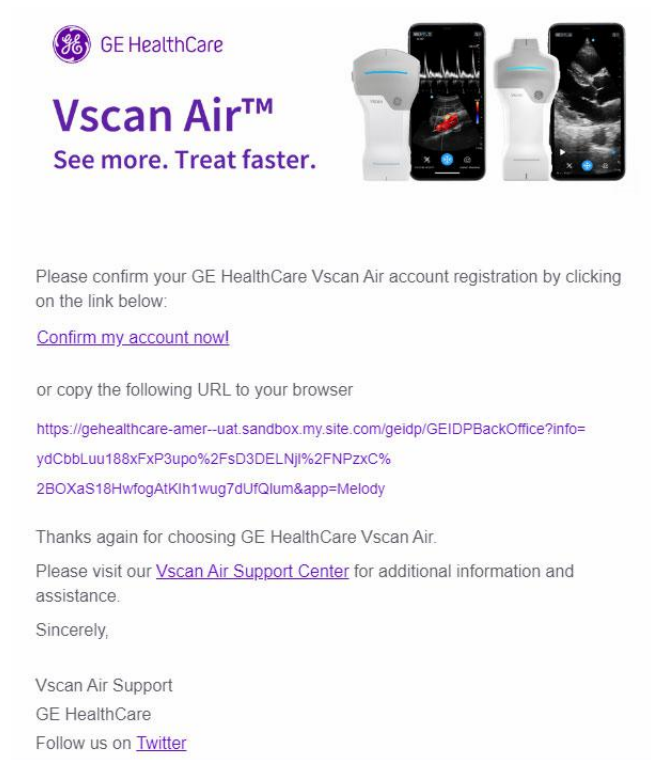
Figure 3-31.   Email message

NOTE: *Email shows example URL.*

Create a Vscan Air account (continued)

15. Click the link in the email to validate the Vscan Air user account.

16. The account is activated. Sign into the new account.
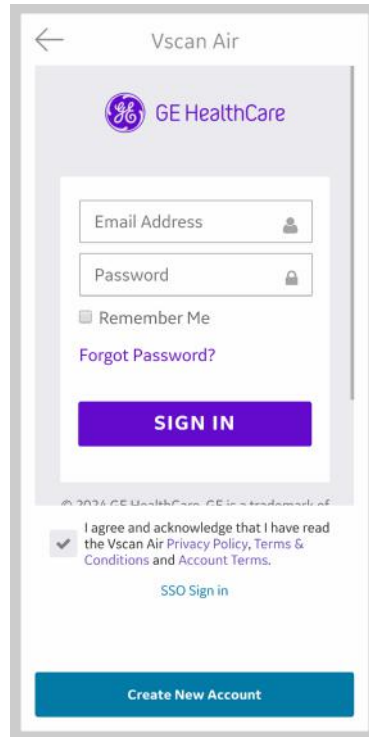
Figure 3-32.   Sign in to the account

NOTE: *Some mobile devices have convenience settings for keyboards such as "slide to type" or swipe keyboard" or "one handed keyboard". Enabling these may assist you in faster entry of the password. These are most often found under language or keyboard menu under general settings.*

Create a Vscan Air account (continued)

17. If the account is not activated by clicking the activation link, Vscan Air application will display a warning message.

    In such scenario, press "**Click here**" to initiate request for resending the activation email from the sign in screen.
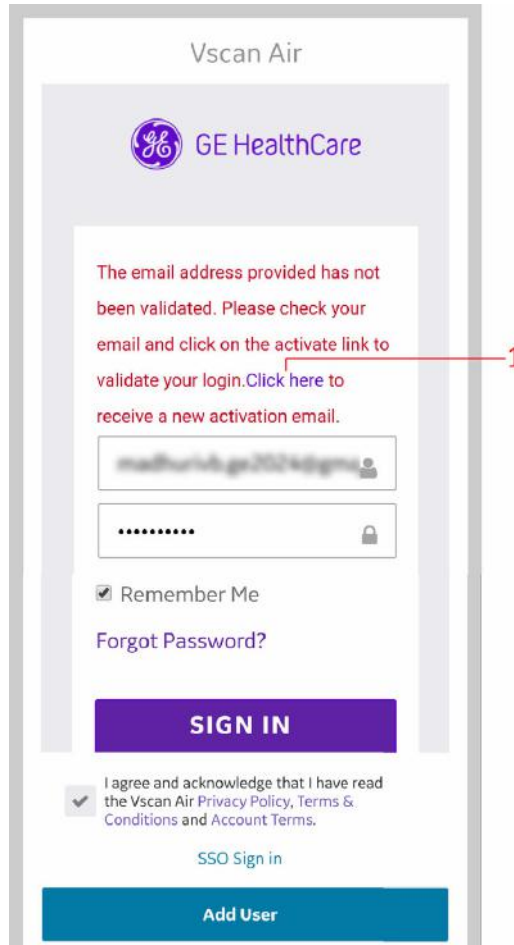
1. Warning message

Figure 3-33.   Resending activation mail

Create a Vscan Air account (continued)

18. Once email is validated, the app screen will show registration details. Click **Confirm** to proceed.
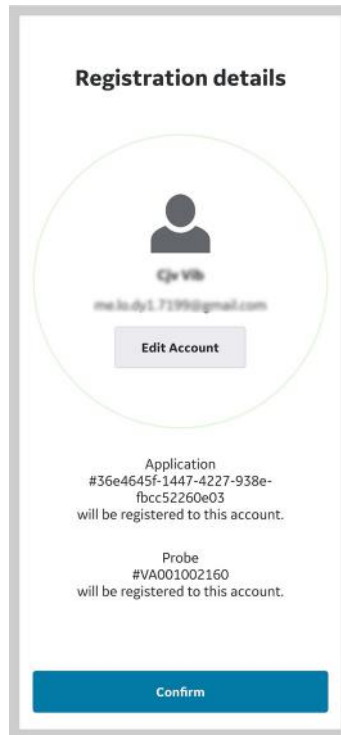
Figure 3-34.   Confirm registration details

Create a Vscan Air account (continued)

19. Registration is complete. Security PIN can be set for secure data access by selecting '**Add security PIN**' or proceed without Security PIN by selecting '**Skip**'.
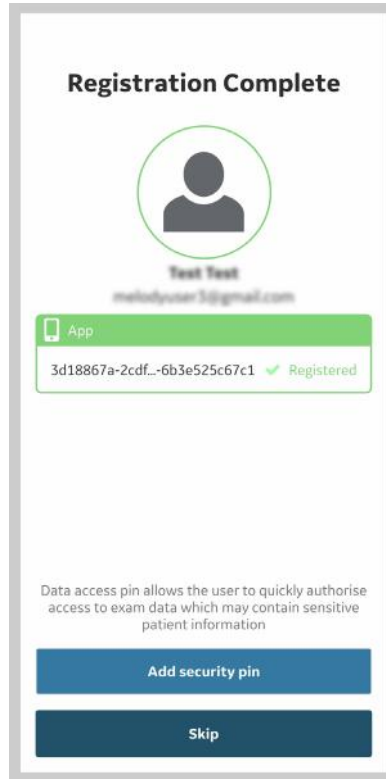
Figure 3-35.   Registration complete

Create a Vscan Air account (continued)

20. To add a security PIN code after completing Vscan Air registration, see 'Ask for data access PIN' on *page 4-49* for more information.

21. The Vscan Air probe is now connected to the app.
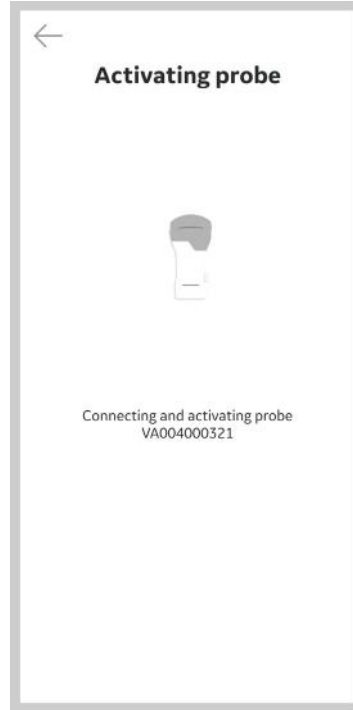
Figure 3-36.   Vscan Air probe activation

Create a Vscan Air account (continued)

NOTE: *When the Wi-Fi connection to the paired probe is*
unexpectedly lost, the Vscan Air App shows the below
warning message as 'Lost connection to Probe'.
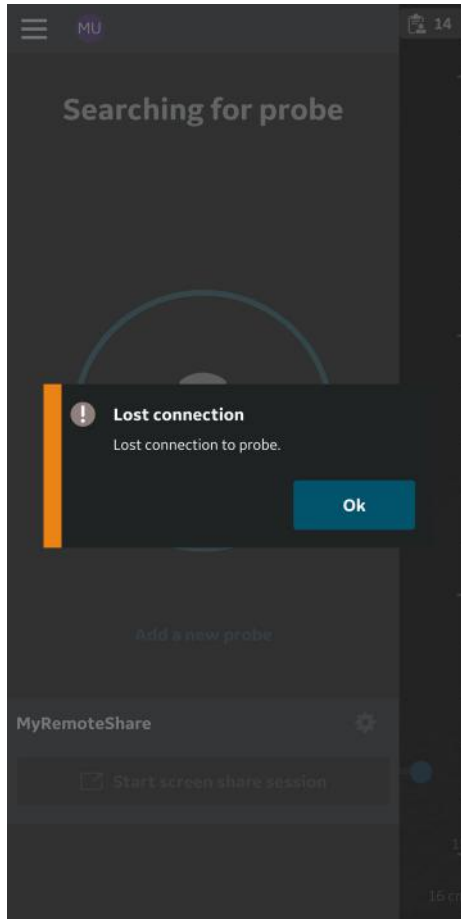
Figure 3-37.   Vscan Air probe Connection Lost

Vscan Air app registration using an existing account

Use the below steps to register the Vscan Air app on a different display device using your existing Vscan Air account.

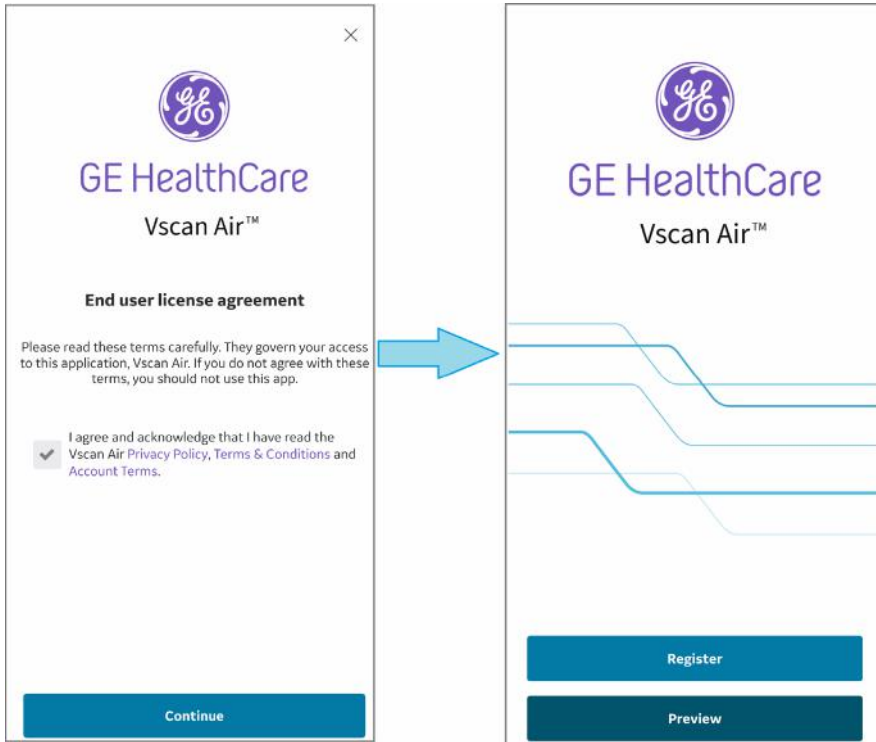1. Press **Register** to start registration.
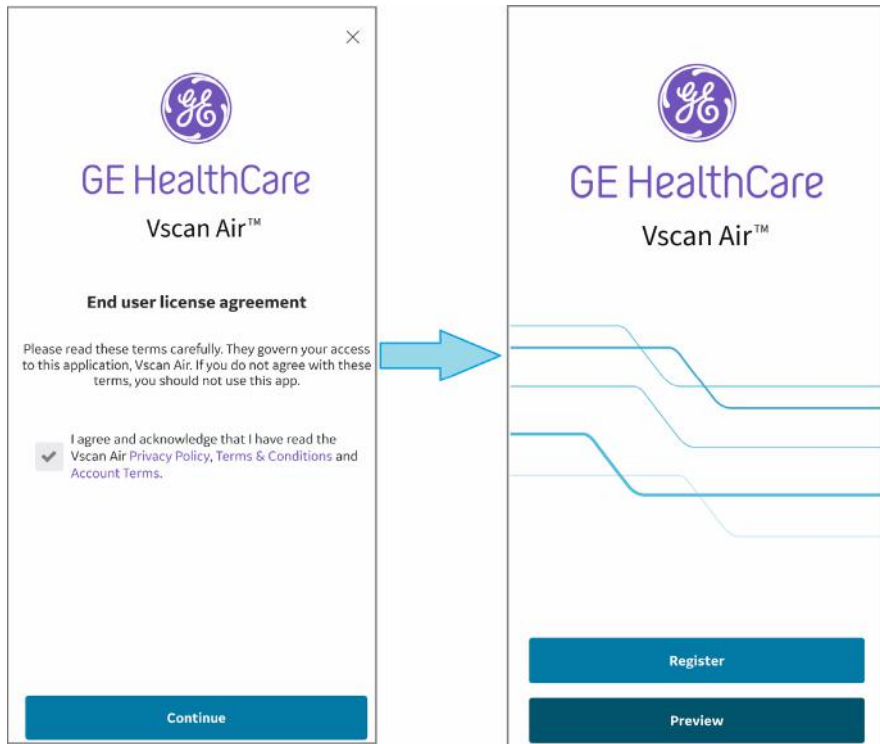
Figure 3-38.   Welcome screen

NOTE: *The app can be explored by selecting 'Preview'. Scanning is disabled while in Preview.*

Vscan Air app registration using an existing account (continued)

2. Enter the email address and password for your existing Vscan Air account.
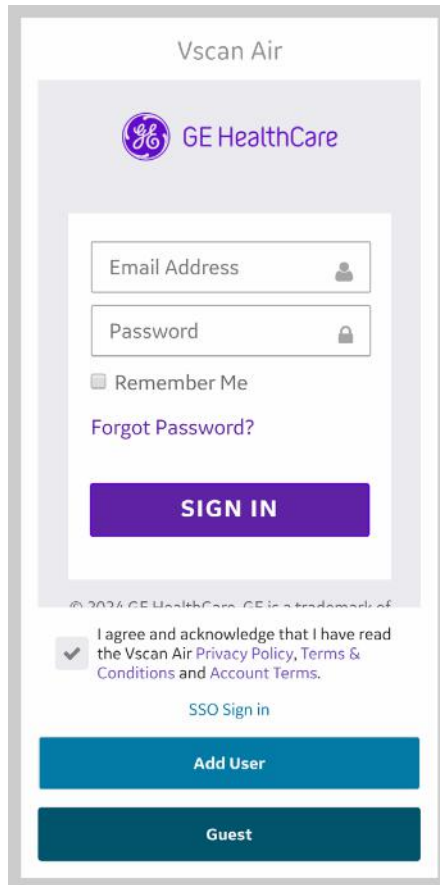
Figure 3-39.   Sign in to the Vscan Air account

Vscan Air app registration using an existing account (continued)

3. Confirm that registration details are correct or edit if needed.
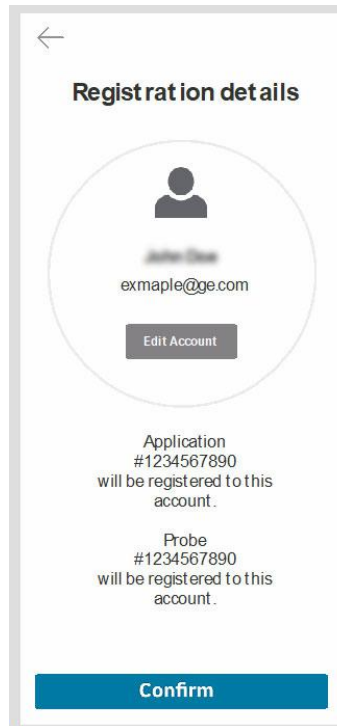
Figure 3-40.   Confirm registration

Vscan Air app registration using an existing account (continued)

4. On confirmation the registration completion screen is displayed.
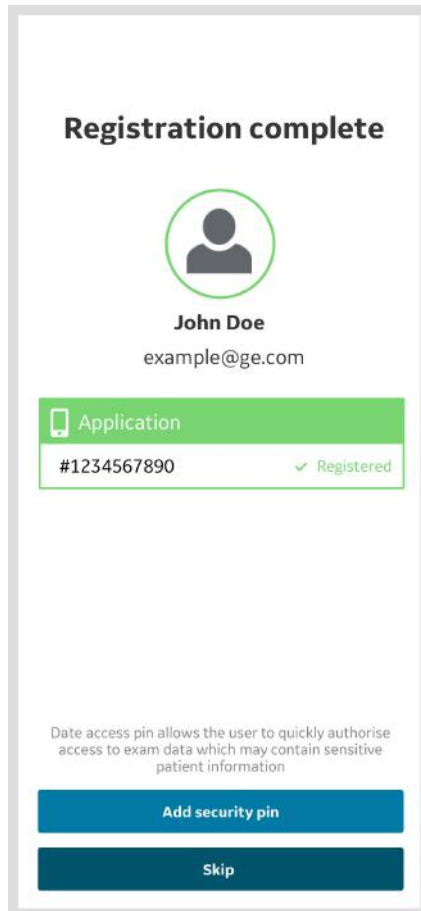
Figure 3-41.   Registration complete

Vscan Air app registration using an existing account (continued)

5. If your user account was created using the "**Add user**" feature (refer 'Adding users' on *page 3-77*), where all the fields needed for device registration are not captured, then the registration screen will be displayed to update the remaining mandatory fields.

Figure 3-42.   Registration with user information

Vscan Air app registration using an Enterprise Single Sign-On (SSO) user account

Use the below steps to register the Vscan Air app on a display device using your Enterprise SSO user account.

1. Press **Register** to start registration.

Figure 3-43.   Welcome screen

NOTE: *The app can be explored by selecting 'Preview'. Scanning is disabled while in Preview.*

Vscan Air app registration using an Enterprise Single Sign-On (SSO) user account (continued)

2.   Tap **SSO Sign in**.
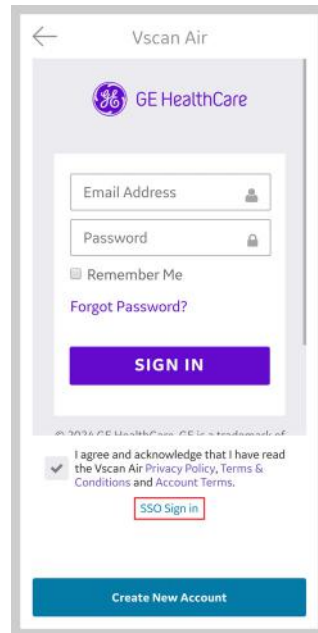
Figure 3-44.   Click on SSO Sign in

Vscan Air app registration using an Enterprise Single Sign-On (SSO) user account (continued)

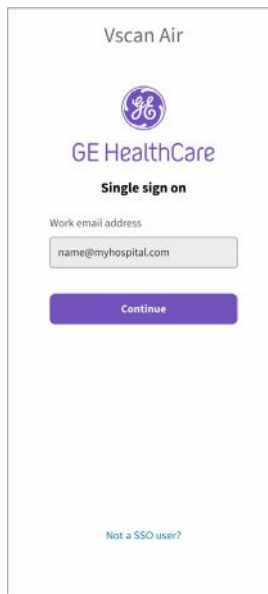3. Enter the email address of Enterprise SSO user account.

Figure 3-45.   Enter email address

4. Enter the code/password required by your organization.

Vscan Air app registration using an Enterprise Single Sign-On (SSO) user account (continued)

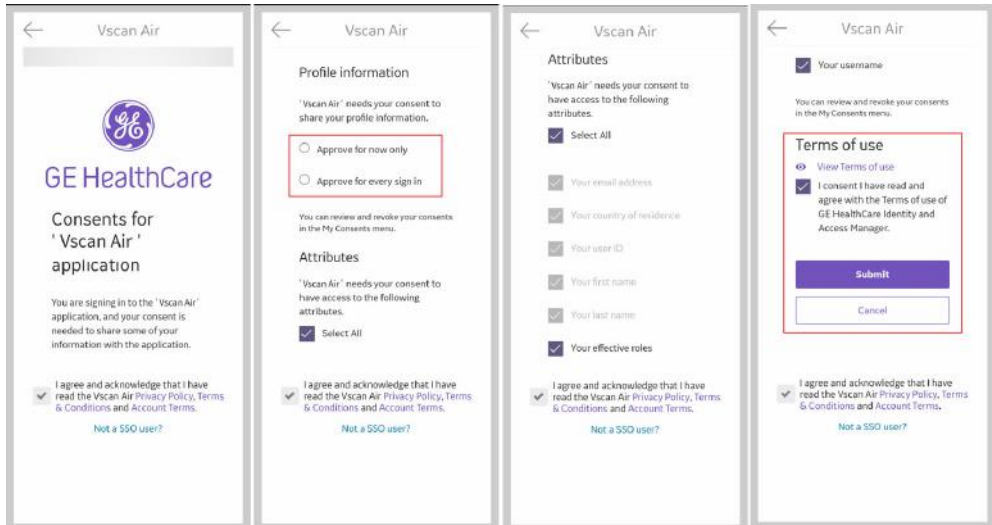5.   Give consent by accepting terms and conditions.

Figure 3-46.   Terms and Conditions

NOTE: 'Approve for now only'

NOTE: 'Approve for every sign in'

6.   Confirm registration.

NOTE: *The organization sign in page will be the default sign in page after successfully registering an Enterprise SSO user account in the app.*

Vscan Air probe registration using existing account

1. Open Vscan Air app.
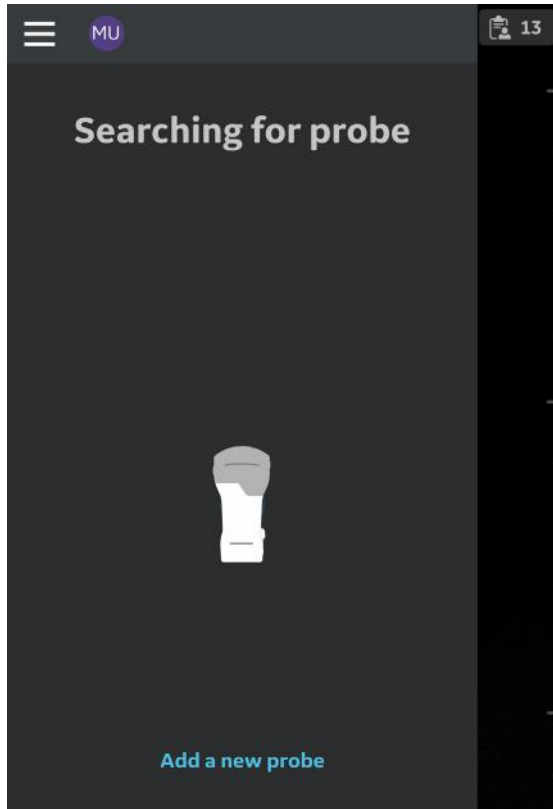2. Select **Add a new probe**.

Figure 3-47.   Search for Vscan Air probe

Vscan Air probe registration using existing account (continued)

3.   If not already turned on, turn on Vscan Air probe now.
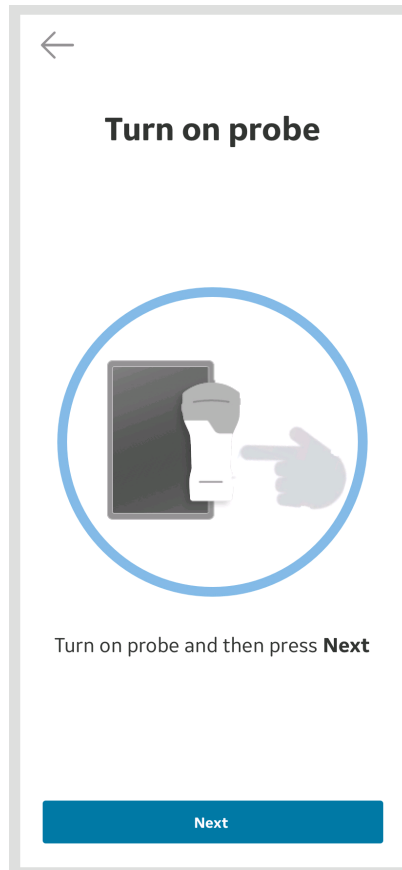

Figure 3-48.   Turn On Vscan Air probe

Vscan Air probe registration using existing account (continued)
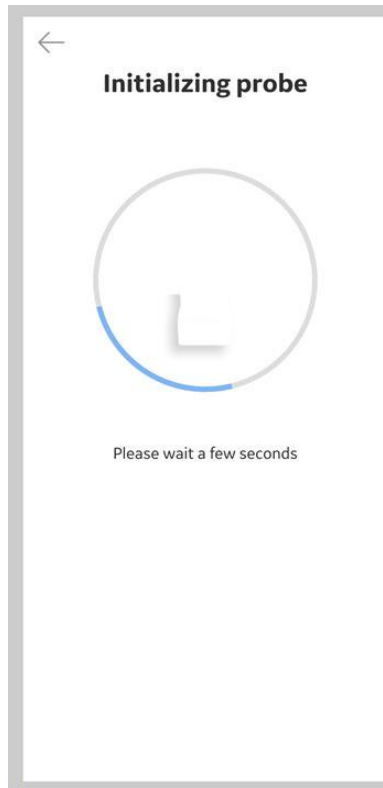
4.   Wait for initialization of Vscan Air probe.

Figure 3-49.   Initialization of Vscan Air probe

Vscan Air probe registration using existing account (continued)

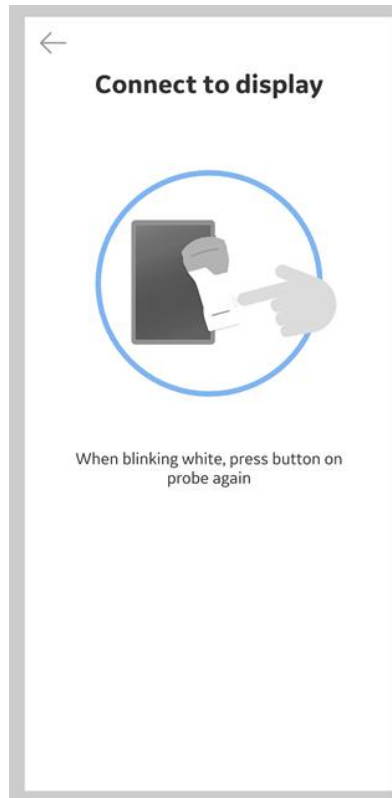5. Press the power button on Vscan Air probe to connect to the Vscan Air app.

Figure 3-50.   Connect to display

NOTE: *When Vscan Air probe is connected to an iOS display device, other Wi-Fi connections will be disconnected.*

Vscan Air probe registration using existing account (continued)

6. Once Vscan Air probe is found, press "**Continue registration**' and '**Connect**' to an existing Vscan Air user account.
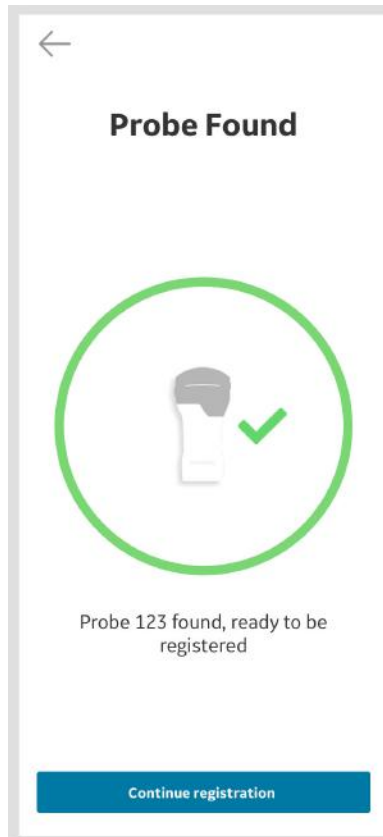

Figure 3-51.   Vscan Air probe detected

Vscan Air probe registration using existing account (continued)

7. **Confirm** that registration details are correct or **edit** if needed.
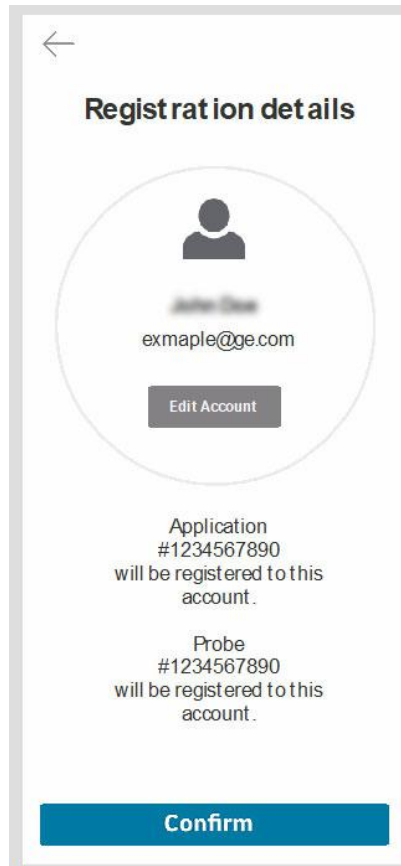

Figure 3-52.   Confirm registration

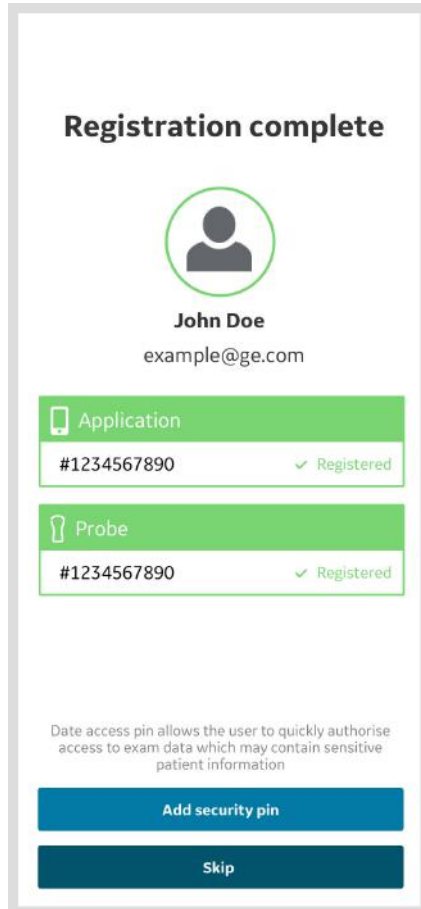**Vscan Air probe registration using existing account (continued)**

Figure 3-53.   Registration complete

Vscan Air probe registration using existing account (continued)

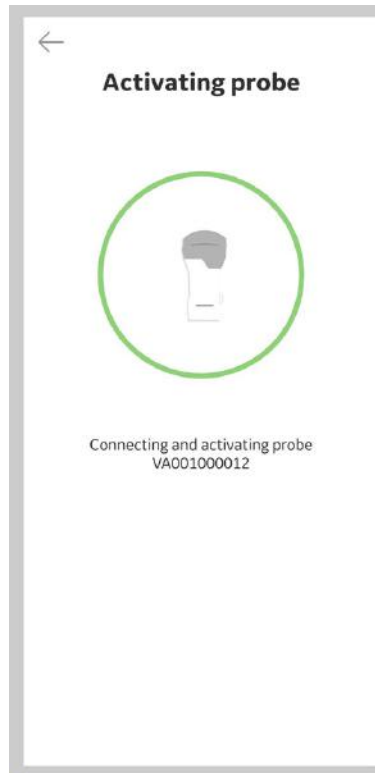8.   Registration is complete.

Figure 3-54.   Vscan Air probe activation

Vscan Air probe registration using existing account (continued)

9. When the scanning is over switch off the probe. The Vscan Air app on screen displays the message '*Probe is shutting down*'.
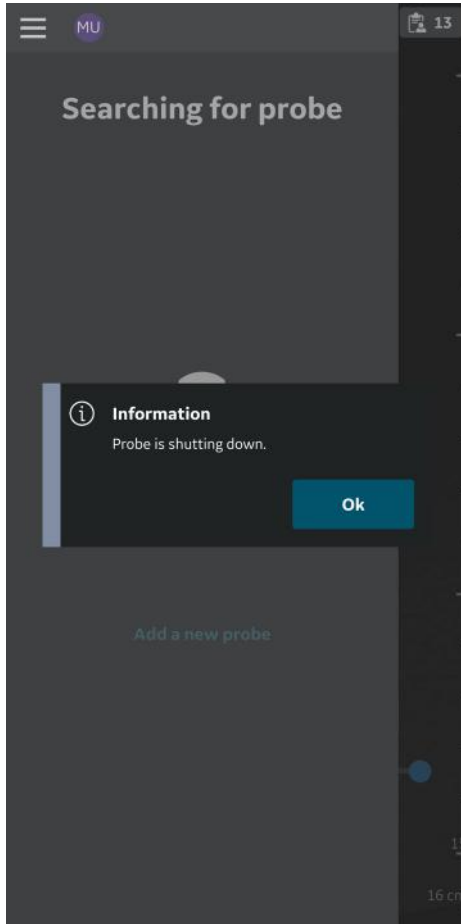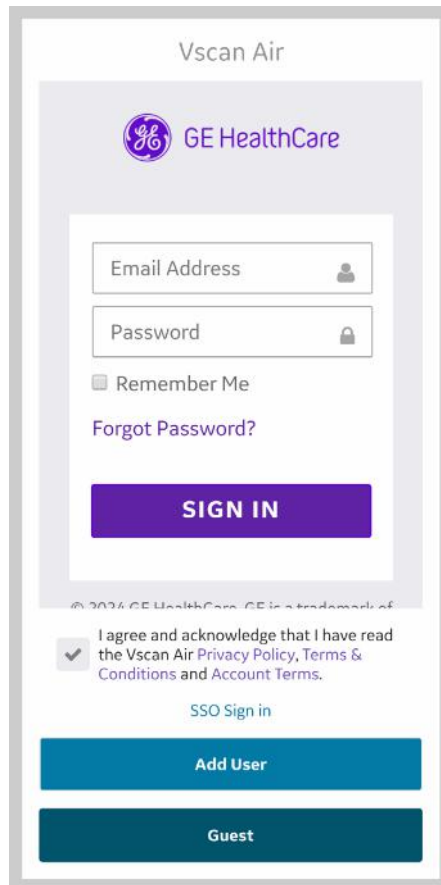
Figure 3-55.   Probe shutting down

Adding users

New users can be added to use a registered application.

1. To add a new user on the sign in page of a registered application, click on Add User button.
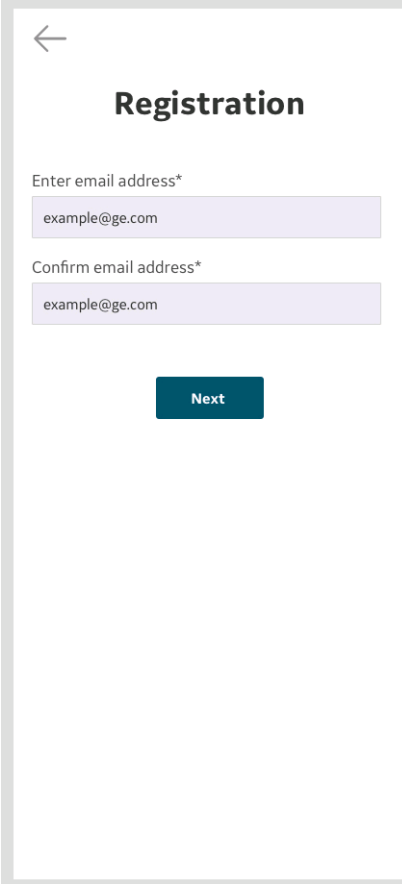
Figure 3-56.   Add new user

Adding users (continued)

2. Enter the user's email address on the registration screen. If the email is found to be already registered, user will be taken to the previous screen to sign in using the existing account credentials.
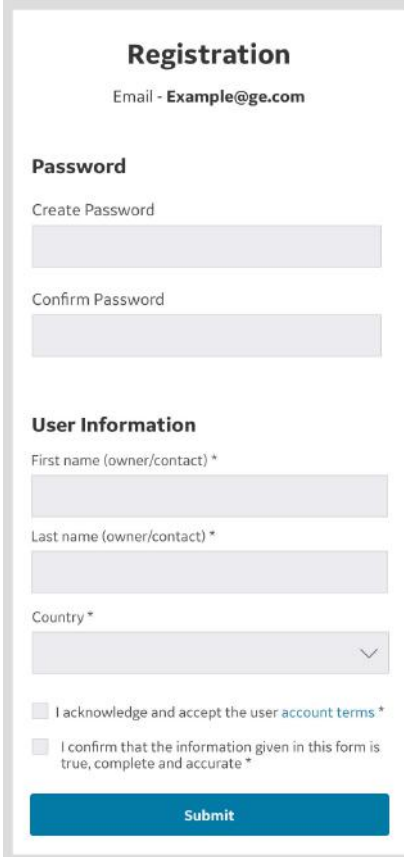
Figure 3-57.   User registration

Adding users (continued)

3. If the entered email is not yet registered, user will be taken to user registration screen.

Figure 3-58.   User registration

Adding users (continued)

4. Once user details are submitted, an email is sent to the registered email address to validate the Vscan Air user account.

NOTE: *Please check your spam folder if you do not receive the email to validate your account.*
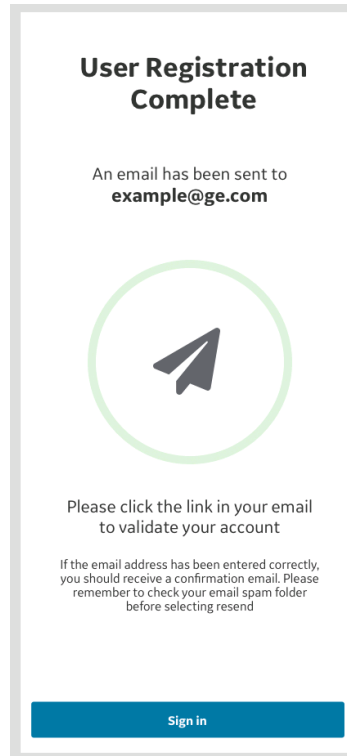
Figure 3-59.   Email validation

5. Click on the link in the email to validate the Vscan Air user account. Confirm registration details.

Registration is complete and user can go to the scan screen by clicking Start Scanning button.

Scan without signing in - Guest

Guest allows the user to scan without having to sign in. This is provided for immediate access to the scan functionality when time is critical or in case of any temporary challenges with signing in when access to scanning is required.

NOTE: *If a user selects to not sign in, access will be limited to scan related functionality only. Guest users will be able to save images during the current exam and review them as well previous exams that were conducted in Guest mode.*

NOTE: *A registered probe will automatically reconnect to an already known mobile device, i.e., the probe has been paired with that specific Vscan Air app mobile device earlier. If the probe has NOT been paired with that specific Vscan Air app mobile device earlier the user needs to press the button on the side of the probe to allow it to pair with a new mobile device.*

NOTE: *Access to assigning patient details or reviewing exams containing patient details will not be available in Guest mode. Access to Modality Worklist will not be available in Guest mode.*

NOTE: *Scanning in Guest mode is supported only for previously registered probes and apps.*

1. To scan without signing in, click the Guest button.
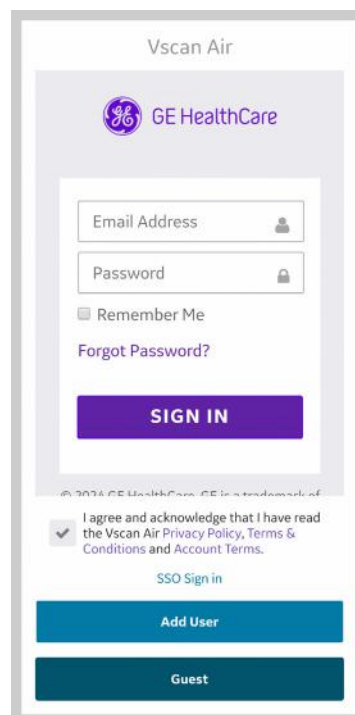
Figure 3-60.   Scan as Guest

Scan without signing in - Guest (continued)

2. Edit Patient button is disabled for guest users under the current exam review screen. Users are required to sign in to add patient details.

Figure 3-61.   Current exam review screen

Scan without signing in - Guest (continued)

3. To exit guest mode, click on the exit button on the top right corner of the left panel menu.
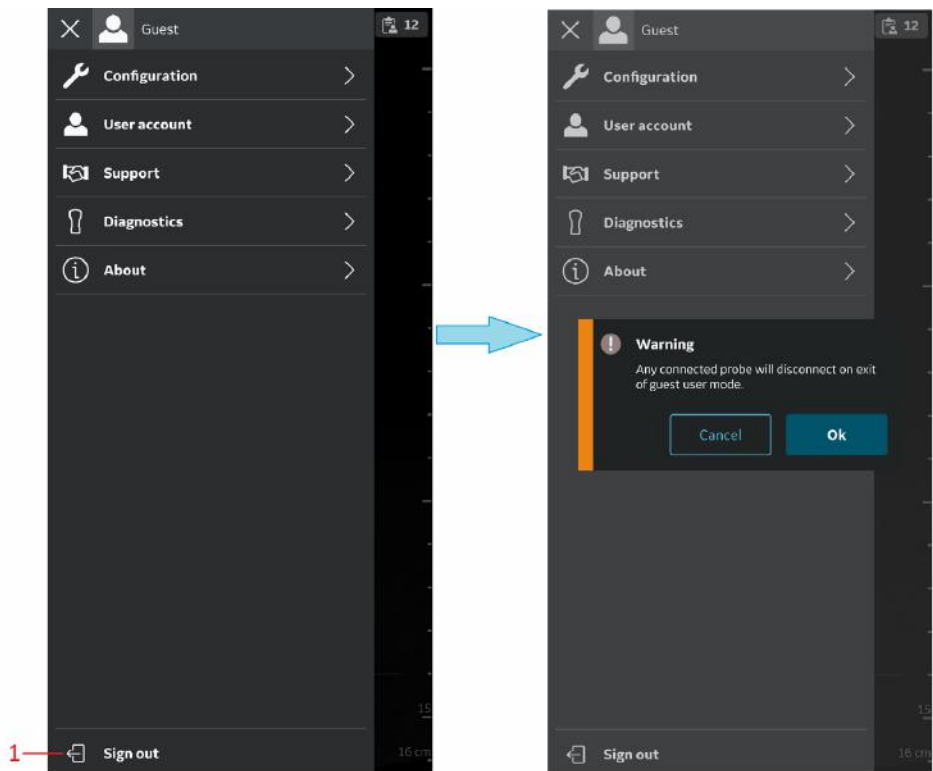
1. Sign out / Exit icon

Figure 3-62.   Exit guest mode

User sign in / sign out

1. Registered users can sign in and sign out from Vscan Air application. Sign in by entering valid credentials on the sign in page. If the entered credentials are incorrect, the application will show an error message.
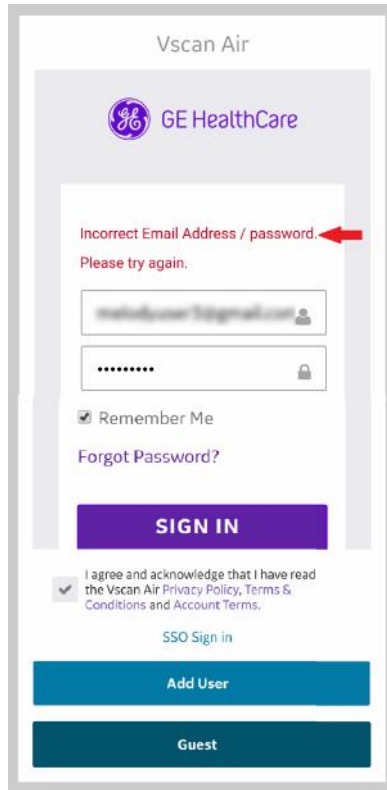
Figure 3-63.   Incorrect credentials

2. The user initials, which is the first letter of the first and last name of the signed in user, will be displayed at the top left corner of the left panel menu screen.

3. The email used when signing in will be displayed at the top of the left panel menu screen. Tapping the email display will hide or unhide the display of the email address.

User sign in / sign out (continued)

4. To sign out click on the Sign out / Exit icon on the top right corner of the left side panel.
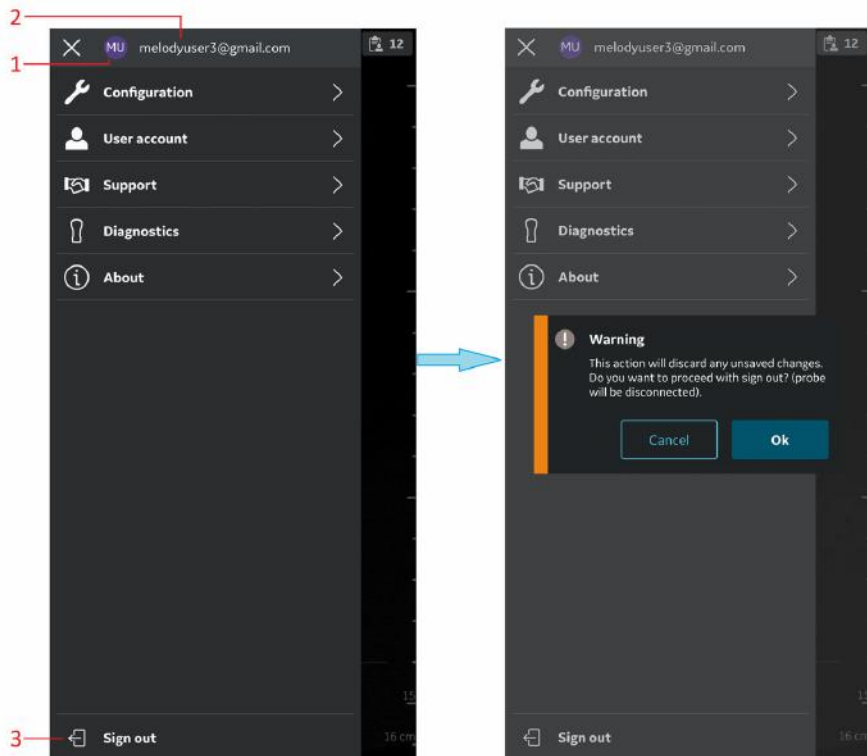
1. User initials - signed in user
2. User email - signed in user
3. Sign out/Exit

Figure 3-64.   Sign out/ Exit

NOTE: *The signed in users email address can be made visible / invisible by tapping the screen area indicated by 2 in the illustration above.*

User sign in / sign out (continued)

5. User will be taken back to the sign in screen on successful sign out.
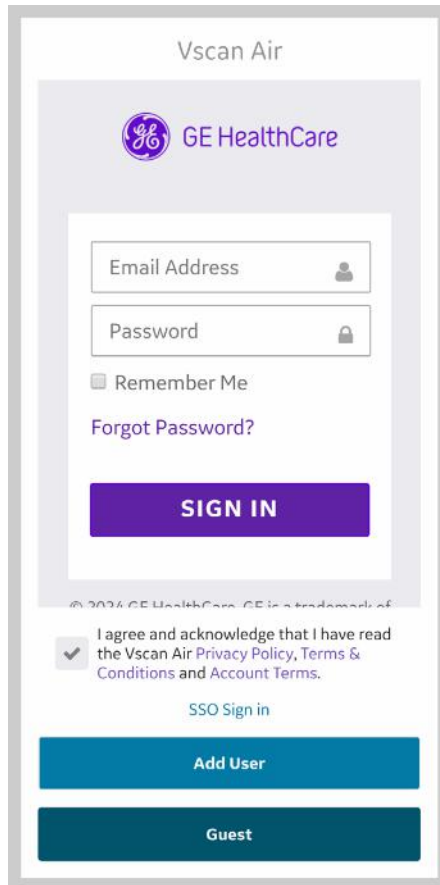
Figure 3-65.   Sign in screen

NOTE: *An automatic sign out duration configuration setting is available. The app will automatically sign out a user per this setting if the user does not sign out manually. The default value is 24 hours, and can be changed via the Configuration menu, see 'Configuration' on page 4-2)*

Delete User Accounts

To delete Vscan Air app user account, follow the below steps:

1. Sign in by entering valid credentials on the sign in page.
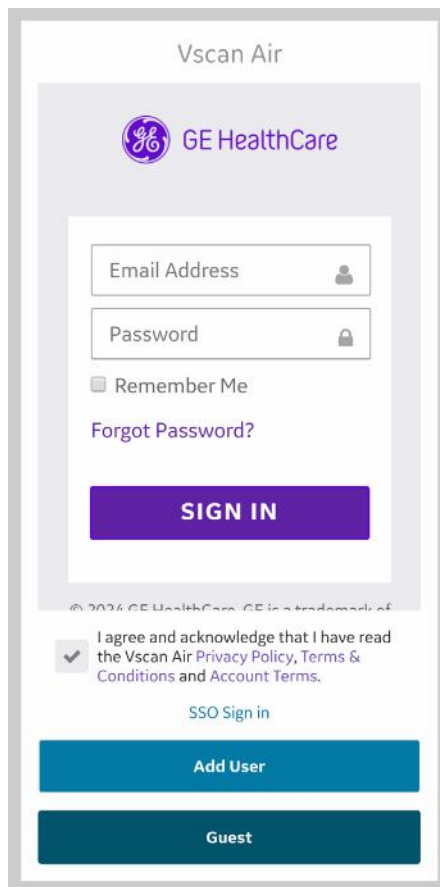
Figure 3-66.   Sign in screen

2. The user initials, which is the first letter of the first and last name of the signed in user, will be displayed at the top left corner of the left panel menu screen.

Delete User Accounts (continued)

3. Tap on the top left corner of menu to display the User account menu which shows **Delete User Account** option.
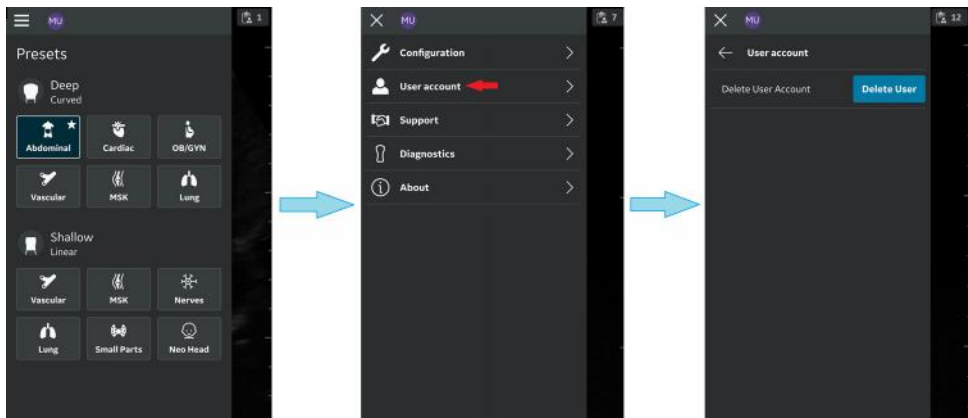
Figure 3-67.   Delete user account

4. Clicking the delete user option will facilitate the delete user account workflow via a web portal.

NOTE:

- When planning to delete a user account please review subscriptions that might be connected to the account. "Manage my subscriptions" can be found when logging in via myvscan.gehealthcare.com as described on 'Subscription Auto Renewal' on *page 4-66*.

- User will be prompted to login once again on the portal with his/her credentials. This is to ensure that the actual logged in user from application is initiating the delete operation.

- In the process of user account deletion, user will be prompted to unregister all owned/registered/activated probes.

- Contact service for assistance in case you have questions, concerns or are being unable to complete the delete user operation.

- If a user continues to use a Vscan Air app in which they had signed in prior to deleting their account (via another mobile device or via the web portal), they will be notified and automatically signed out as soon as they try to perform an operation where a connection to GEHC servers is required (e.g. exporting a log file or using the (optional) digital or AI tools).

Multiple Vscan Air probes detection

When a Vscan Air probe is not detected near the display device, the search is on continuously.

When there are two Vscan Air probes (for example A and B) in the vicinity of the display device, the closest one is detected. If you wish to use Vscan Air probe A, **turn off** Vscan Air probe B or put it far away from the display device. Press the power button on Vscan Air probe to connect to the Vscan Air app.

Preview mode

The Vscan Air App functions in a non-medical Preview mode until activated. The Vscan Air probe has no ability to connect to Vscan Air App while in Preview mode. Users can explore all the main functionality of the app, but some functions are disabled. If saving an image or video, there will be an "*Example image*" watermark on image.

You can activate Preview mode from Start Screen, or from Configurations in Menu after having activated the Vscan Air App.

1.   Activate Preview mode via **Start** Screen.

    •   Select **Preview**

2.   Activate Preview mode via activated Vscan Air App.

    •   Go to Configuration in Menu and **turn on** Preview mode.

To exit Preview mode:

•   Press on the banner at the bottom of the screen.
•   Go to Configuration in Menu and **turn off** Preview mode.

Precautions

⚠ CAUTION	If the display device storage space is less than 700Mb, an error message is displayed.

NOTE: *Scanning does not start if the Vscan Air probe is not connected to a Vscan Air app.*

NOTE: *The Vscan Air probe will not be able to connect to the Vscan Air App if the Android or iOS mobile device is in 'Flight mode'.*

NOTE: *If using 'Hotspot', Wi-Fi will not be available for connecting to Vscan Air probe.*

NOTE: *Scanning stops if the Vscan Air App is sent to the background on the display device.*

NOTE: *Scanning stops within 10 seconds if the Wi-Fi link to the Vscan Air probe is lost.*

NOTE: *Scanning never starts when there is a critical error (e.g., battery critically low) on the Vscan Air probe.*

NOTE: *Scanning stops within 10 seconds when there is a critical error (e.g. battery critically low) on the Vscan Air probe.*

NOTE: *To store new or access any already stored images or videos, the display device shall be encrypted and secured with a PIN, passcode, or biometric protection such as FaceID or fingerprint.*

Unregister Vscan Air Probe

To Unregister Vscan Air Probe, follow the procedure below:

1. Press Menu -> About -> Registered devices
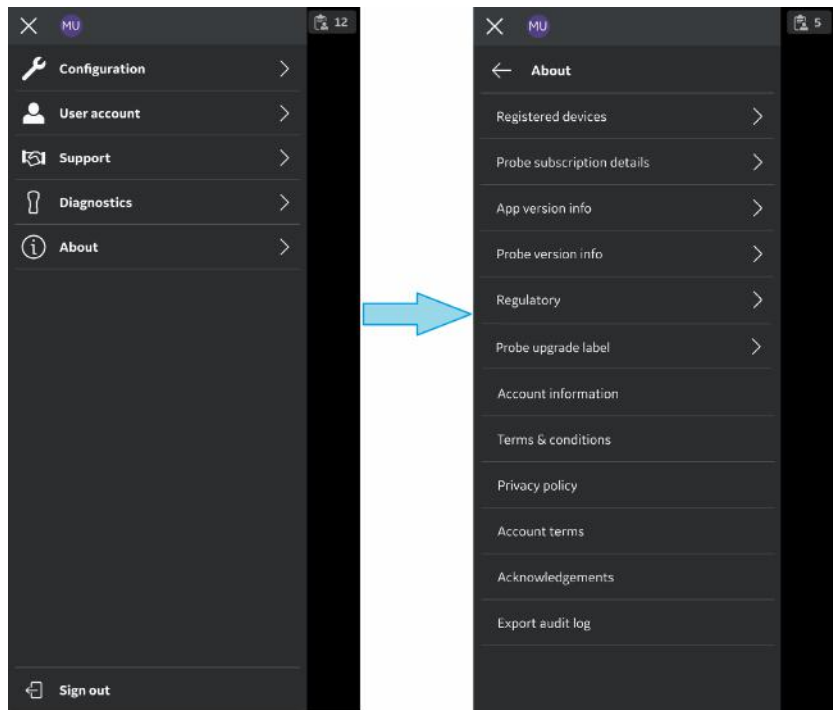
Figure 3-68.   Registered devices

2. Press **Unregister** button on "Connected probe" tab on Registered devices screen to Unregister Vscan Air Probe.
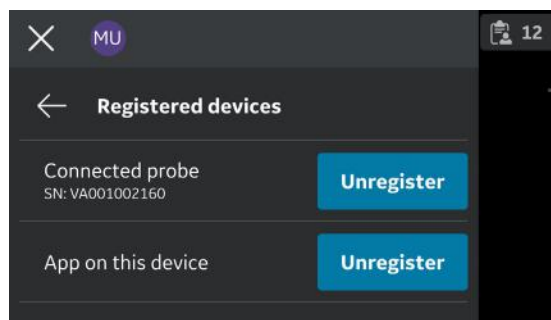
Figure 3-69.   Unregister probe

Unregister Vscan Air Probe (continued)

3. After selecting **Unregister** button, the below message appear.
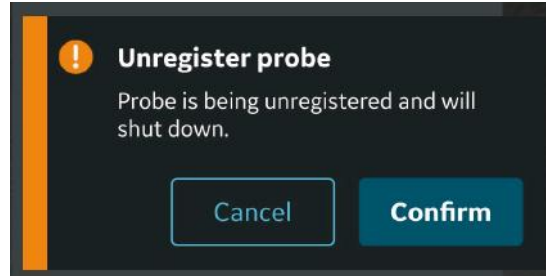
Figure 3-70.   Unregister app warning

NOTE: *It is important to unregister the Vscan Air if a new person will be taking over the ownership of the probe. The new person will be required to register the probe before starting to use it and will be the new owner of the device.*

NOTE: *When unregistering a probe please consider reviewing subscriptions that might be connected to that probe. "Manage my subscriptions" can be found when logging in via myvscan.gehealthcare.com as described on 'Subscription Auto Renewal' on page 4-66.*

Unregister Vscan Air app

To Unregister Vscan Air app, follow the procedure below:

1. Press Menu -> About -> Registered devices
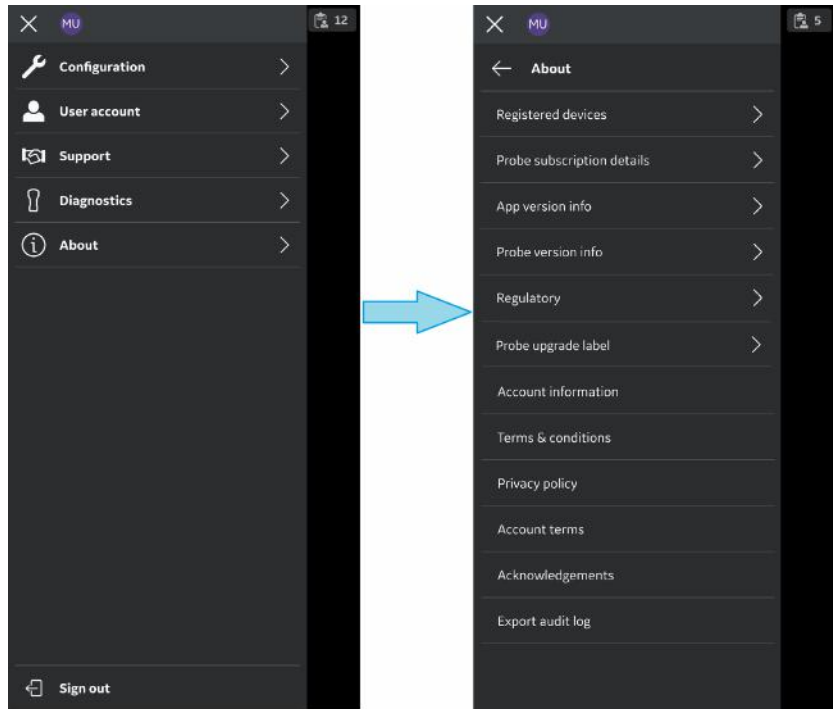
Figure 3-71.   Registered devices

2. Press **Unregister** button on "App on this device" tab on Registered devices screen to Unregister Vscan Air app.
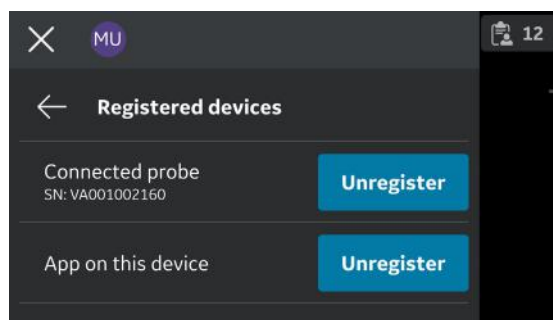
Figure 3-72.   Unregister app

Unregister Vscan Air app (continued)

3. After selecting Unregister button, the below message appears. Press **Proceed** button after reading the message.
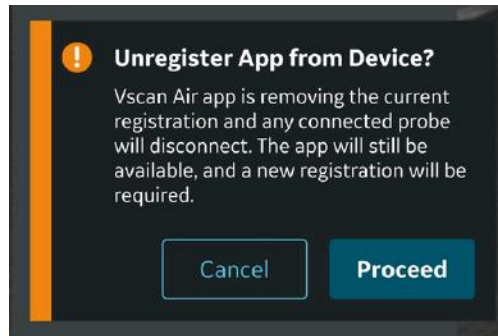
Figure 3-73.   Unregister app warning

4. Press **Erase** button on Confirmation screen. On selecting the Erase button, the app is unregistered from the display device and all the patient data is erased.
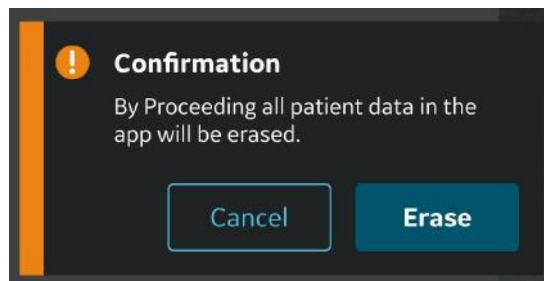
Figure 3-74.   Erase data

NOTE: *It is important to unregister the Vscan Air app if a new person will be taking over the ownership of the app. The new person will be required to register the app before starting to use it and will be the new owner of the device.*

NOTE: *The Vscan Air favorite preset/tool, server settings and exam count will be retained when unregistering the Vscan Air app. To clear all settings the Vscan Air app will need to be uninstalled and reinstalled.*

Chapter 4

Vscan Air Configuration (for iOS and Android)

Contents:

Configuration

The following functions are available under the main menu.

1. 'Configuration' on *page 4-3*
2. 'User account' on *page 4-56*
3. 'Support' on *page 4-57*
4. 'Diagnostics' on *page 4-60*
5. 'About' on *page 4-63*
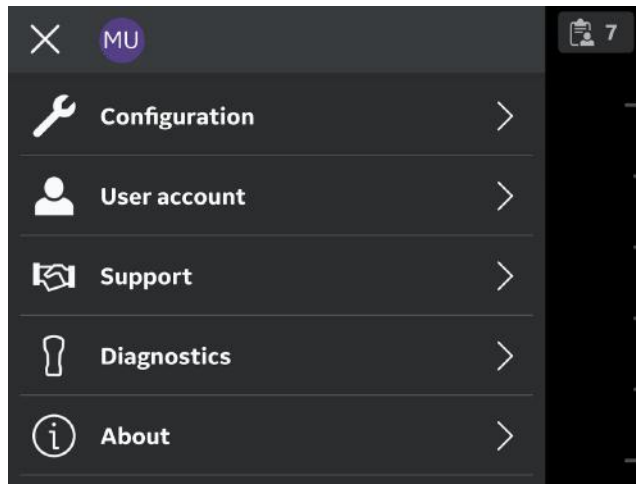
Figure 4-1.   Menu

Configuration

To adjust the scan settings, tap the **Menu icon**.

If the preset panel is displayed, select **Menu** at the top to access the settings panel.

The **Configuration** option displays - *Centerline marker, Focus marker, TGC control, Doppler audio, Cardiac Flip L/R, Auto freeze time, Automatic sign out, Video duration, Probe button action, Measurement unit, Heart rate calculation, Preview mode, Store binary image data, Language, Display Calibration, Device configuration, Server settings, Security,* Automatic transducers check *and Storage Mode.*
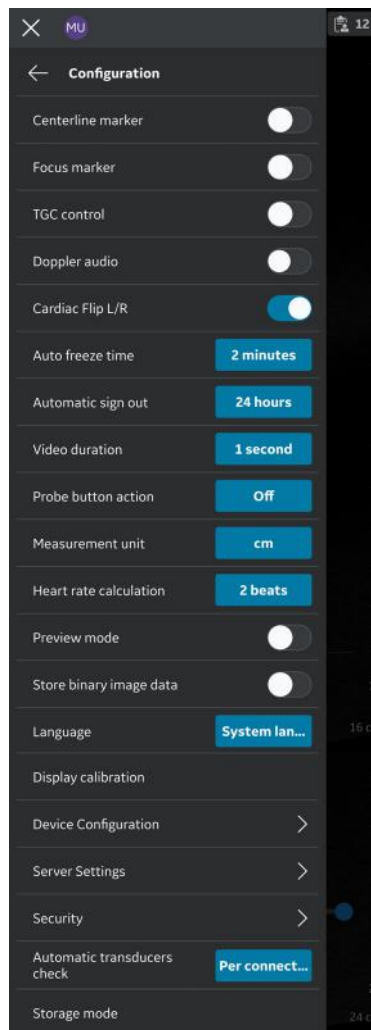
Figure 4-2.   Configuration

Configuration (continued)

1. **Centerline Marker** (see 'Configuration' on *page 4-3*) - Tap the **ON/OFF** toggle switch to turn **ON** or **OFF** the Centerline Marker. When turned **ON**, Vscan Air app displays the Centerline Marker during black and white, color imaging, in Freeze mode and on recalled images and videos.
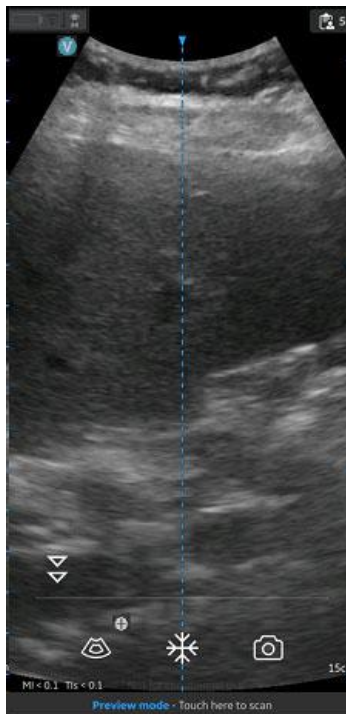
Figure 4-3.   Centerline marker

NOTE: *Configure the display device with an adequate 'screen-save' timeout. Configure the app with an adequate 'auto freeze' timeout in case of performing guidance procedures where no user interface interactions are expected during the course of the procedure.*

2. **Focus Marker** (see 'Configuration' on *page 4-3*)- Tap the **ON/OFF** toggle switch to turn **ON** or **OFF** the Focus Marker. When turned **ON**, Vscan Air app displays the focus marker in black and white, color imaging, in freeze mode and during replay.

Configuration (continued)

3. **Time Gain Compensation (TGC) Control** (see 'Configuration' on *page 4-3*) - Tap the **ON/OFF** toggle switch to turn **ON** or **OFF** TGC controls. When TGC is **ON**, you can adjust the black and white image via the TGC controls on the scan screen.

NOTE: *For adjustment up to 6 TGC controls are available in portrait and landscape layouts.*

NOTE: *The active gain control is disabled as long as the TGC controls are active.*

4. **Doppler audio** (see 'Configuration' on *page 4-3*) - Tap the **ON/OFF** toggle switch to turn **ON** or **OFF** Doppler audio. Doppler audio output is enabled when installing the Vscan Air app. The Doppler signal is heard through the display device audio output. Adjust volume of display device to adjust the Doppler audio.
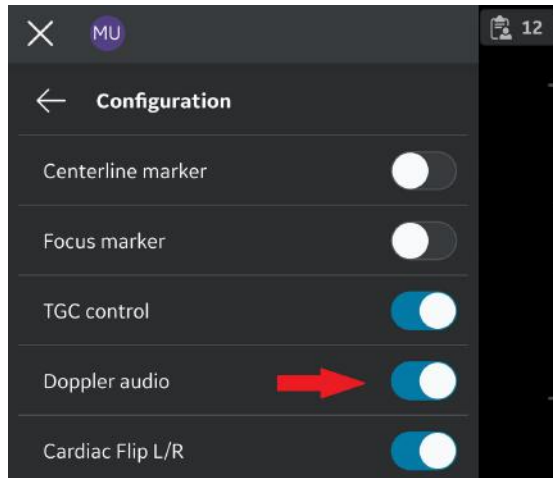
Figure 4-4.   Doppler audio

NOTE: *If there is no audio output check that Doppler audio is enabled via the Vscan Air app configuration settings, check the display device audio settings and make sure that the audio volume is set sufficiently high. If using an iPhone, please also make sure that the iPhone Ring/Silent switch is set to Ring to enable doppler audio.*

Configuration (continued)

5. **Cardiac Flip L/R (see** 'Configuration' on *page 4-3*)-

   Setting the **Cardiac Flip L/R** option true, will flip the cardiac image and orientation marker horizontally to right and vice versa.

   The Cardiac Flip Left Right option will have impact only when the Cardiac preset is selected. Cardiac Flip L/R is enabled when installing the Vscan Air app. The image orientation marker will then when using Cardiac presets be present on the right side of the screen.
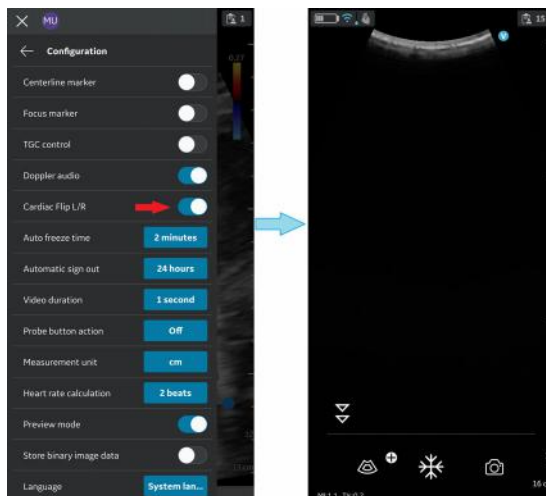
Figure 4-5.   CLA-Cardiac (flip)
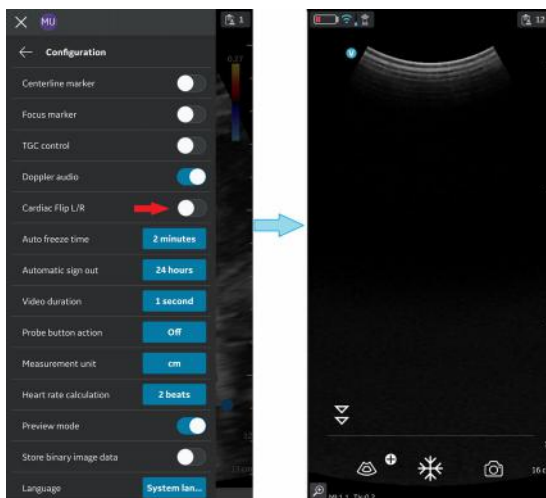
Figure 4-6.   CLA-Cardiac (no flip)

Configuration (continued)

6. **Auto Freeze Time** (see 'Configuration' on *page 4-3*) -
    •   Press **Auto Freeze Time**
    •   Tap on the desired value to set the auto freeze time. This sets the time after which the system enters Freeze mode when not in use.
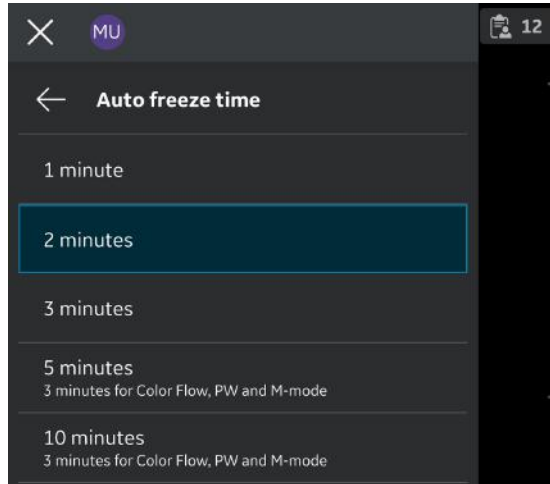
Figure 4-7.   Auto freeze time

NOTE: *Configure the display device with an adequate 'screen-save' timeout and 'auto freeze' timeout in the case of performing guidance procedures where there is no user interface interaction over the course of the procedure.*

Configuration (continued)

7. **Automatic sign out** (see 'Configuration' on *page 4-3*)

   The automatic sign out setting gives user an option to control the duration of the signed in session. The default value is 24 hours. Other available options are shown below.

   To change the auto sign out setting, navigate to Menu->Configuration -> Auto sign out setting.
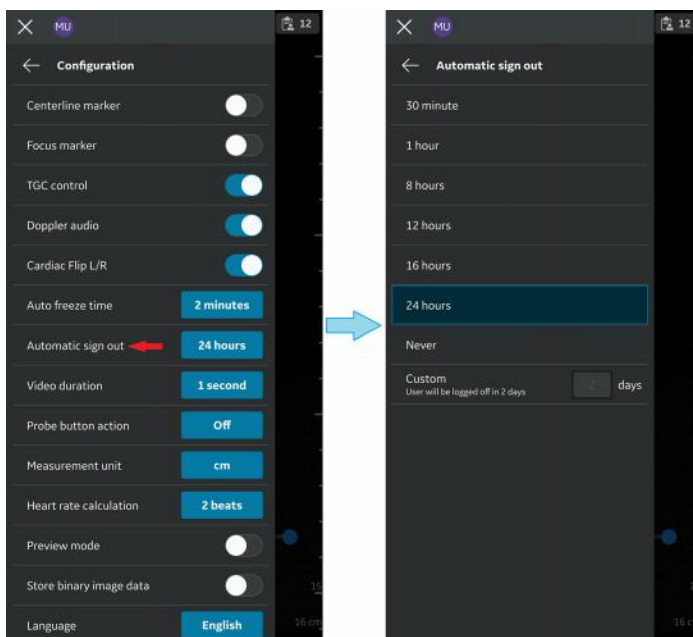
Figure 4-8.   Automatic sign out

The app will maintain the user session for the set duration unless the user explicitly signs out. The auto sign out will not be triggered when a scan is in progress.

Configuration (continued)

8. **Video duration** (see 'Configuration' on *page 4-3*) -

    • Press **Video duration** - The video duration is related to the number of seconds of scan data that is available in the buffer after freezing the image.

    • Tap on the desired value to set the buffer size.
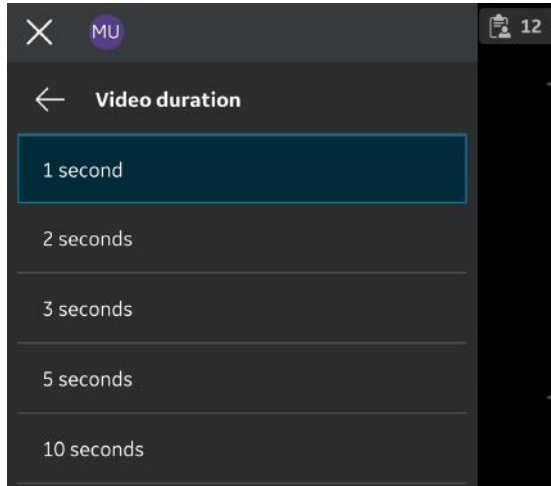
Figure 4-9.   Video duration

9. **Probe Button Action** (see 'Configuration' on *page 4-3*) -

    • Press **Probe Button Action**.

    • Tap to choose either **Freeze** or **Save** with probe button press. Choose '**Off**' to configure no action with the button press.
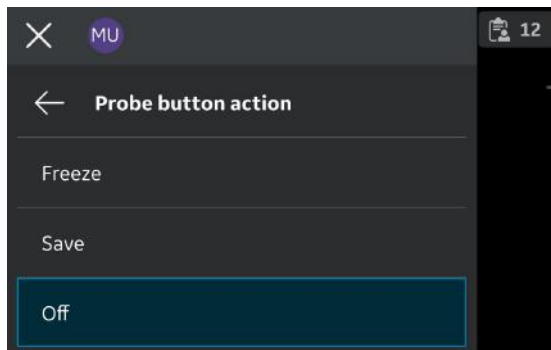
Figure 4-10.   Probe button action

Configuration (continued)

10. **Measurement Unit** (see 'Configuration' on *page 4-3*) - Tap to choose either cm or mm.
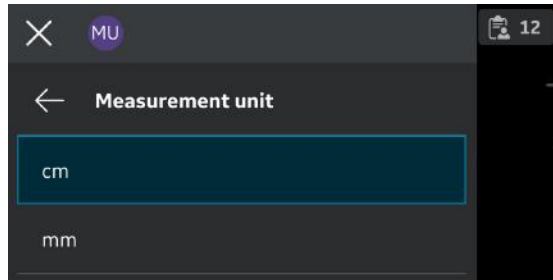
Figure 4-11.   Measurement unit

11. **Heart rate calculation** (see 'Configuration' on *page 4-3*) - For Heart rate calculation in PW and M-mode, select the number of beats (1, 2, 3 beats) from the Configuration menu.
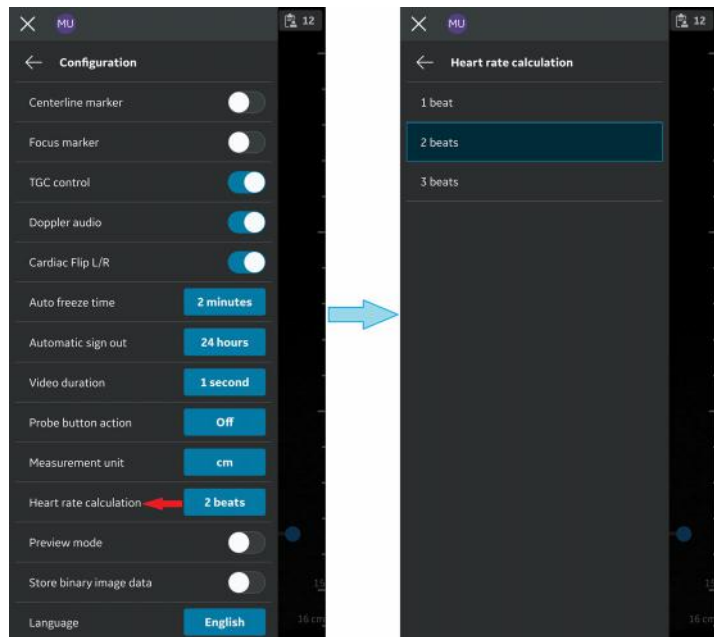
Figure 4-12.   Heart rate calculation

Configuration (continued)

12. **Preview mode** (see 'Configuration' on *page 4-3*) - Tap the **ON/OFF** toggle switch to turn **ON** or **OFF** the preview mode.

Press **OK** if you wish to use the preview mode.
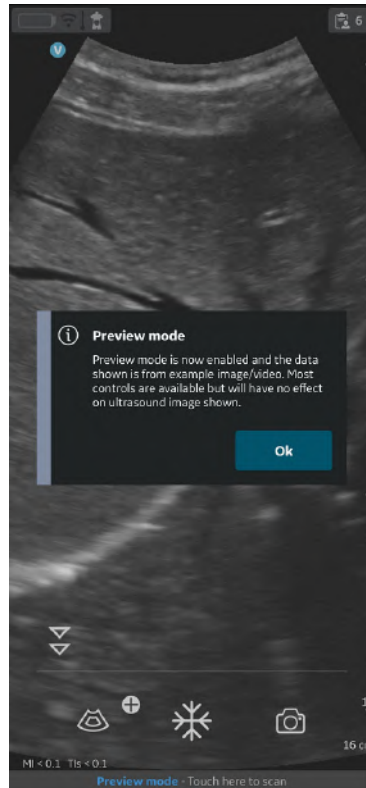
Figure 4-13.   Preview mode pop-up

Configuration (continued)

13. **Store binary image data** (see 'Configuration' on *page 4-3*) - Tap the **ON/OFF** toggle switch to turn binary image data ON or OFF. When binary image data is turned ON unprocessed data is stored alongside any saved videos. This uses some additional storage space. Binary image data is useful for research and development in collaboration with GE HealthCare.
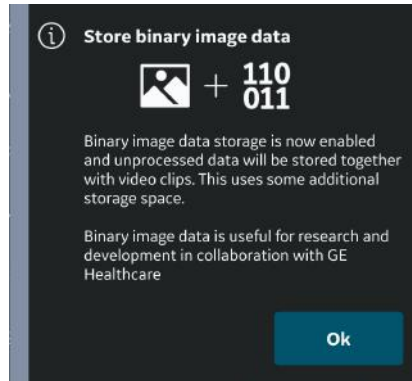
Figure 4-14.   Binary image data store pop-up

Press **OK** to confirm that you wish to configure your device with the binary image data store functionality.

Configuration (continued)

14. **Language** (see 'Configuration' on *page 4-3*) - Choose the desired language
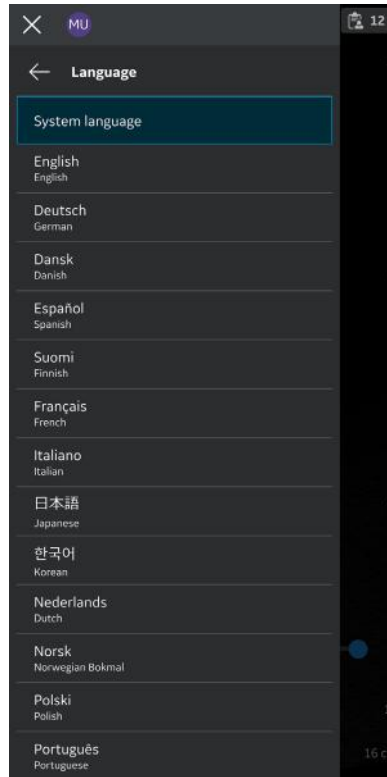
Figure 4-15.   Language

⚠ CAUTION   Vscan Air App defaults to English if the current language setting on the mobile device is not supported by the Vscan Air app.

Configuration (continued)

15. **Display calibration** (see 'Configuration' on *page 4-3*) - The images can be used to adjust the brightness level of the device, so that a full range of grey scale level is visible. It is recommended to turn off adaptive brightness and color filters on the device.

Figure 4-16.   Display calibration

Configuration (continued)

16. **Device configuration**
    a. Follow the procedure below to configure the device.

        Configuration -> Device configuration.
    b. Enter the default values for the Device configuration
        (Vscan Air) on the screen to establish communication
        with DICOM servers.
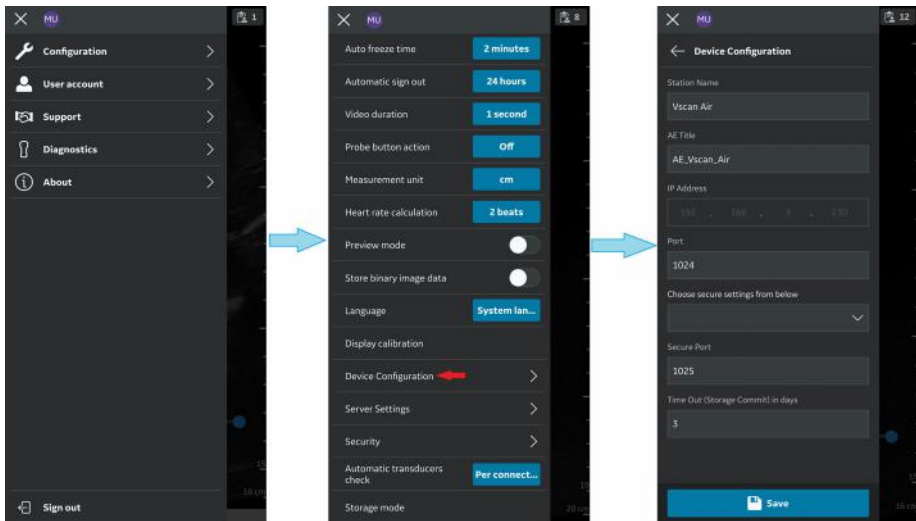
Figure 4-17.   Device configuration

Configuration (continued)

17. **Server Settings** (see 'Configuration' on *page 4-3*) -

    Allows to configure the Modality Worklist Server, DICOM Image Server, Network Shared Folder.

    - **Modality Worklist Server** - Retrieves patient and intended study information, refer 'Configure Modality Worklist Server' on *page 4-19*.

    - **DICOM Image Server** - Remote store location for videos/images, refer 'Configure DICOM Image Server' on *page 4-24*.

    - **Network Shared Folder** - Share images/videos to a shared folder on a PC, refer 'Configure Network Shared Folder' on *page 4-36*.

    - **DICOM Web Server** - Exports data to a cloud based/ remote server using the DICOM Web protocol, refer 'Configure DICOM Web Server' on *page 4-41*.

    - **Modality Performed Procedure Step (MPPS) Server** - MPPS service works in conjunction with the Modality Work List service to provide exam status updates, refer 'Configure Modality Performed Procedure Step (MPPS) Server' on *page 4-29*.

Configuration (continued)

18. **Security** (see 'Configuration' on *page 4-3*) - Choose for protecting exam and patient information, refer 'Security' on *page 4-48*.

19. **Automatic transducers check** (see 'Configuration' on *page 4-3*) - Select the interval for automatic transducers check on the configuration menu. One of the following intervals can be selected: Per connection/Once per day/ Once per week/Once per month/Never.
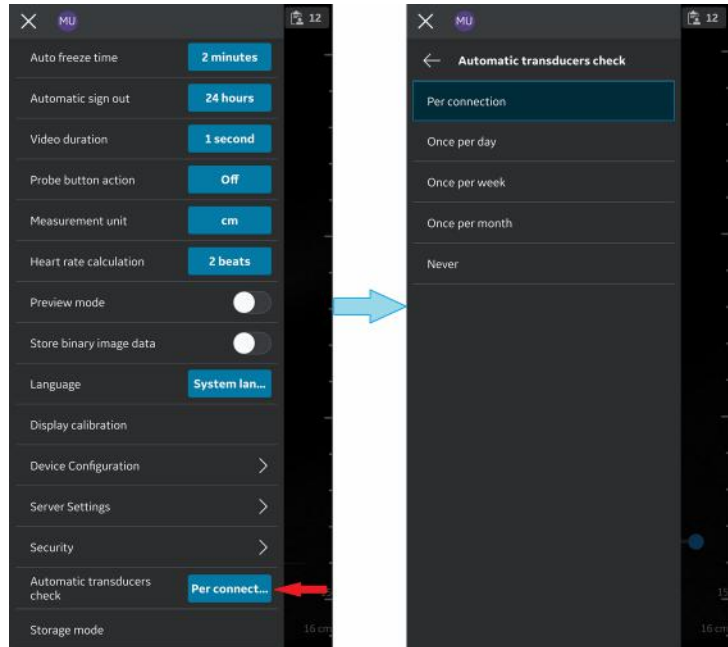
Figure 4-18.   Automatic transducers check

Configuration (continued)

20. **Storage Mode -** Storing the Vscan Air Probe (see 'Configuration' on *page 4-3*).

    If there is a need to store a Vscan Air probe for a short or long period, it is recommended to utilize 'Storage mode' available via the Vscan Air app Menu. 'Storage Mode' allows the user to keep a probe stored for up to 36 months without significant probe battery degradation. If the probe must be available on short notice, it can easily be removed from 'Storage mode' by placing it onto a Vscan Air charger.

    For more information refer 'Storing devices in between uses' on *page 5-135*.
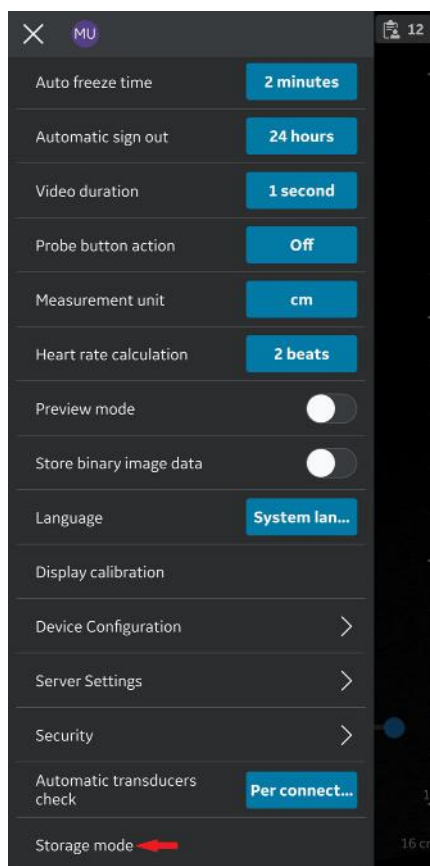
Figure 4-19.   Storage Mode

Configure Modality Worklist Server

Follow the procedure below to configure a new Modality Worklist Server.

1. Press Menu -> Configuration -> Server Settings.
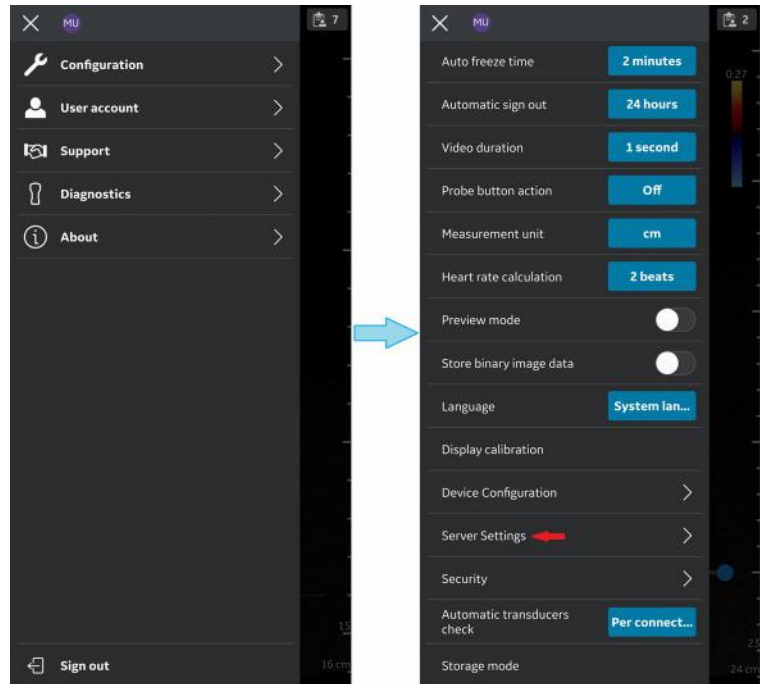
Figure 4-20. Server Settings

Configure Modality Worklist Server (continued)

2.   Press **Add Server** in "Server Settings" screen.
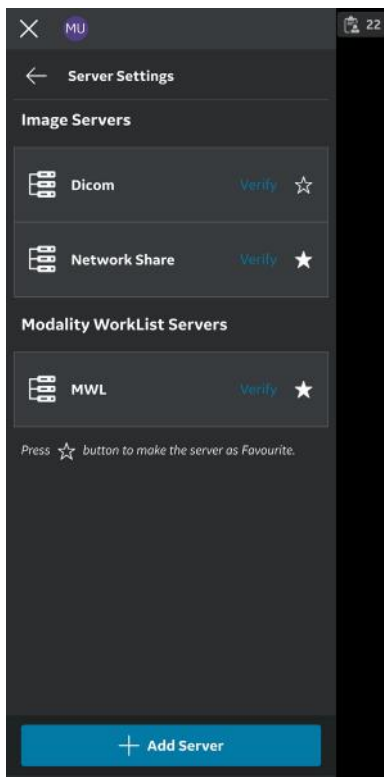
Figure 4-21.   Add Server

Configure Modality Worklist Server (continued)

3. In "**Add New Server**" screen, select "Modality Worklist Server" from the drop down list of "Server Type" and enter the configuration information in the respective fields to add Modality Worklist Server.

    If Modality Worklist Server is of Secure DICOM (TLS communication), select the check box "Secure DICOM". See 'Secure DICOM' on *page 5-117* for more information.
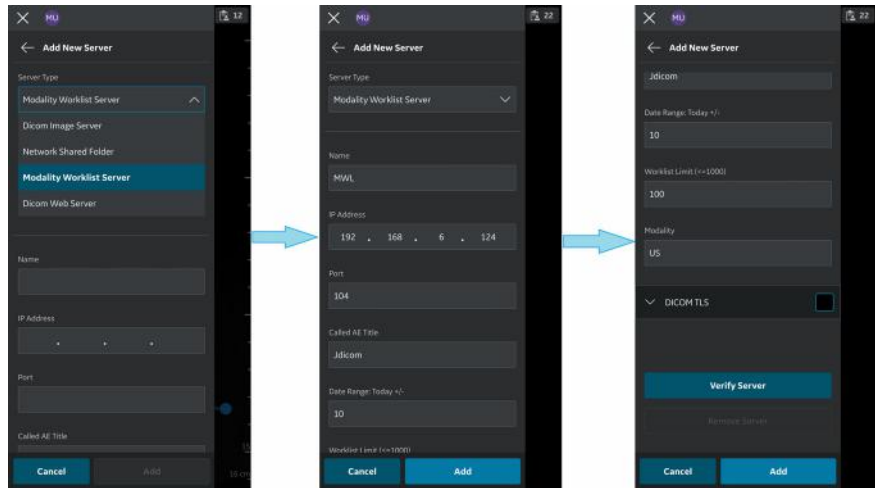
Figure 4-22.   Enter configuration information

Configure Modality Worklist Server (continued)

4. Press "**Verify Server**" to verify communication with the Modality Worklist Server.

    "Verify server succeed" pop-up message displays if the communication with the Worklist Server is 'established successfully'.

    Press **OK** and then Press "**Add**" to add the Modality Worklist Server.

    If communication fails, check the server settings and make necessary corrections.
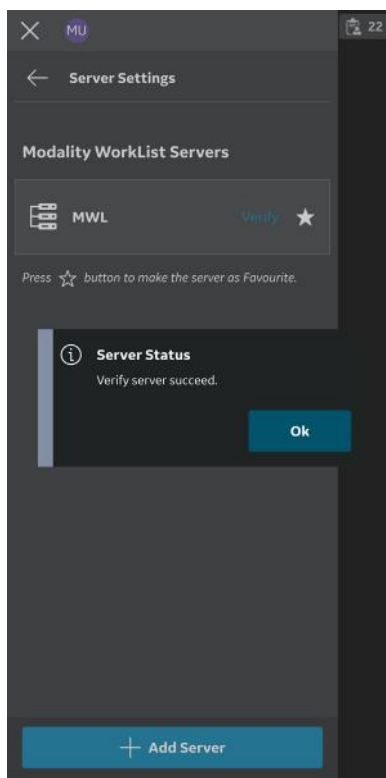
Figure 4-23.   Verify server

NOTE: *Make sure that the display device hosting the Vscan Air app and the configured network folder are connected to the same network.*

Configure Modality Worklist Server (continued)

5. Once the Modality Worklist Server is added, the server name will be available under Server Settings. If this is the first Modality Worklist (MWL) server that is added, it will be set as the favorite server by default. If there are more than one MWL/Radiology Information System (RIS) server then one of them has to be chosen as a favorite server. To select a MWL server as a favorite, tap on the respective star mark and press **YES** on the pop-up message screen.
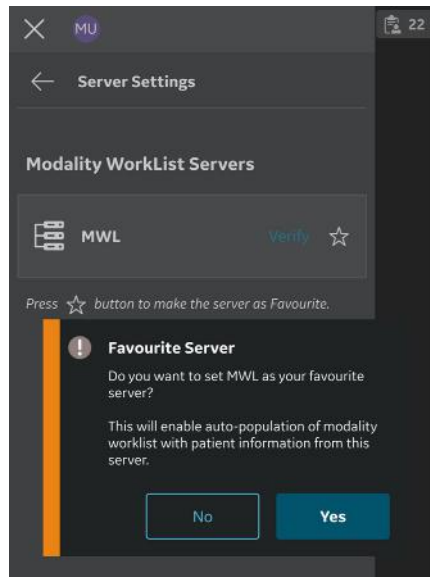
Figure 4-24.   Worklist server as Favorite

Configure DICOM Image Server

Follow the procedure below to configure a new DICOM Image Server.

1. Press Menu -> Configuration -> Server Settings.
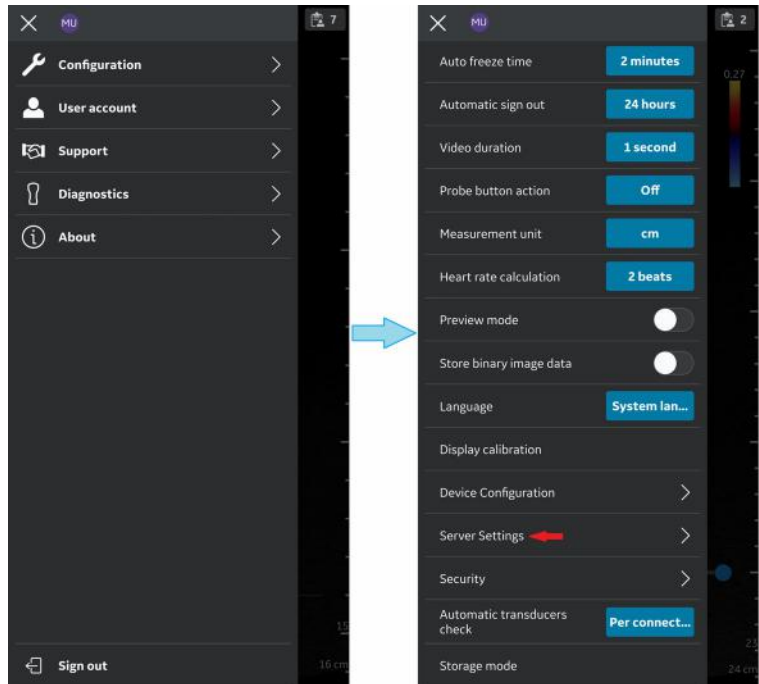
Figure 4-25. Server Settings

Configure DICOM Image Server (continued)

2. Press **Add Server** on the "Server Settings" screen.
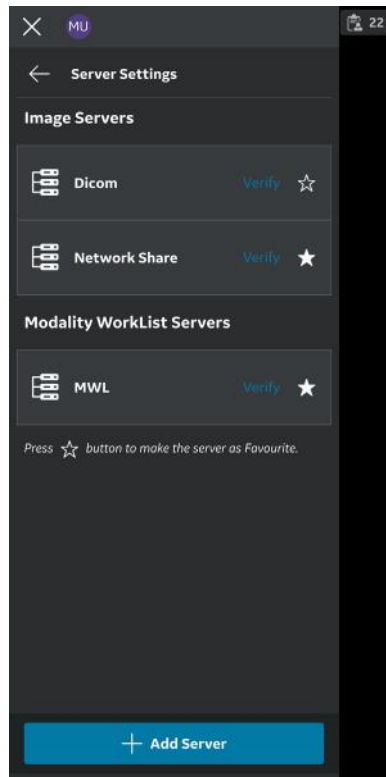
Figure 4-26.   Add Server

Configure DICOM Image Server (continued)

3. On "**Add New Server**" screen, select "**DICOM Image Server**" from the drop-down list of "Server Type" and enter the configuration information in the respective fields to add the DICOM Image Server.

    If DICOM Image Server is of Secure DICOM (TLS communication), select the check box "**Secure DICOM**". See 'Secure DICOM' on *page 5-117* for more information.

Figure 4-27.   Enter Configuration Information

Configure DICOM Image Server (continued)

4. Press "**Verify Server**" to verify communication with the DICOM Image Server.

   "Verify server succeed" pop-up message displays if the communication with the Server is established successfully.

   Press **OK** and then Press "**Add**" to add the DICOM Image Server.

   If communication fails, check the server settings and make necessary corrections.
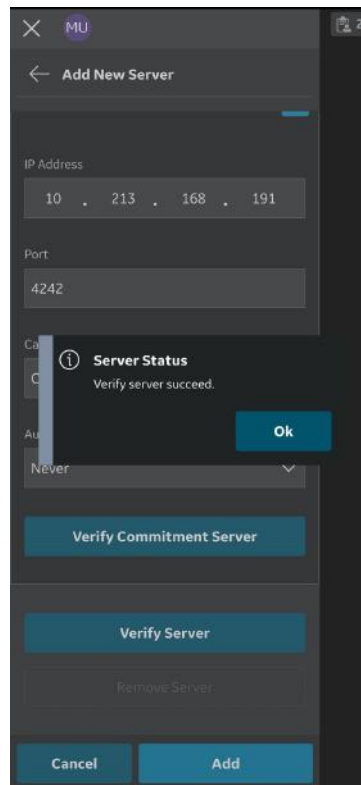
Figure 4-28.   DICOM Image Server

NOTE: *Make sure that the display device hosting Vscan Air app and the PC in which server is configured are connected to same network.*

Configure DICOM Image Server (continued)

5. Once the DICOM Image Server is added, you will find the server name under Server Settings. If there are more than one DICOM Image Servers, you have to choose the desired DICOM Image Server as a favorite server. To set DICOM Image Server as favorite, tap on the respective star mark and press **YES** on the pop-up message screen.
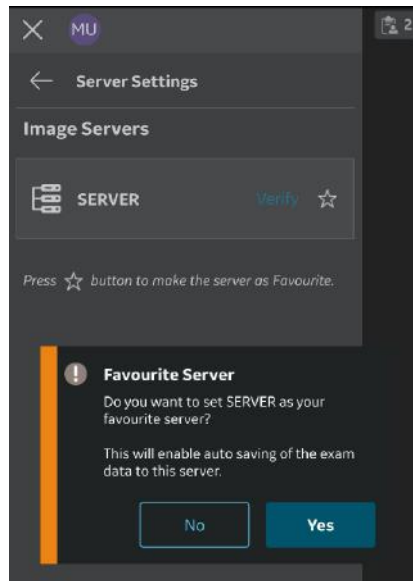
Figure 4-29.   Select DICOM Image server as favorite

Configure Modality Performed Procedure Step (MPPS) Server

Follow the procedure below to configure a new MPPS Server.

1. Press Menu -> Configuration -> Server Settings.
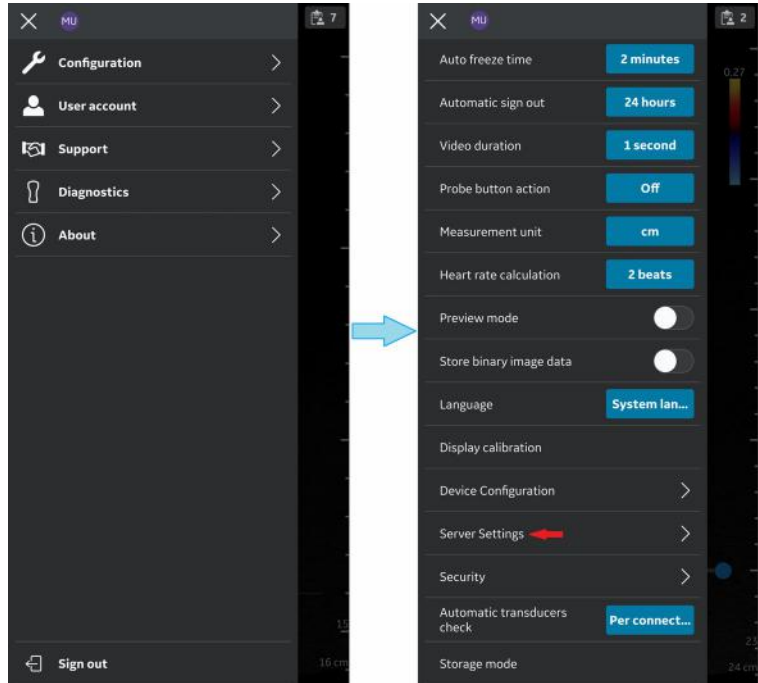
Figure 4-30. Server Settings

Configure Modality Performed Procedure Step (MPPS) Server (continued)

2.   Press **Add Server** on the "Server Settings" screen.
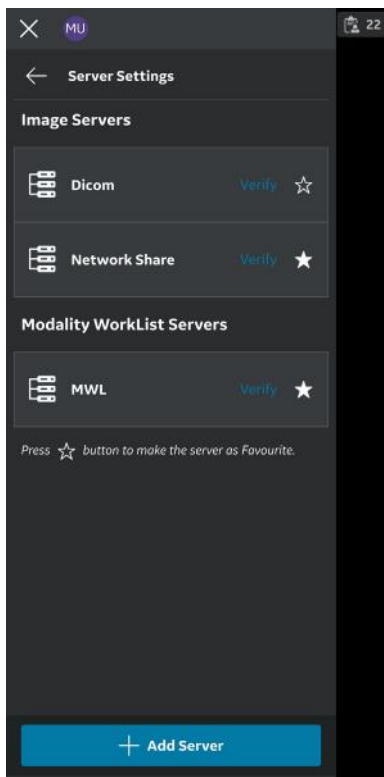
Figure 4-31.   Add Server

Configure Modality Performed Procedure Step (MPPS) Server (continued)

3. On "**Add New Server**" screen, select "**MPPS Server**" from the drop-down list of "Server Type" and enter the configuration information in the respective fields to add the MPPS Server.

    Select "Secure DICOM" if applicable to the MPPS Server selected. See 'Secure DICOM' on *page 5-117* for more information.
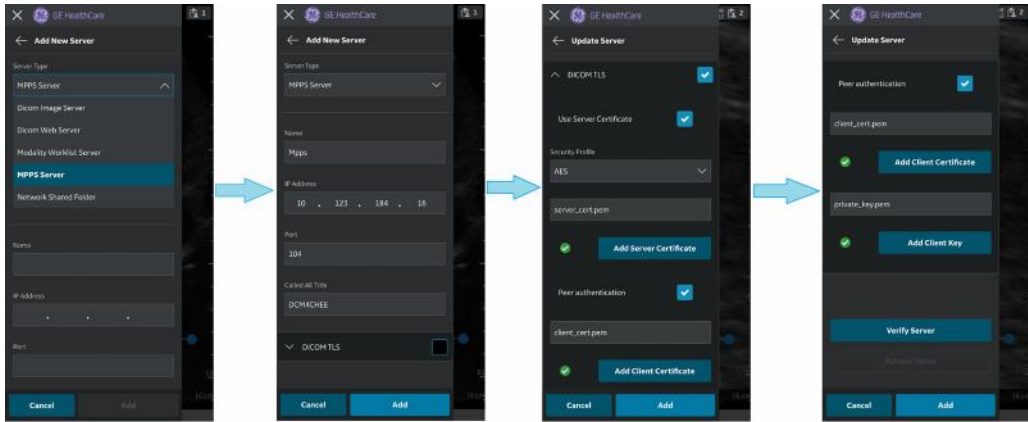
Figure 4-32.   Enter Configuration Information

Configure Modality Performed Procedure Step (MPPS) Server (continued)

4. Press "**Verify Server**" to verify communication with the MPPS Server.

   "Verify server succeed" pop-up message displays if the communication with the Server is established successfully.

   Press **OK** and then Press "**Add**" to add the MPPS Server.

   If communication fails, check the server settings and make necessary corrections.
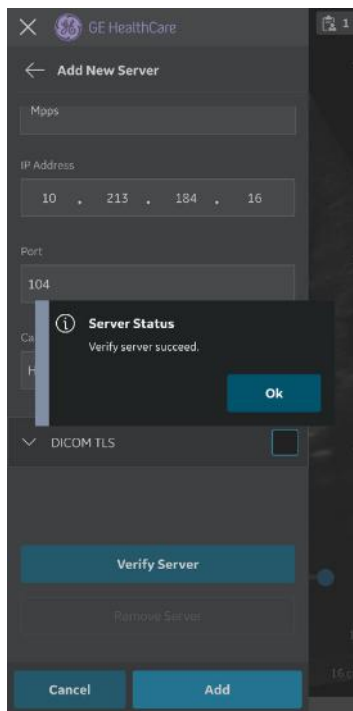
Figure 4-33.   MPPS Server

NOTE: *Make sure that the display device hosting the Vscan Air app and the configured MPPS server is connected to the same network.*

Configure Modality Performed Procedure Step (MPPS) Server (continued)

5. Once the MPPS Server is added, you will find the server name under Server Settings. If there are multiple MPPS Servers, you have to choose the desired MPPS Server as a favorite server. To set MPPS Server as favorite, tap on the respective star mark and press **YES** on the pop-up message screen.
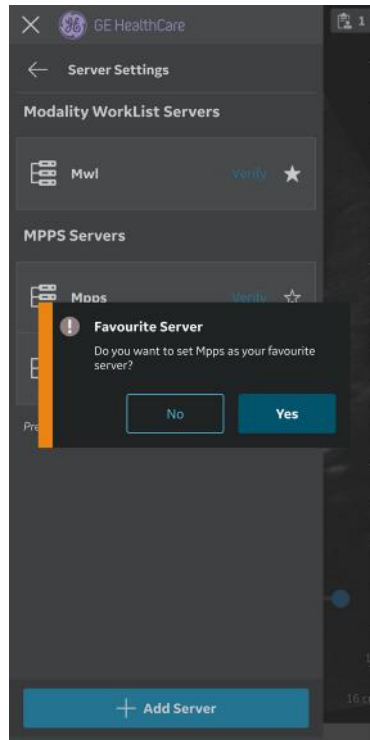
Figure 4-34.   Select MPPS server as favorite

Storage Commit

Storage Server

Storage server is the DICOM image server that receives and stores exam data from Vscan Air app.

Commitment Server

Commitment Server sends confirmation to the Vscan Air app when the Storage Server successfully receives and stores the exam data.
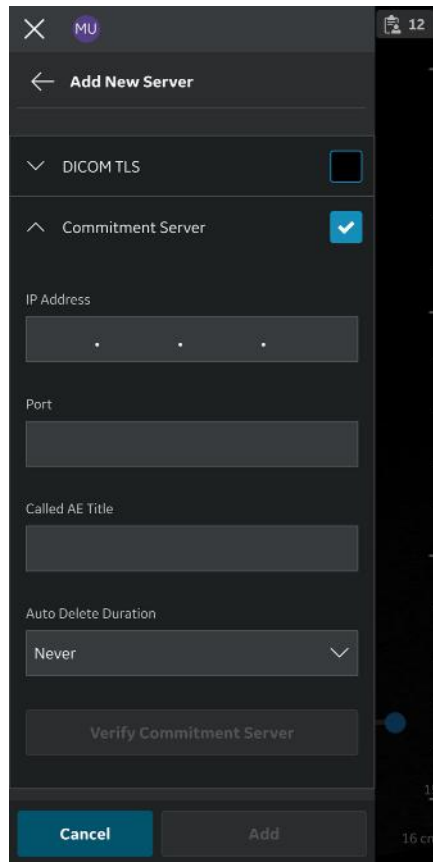
Figure 4-35. Commitment Server

Auto Delete

While configuring a DICOM Image Server (Storage Server), if you have enabled "Auto Delete" functionality, the exam data will be deleted automatically from the display device after exporting it to specified DICOM Image Server.

To enable "Auto Delete" functionality, follow the steps below:

1. While configuring the DICOM Image Server, tap on the Commitment Server drop-down button. See "Configure DICOM Image Server' on *page 4-24* for more information.

2. Enter the commitment server details in the respective fields on the Commitment Server screen.

3. Press Verify Commitment Server button to verify communication with the commitment server.

"Verify server succeed" pop-up message displays if the communication with the server is established successfully.

If communication fails, check the server settings and make necessary corrections.
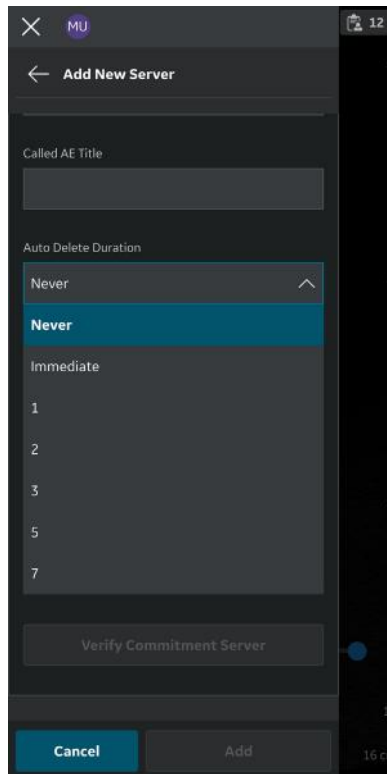
Figure 4-36.   Auto delete

Configure Network Shared Folder

Follow the procedure below to configure a new Network Shared Folder.

1. Press Menu -> Configuration -> Server Settings.
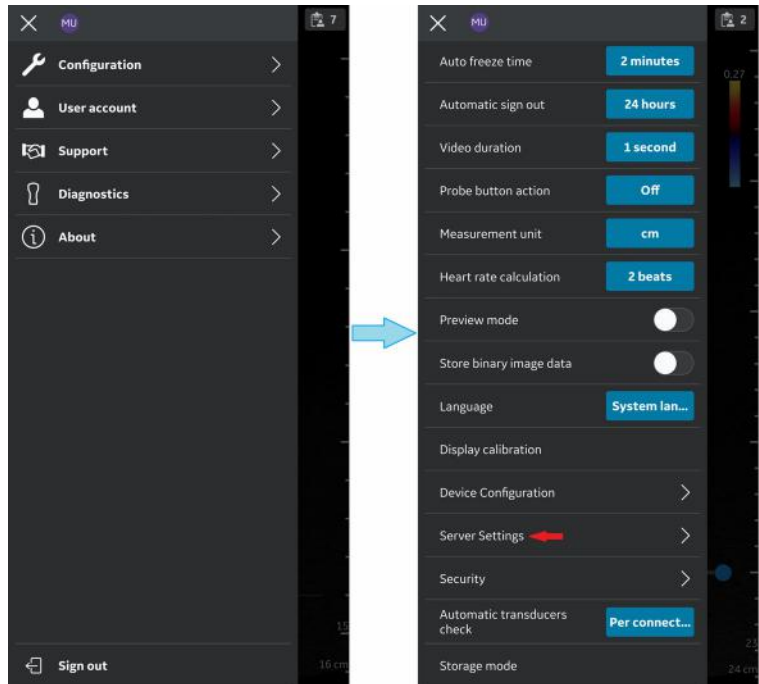
Figure 4-37. Server Settings

Configure Network Shared Folder (continued)

2. Press Add Server in "**Server Settings**" screen.
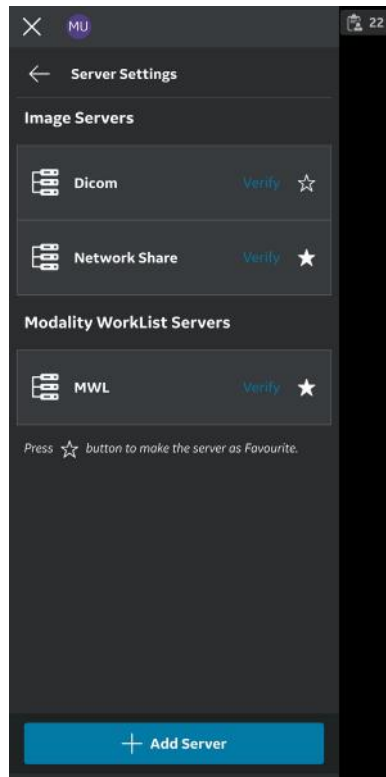
Figure 4-38.   Add Server

Configure Network Shared Folder (continued)

3. In "**Add New Server**" screen, select "**Network Shared Folder**" from the drop-down list of "Server Type" and enter the configuration information in the respective fields to add Network Shared Folder.

    If you wish to share additional comprehensive exam information (Patient/Exam information), select the check box "**Add exam info**". See 'Comprehensive exam info' on for more information.
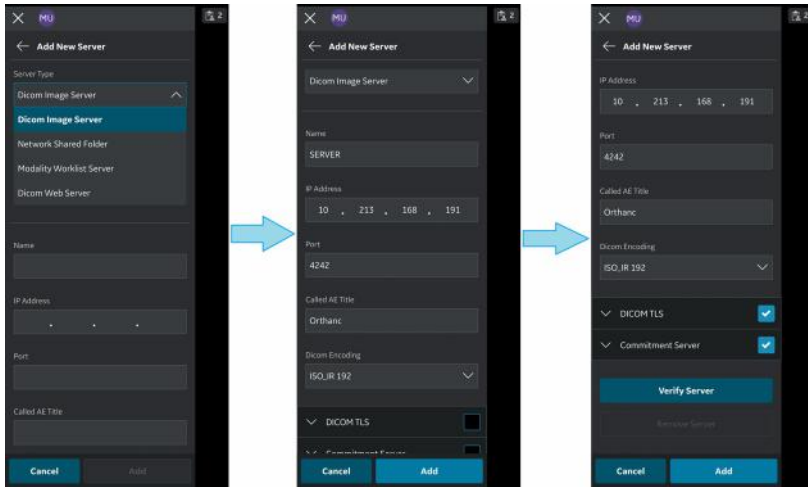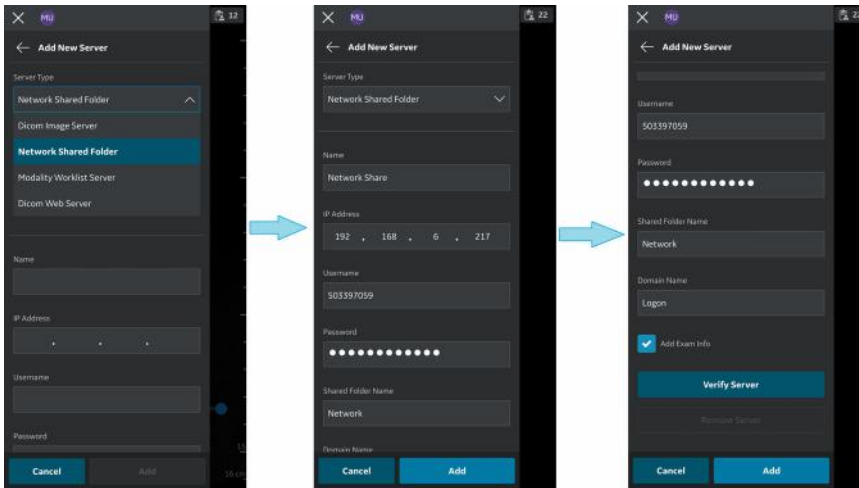

Figure 4-39.   Enter Configuration Information

Configure Network Shared Folder (continued)

4. Press "**Verify Server**" to verify communication with the Network Shared Folder.

   "**Verify server succeed**" pop-up message displays if the communication with the server is established successfully.

   Press **OK** and then Press "**Add**" to add the Network Shared Folder.

   If communication fails, check the server settings and make necessary corrections.
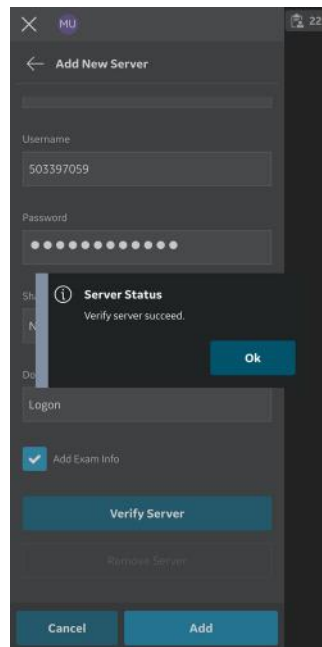
Figure 4-40.   Verify network shared folder

NOTE: *Make sure that the display device hosting the Vscan Air App and the configured network folder are connected to the same network.*

Configure Network Shared Folder (continued)

5. Once the Network Shared Folder is added, the server name will be available under Server Settings. If there are more than one Network shared folders configured, then one of them has to be chosen as the favorite Network Shared Folder. To select a Network Shared Folder as a favorite, tap on the respective star mark and press **YES** on the pop-up message screen.
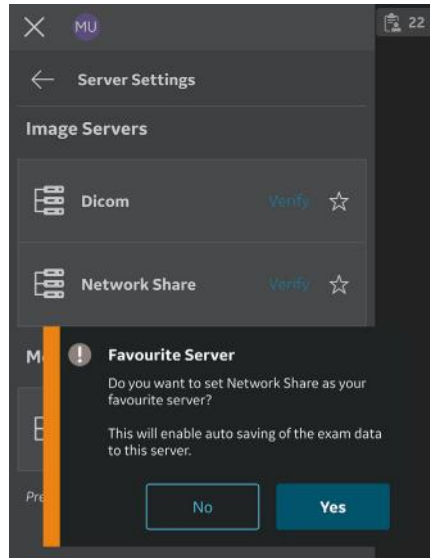
Figure 4-41.   Network shared folder as favorite

Configure DICOM Web Server

This feature allows data to be exported to a cloud based/ remote server using the DICOM Web (STOW-Store over the web) protocol.

Follow the procedure below to configure a new DICOM Web Server.

1. Press Menu -> Configuration -> Server Settings.
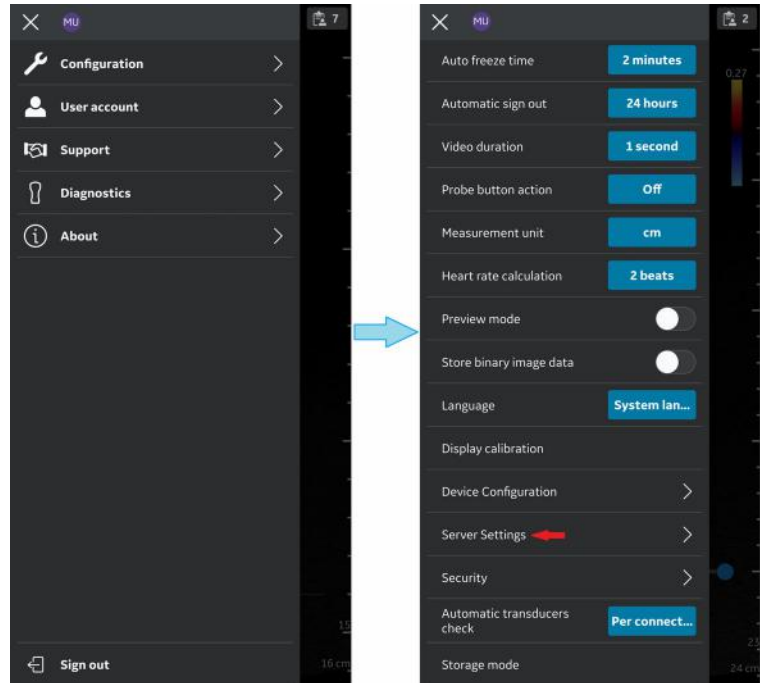
Figure 4-42. Server settings

Configure DICOM Web Server (continued)

2.   Press Add Server on the "**Server Settings**" screen.
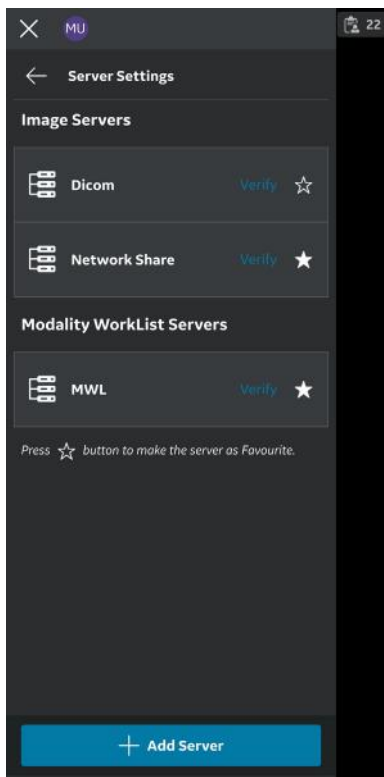
Figure 4-43.   Add server

Configure DICOM Web Server (continued)

3. On "**Add New Server**" screen, select "**DICOM Web Server** "
    from the drop-down list of "Server Type" and enter the
    configuration information in the respective fields to add the
    DICOM Web Server.
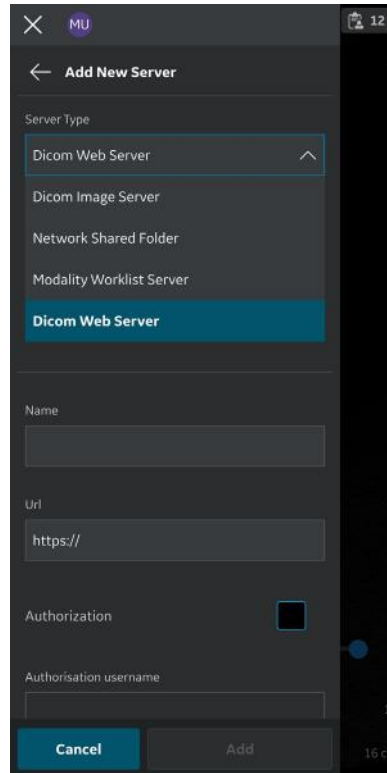
Figure 4-44.   Add DICOM Web Server

4. "Authorization" is an optional feature for servers that need
    basic authentication using credentials.

5. For DICOM Web Server , the only option is secure
    communication. So, the check box is by default enabled.
    See 'Secure DICOM' on *page 5-117* for more information.

6. Press "**Verify Server**" to verify communication with the
    DICOM Web Server. "Verify server succeed" pop-up
    message displays if the communication with the Server is
    established successfully.

Configure DICOM Web Server (continued)

Press **OK** and then Press "**Add**" to add the DICOM Web Server. If communication fails, check the server settings, and make necessary corrections.
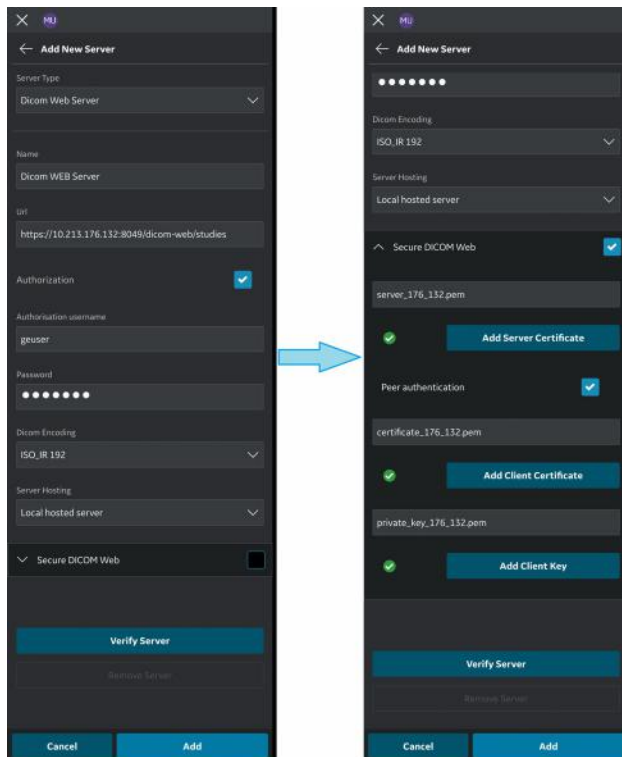
Figure 4-45.   DICOM Web Server details

Once the DICOM Web Server is added, you will find the server name under Server Settings.

Remove Server

1. To remove a server from the configured list of servers, Press Menu -> Configuration -> Server Settings.
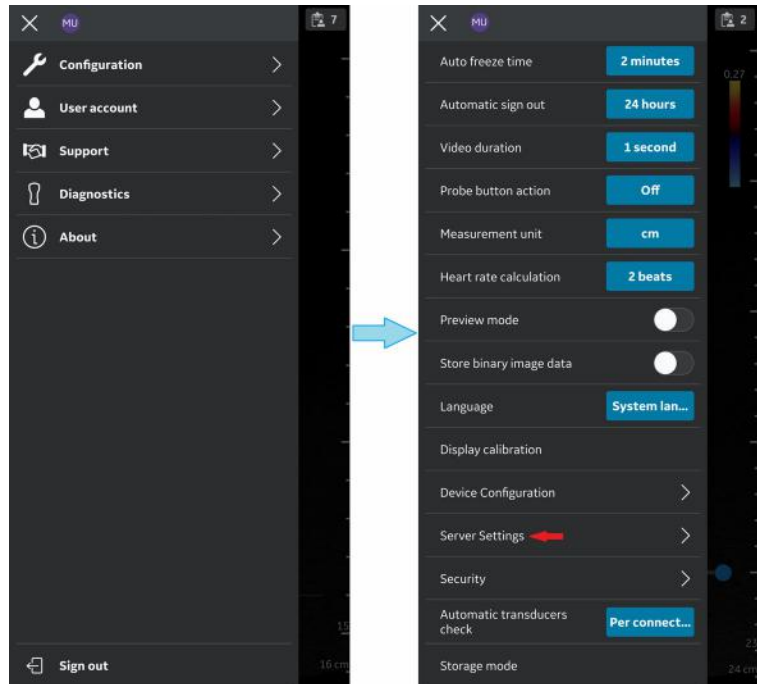
Figure 4-46. Server Settings

Remove Server (continued)

2.   Press to select the desired server that needs to be removed.
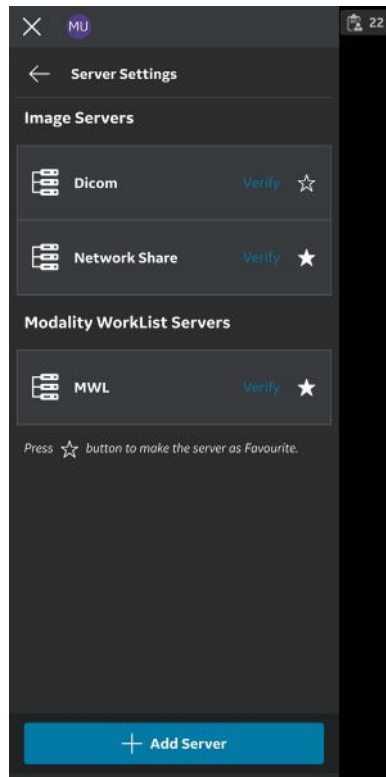
Figure 4-47.   List of Servers

Remove Server (continued)

3. Swipe up and select "**Remove Server**". The message "Do you want to delete server from list?" appears. Press **YES** to delete the server.
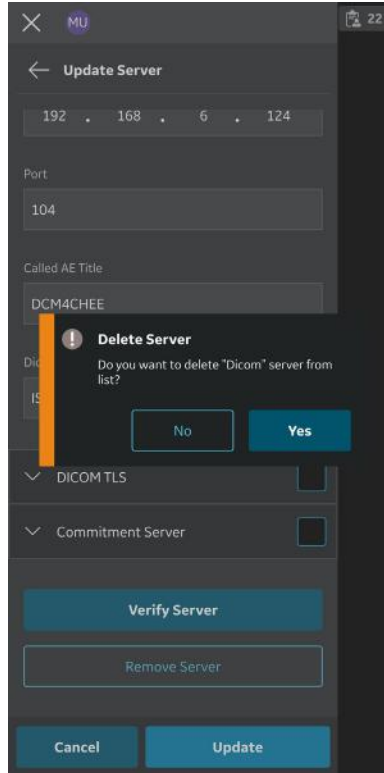
Figure 4-48.   Remove Server

Security

Exam and patient information can be protected by enabling a data access PIN. Biometric authentication will, if additionally enabled, replace the need to enter the data access PIN.

NOTE: *If uninstalling the Vscan Air app from the display device, the app data, including all exam data including the images and videos will be deleted.*

NOTE: *If unregistering the Vscan Air app from the display all exam data including the images and videos will be deleted.*

NOTE: *On an Android device it is possible to go into settings and clear data for an app. If selecting to do so, all app related data including exam data holding the images and videos will be deleted.*

Ask for data access PIN

A data access PIN can be configured to authorize access to exam data which may contain sensitive patient information. The data access PIN can be configured after having registered the Vscan Air App. Follow the procedure below to set a data access PIN.

1. Press Menu -> Configuration -> Security.
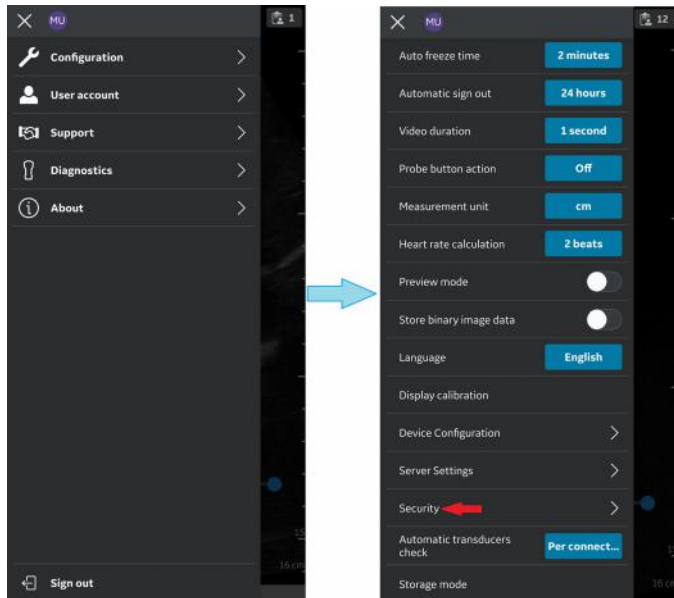
Figure 4-49. Security settings

Ask for data access PIN (continued)

2. Tap on the **Ask for data access PIN** button on the Security screen.
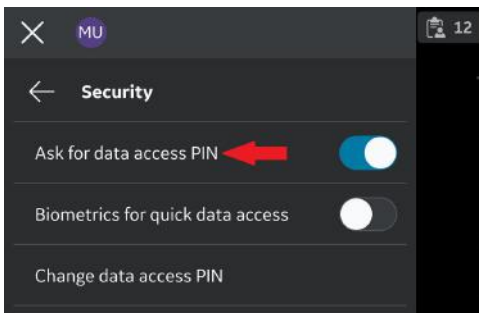
Figure 4-50.   Tap on the Ask for data access PIN button

3. Enter a new 6 digit PIN in the field on the "**Set up data access PIN**" screen and Press **Next** button.
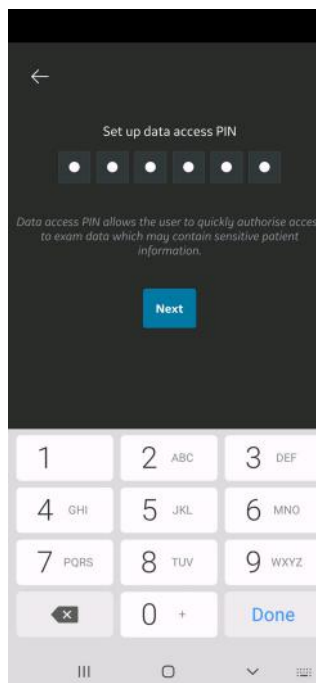
Figure 4-51.   Enter data access PIN

NOTE: *Please make sure to use a strong PIN and avoid using PIN codes that are easy to guess.*

Ask for data access PIN (continued)

4. Re-enter the PIN on the "**confirm data access PIN**" screen and Press **Save button**. After successful set up of data access PIN, application takes you to the Security screen.
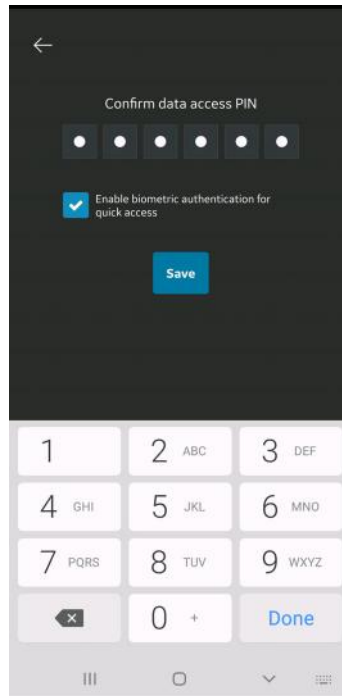
Figure 4-52.   Confirm data access PIN

TouchID for quick data access (Biometric authentication)

To enable biometric authentication for quick data access, follow the procedure below

1. Press Menu -> Configuration -> Security.
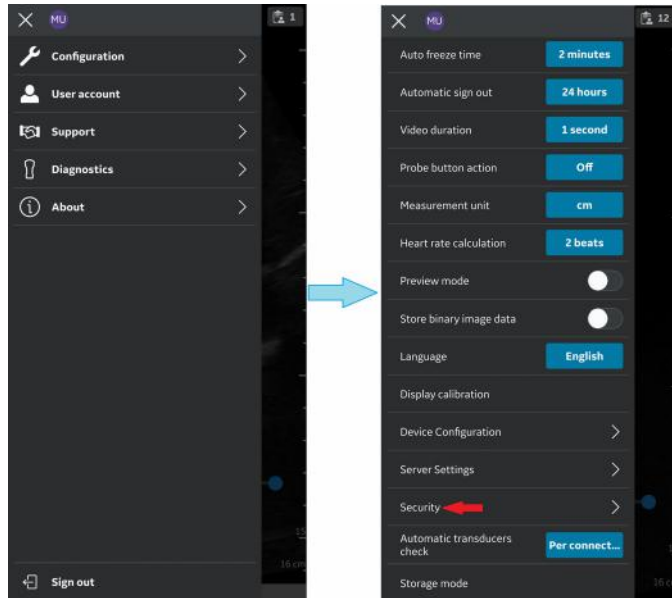
Figure 4-53.   Security settings

2. Tap on the **TouchID for quick data access** button on the Security screen to activate biometric authentication.
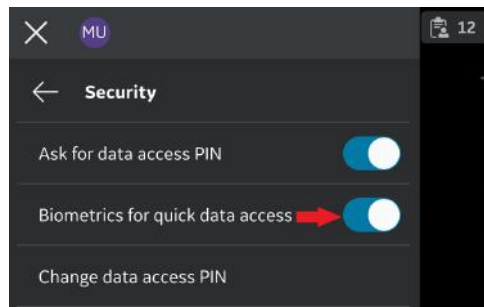
Figure 4-54.   Activate biometric authentication

TouchID for quick data access (Biometric authentication) (continued)

> *NOTE:* *Before enabling biometric authentication in the Vscan Air application, make sure you have activated finger print unlock or face recognition unlock in your display device. Failure to do so may pop-up the following warning message while enabling biometric authentication in the Vscan Air application.*
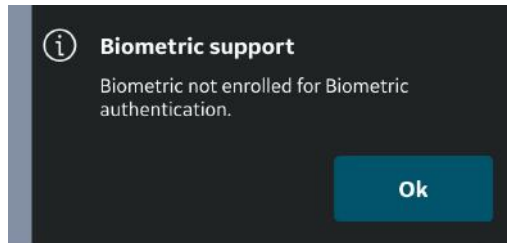
Figure 4-55.   Biometric authentication error

Change data access PIN

Follow the procedure below to change the data access PIN.

1.   Press Menu -> Configuration -> Security.
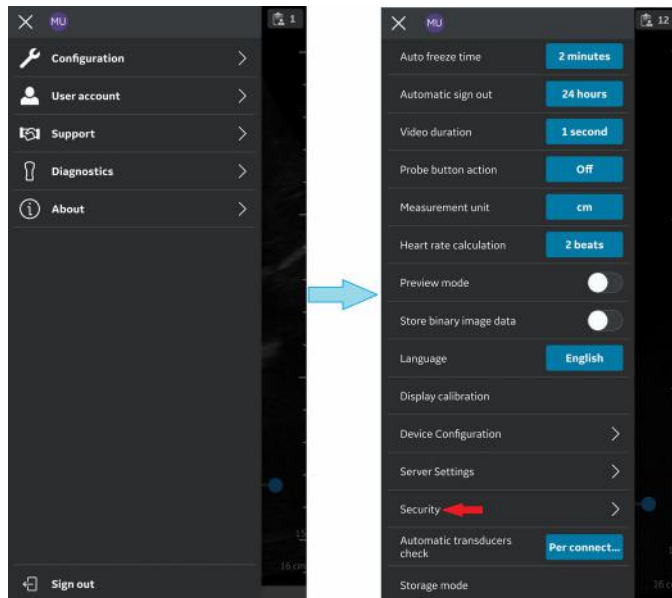
Figure 4-56.   Security settings

Change data access PIN (continued)

2. Tap on Change data access PIN on the Security screen.
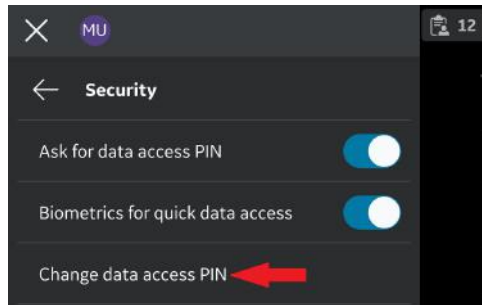
Figure 4-57.   Change data access PIN

3. Under the "Change data access PIN" screen, enter your **existing PIN**, then enter **new PIN** and Confirm the new PIN.

Change data access PIN (continued)

Press **Save** button. After successful set up of new data
access PIN, application takes you back to the Security
screen.
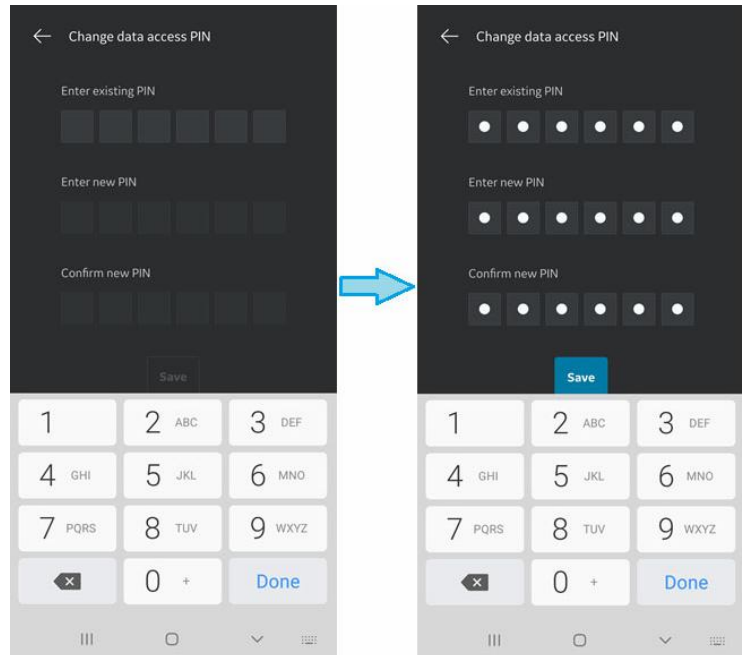
Figure 4-58.   Confirm data access PIN

NOTE: *Please make sure to use a strong PIN and avoid using PIN
                codes that are easy to guess.*

Entering an incorrect PIN

Be aware that all clinical data will be erased if an incorrect PIN is
entered 10 times.

User account

User account

The User account feature displays "**Delete user**" option.

To delete Vscan Air app user account, tap on "User account" which directs to "**Delete user**".
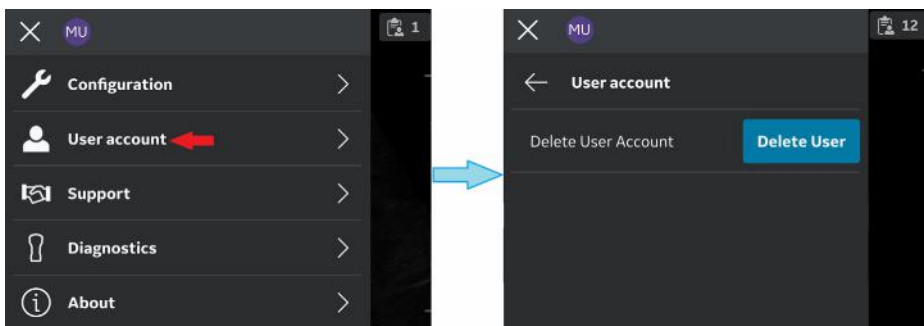
Figure 4-59.   User account

User account deleted

A message is triggered when remote server call operation is initiated by a deleted account owner from Vscan Air application.
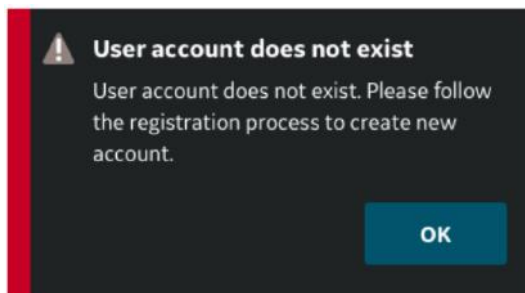
Figure 4-60.   User account does not exist

Support

Support - Vscan Air probe not registered

When the Vscan Air probe is not registered, the Support option displays - User manual, Knowledge center and Contact us.
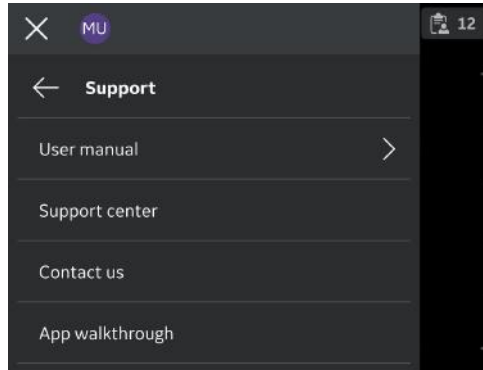
Figure 4-61.   Support

- • **User Manual** - To access the e-manual in the desired language.
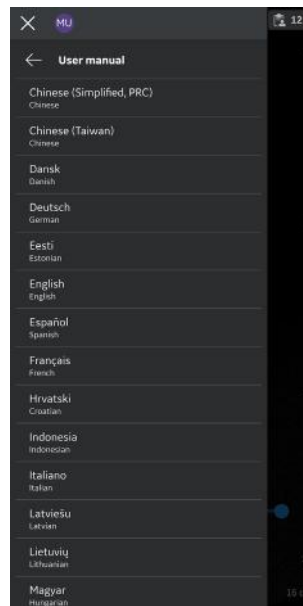
Figure 4-62.   User manual

Support - Vscan Air probe not registered (continued)

- **Knowledge center** - Directs to the Vscan Air support web page that provides access to product information.
- **Contact us** - To access list of GEHC Service Centre contact numbers.
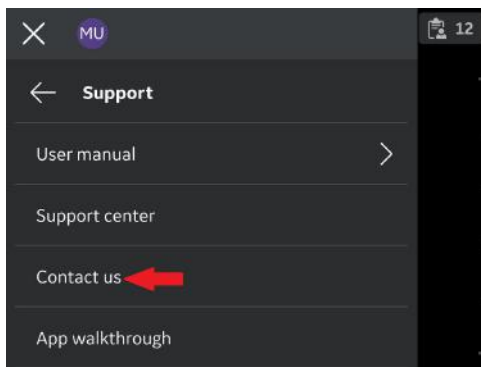
Figure 4-63.   Contact us

Support - Registered Vscan Air probe

When connected to a registered Vscan Air probe, the support option displays App walkthrough.

Follow the steps below to start App walkthrough.

4.   Press Main menu > Support.

5.   The Vscan Air App walkthrough option is available.
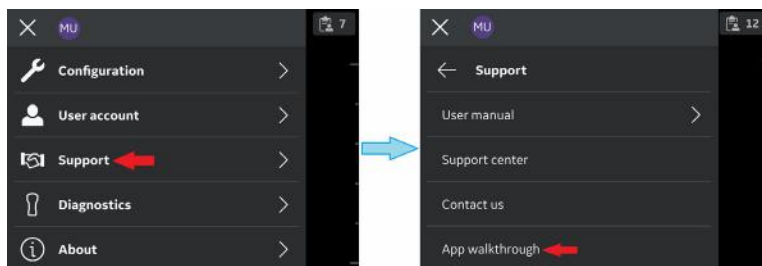
Figure 4-64.   Vscan Air App walkthrough

Support - Registered Vscan Air probe (continued)

6. The walkthrough will guide through the basic app functions.
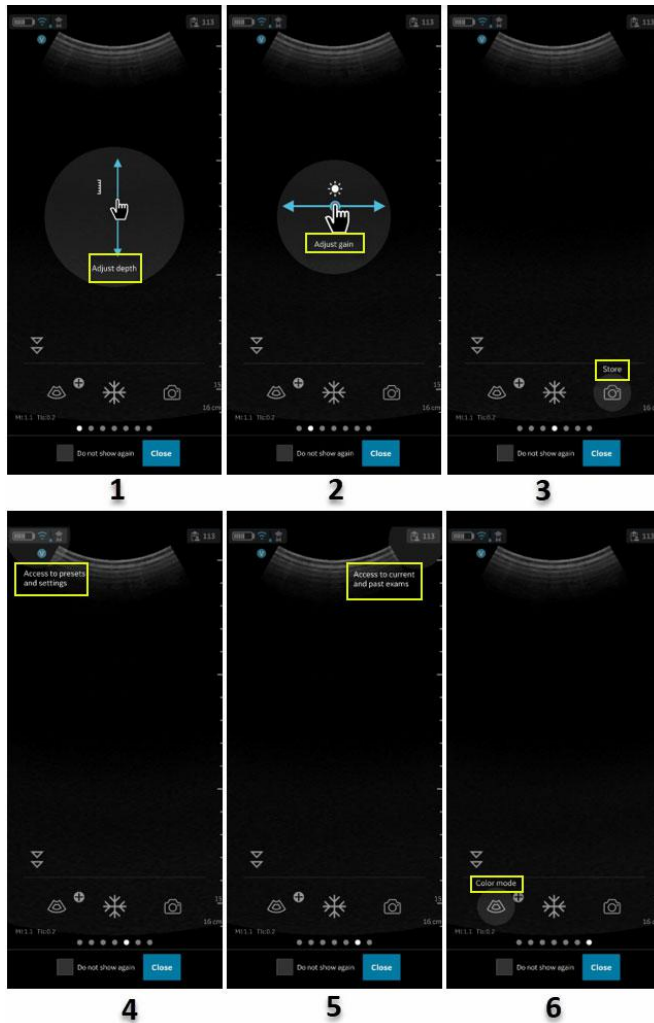
1. Tap on scan and move vertical to change the depth.
2. Tap on scan and move horizontal to change the Gain.
3. Select store button user can save image/video.
4. Navigate to preset screen or settings screen.
5. Access Current or Past exam.
6. Select color flow (CF) mode button App switch to CF mode.

Figure 4-65.   App walkthrough functionality

Diagnostics

Diagnostics

The **Diagnostics** option displays - Run transducer check, Run diagnostics and Send log.
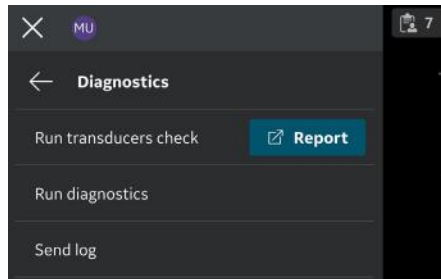
Figure 4-66.   Diagnostics

*   **Run transducers check** - To run all transducer check refer the section Figure *on page 6-48*
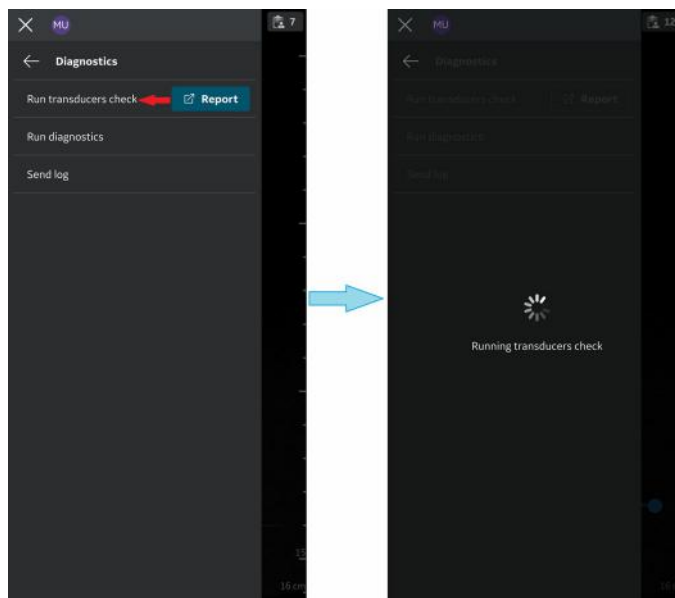
Figure 4-67.   Transducer element check

Diagnostics (continued)

- • **Run diagnostics -** To run all the Diagnostic tests refer the section 'Diagnostics Test' on *page 6-43*.
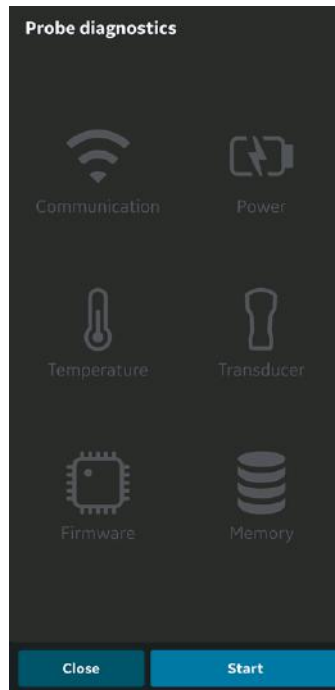
Figure 4-68.   Run diagnostics

Diagnostics (continued)

- • **Send log** - On selecting the send log button, the device will send probe logs and app logs to the server.
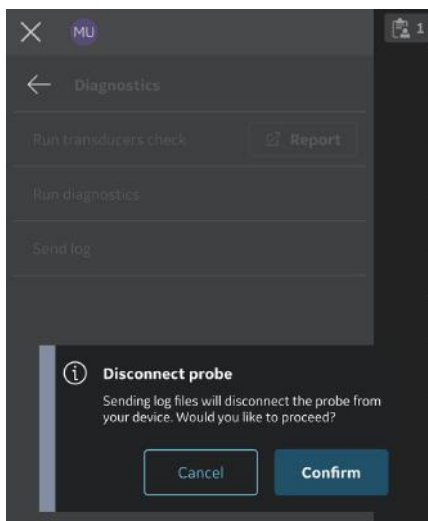
Figure 4-69.   Send log warning - iOS

NOTE: *Please stay connected to the Vscan Air probe when initiating the Send log activity to fetch the most recent log from the probe for transfer to the server.*

NOTE: *Android devices do use WiFi-direct and the display device will stay connected to the Vscan Air probe while sending the logs.*

NOTE: *iOS devices might need to disconnect from the Vscan Air probe to send the logs depending on the availability of a mobile data connection.*

NOTE: *If the iOS display device has a mobile data connection and mobile data is enabled, it will not need to disconnect from the Vscan Air probe.*

About

About

The **About** option displays - Registered devices, Probe subscription details, App version info, Probe version info, Regulatory, Probe upgrade label, Account information, Terms & conditions, Privacy policy, Account terms, Acknowledgements and Export audit logs.
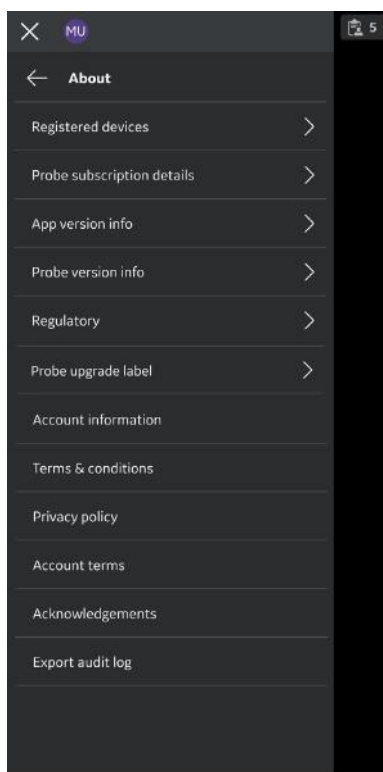
Figure 4-70.   About

About (continued)

- • **Registered devices** - Displays status for the Vscan Air app registration and the connected Vscan Air probe.

  Vscan Air probe serial number - The probe serial number identifying the connected probe is displayed.
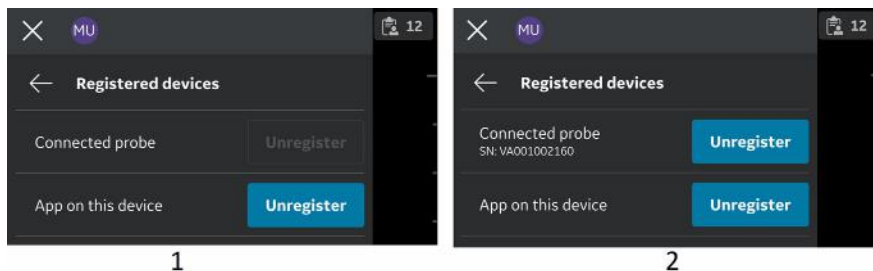
1. Probe not connected
2. Registered Probe

Figure 4-71.   Registered devices

Unregister:

To unregister the Vscan Air probe or the Vscan Air App, please select "**Unregister**" and confirm.

When unregistered, the Vscan Air probe will be disconnected. To re-register, you must connect and complete registration.

When unregistered, the Vscan Air App current registration and any connected probe will disconnect. The app will still be available. To re-register, a new registration will be required.

About (continued)

- • **Probe subscription details -** Displays subscription to any digital or AI tools..

  Click '**Probe subscription details**' > Tap on Get Latest to apply subscription information.
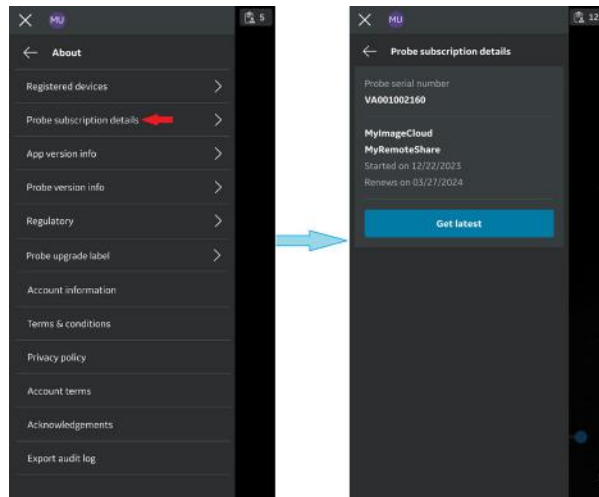
Figure 4-72.   Probe subscription details

The subscribed tools appear.
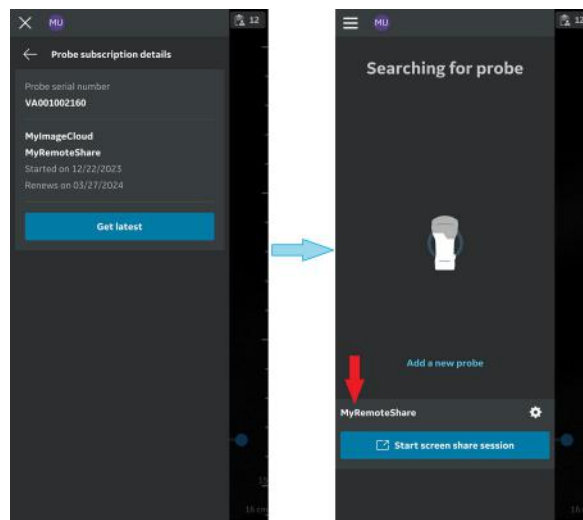
Figure 4-73.   Subscription details

About (continued)

- **Subscription Auto renewal:**

   90 Days prior to expiration date - The user will be notified 90 days prior to a subscription expiration date about the subscription auto renewal via the following message:

   "Your subscription will be automatically renewed on <xx.yy.zzzz>. If you do not wish to renew, please sign in on myvscan.gehealthcare.com with the same username and password as your Vscan Air app.

   On the profile page select "Manage my subscriptions".
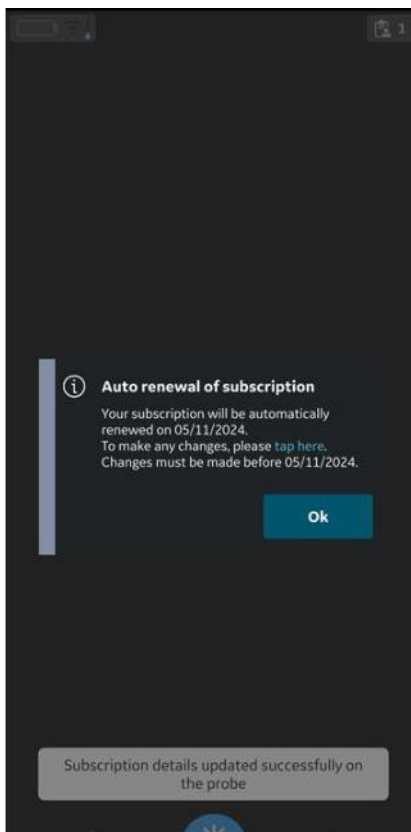
Figure 4-74.   Subscription Auto Renewal

NOTE: *Subscription expiry notifications are not applicable to probes managed via the enterprise management tool MyDeviceHub.*

NOTE: *Subscription expiry notifications will not appear while using the Vscan Air app in Guest mode.*

About (continued)

- • **Subscription Expiry Date:**

  User will be notified when subscription expires.

  User will receive the below notification once a subscription has expired:

  "One or more subscriptions registered to the connected probe has ended. Consider renewing the subscription to continue accessing the related digital solutions".
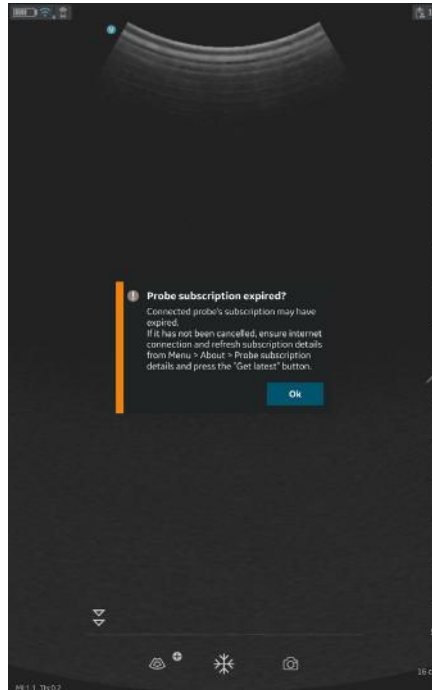
Figure 4-75.   Subscription Expired

NOTE: *Subscription expiry notifications are not applicable to probes managed via the enterprise management tool MyDeviceHub.*

NOTE: *Subscription expiry notifications will not appear while using the Vscan Air app in Guest mode.*

About (continued)

- **App version info** - Displays App software version, App software revision and the unique identifier of the installed Vscan Air app.
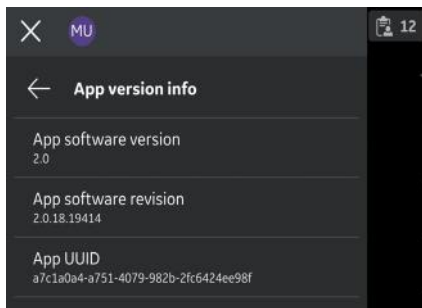
Figure 4-76.   App version info (example)

- **Probe version info**

  Probe version info - Displays Probe software version and Probe software revision
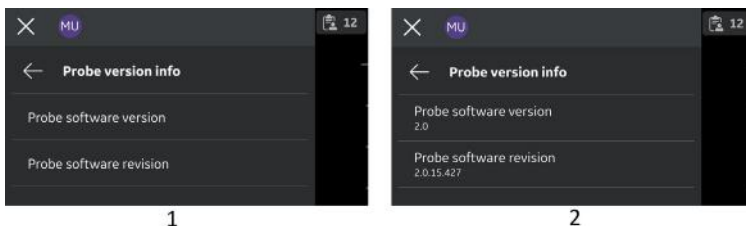
1. Probe not connected
2. Registered Probe

Figure 4-77.   Probe version info (example)

NOTE: *The UDI information and the separate listing of the probe serial number can be found as part of the probe label.*

NOTE: *The UDI information relating to the App can be found on the Regulatory page.*

About (continued)

- **Regulatory -** Displays Regulatory information
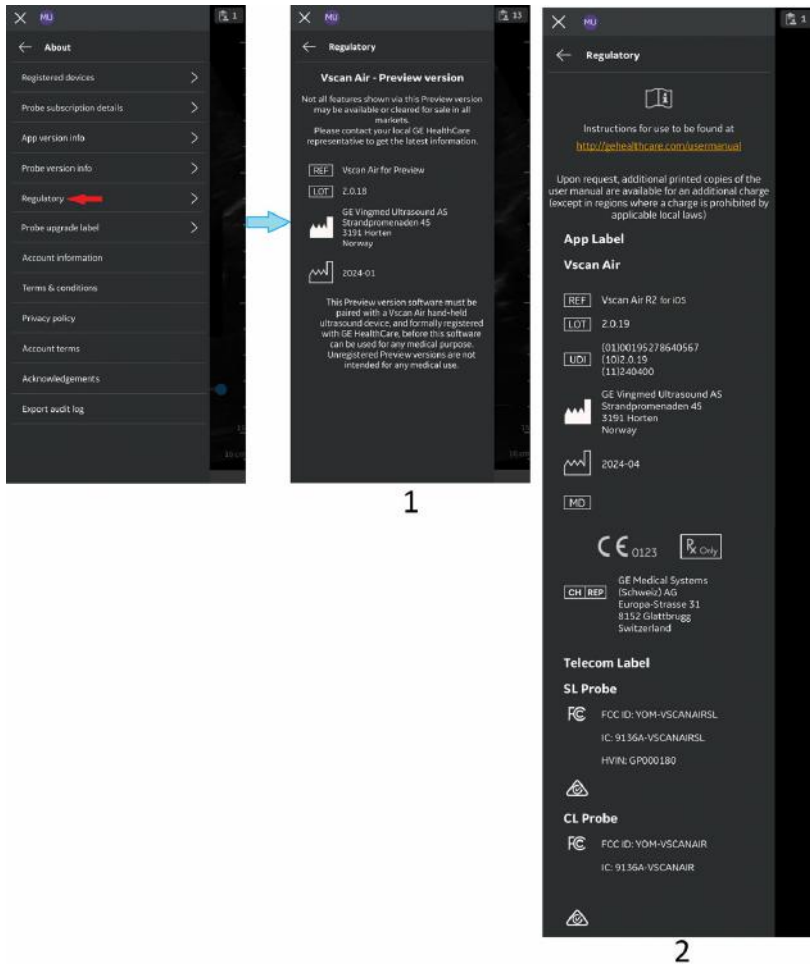
1. Before registration
2. After registration - Entire regulatory page

Figure 4-78.   Regulatory

About (continued)

- "**Probe upgrade label**" lists the Regulatory information related to the Vscan Air CL upgrade.
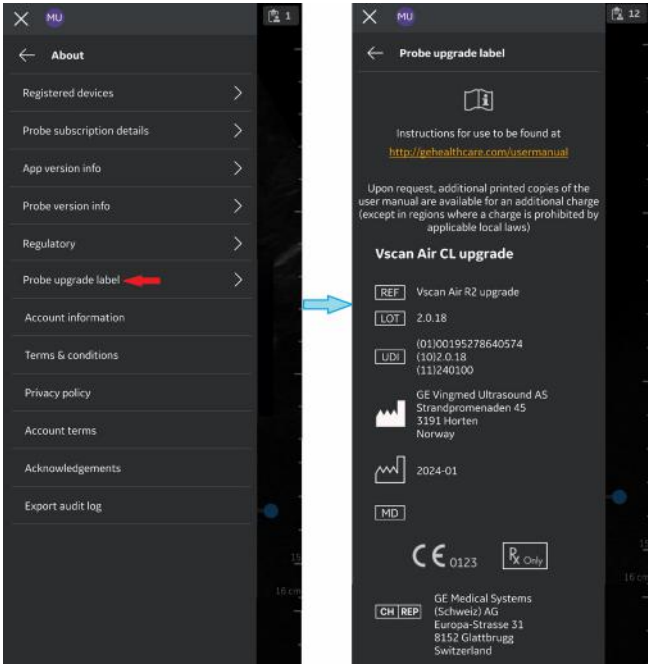
Figure 4-79.   Probe upgrade label

About (continued)

- **Account information**

  1. Press the '**Account information'** tab.
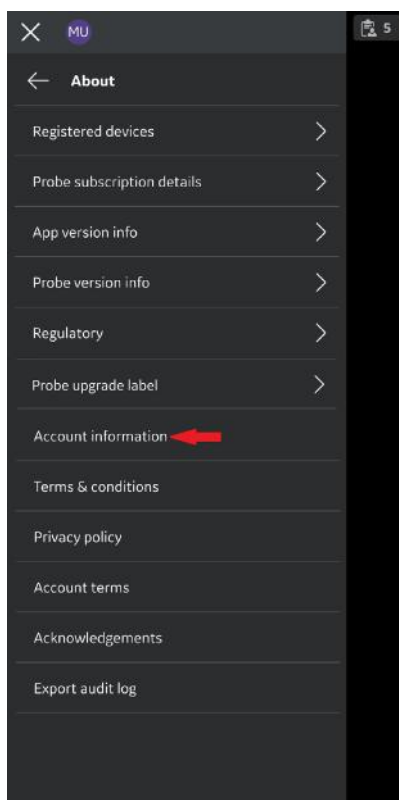
Figure 4-80.   Account Information

About (continued)

2. Update the account details if needed.

Figure 4-81.   Account details

About (continued)

3. Check to confirm the given information.

4. Press **Submit**, to update the Account details.
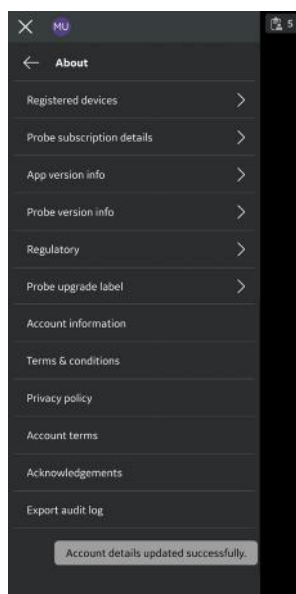
Figure 4-82.   Account details Updated

About (continued)

• **Terms & conditions - Displays terms and conditions**
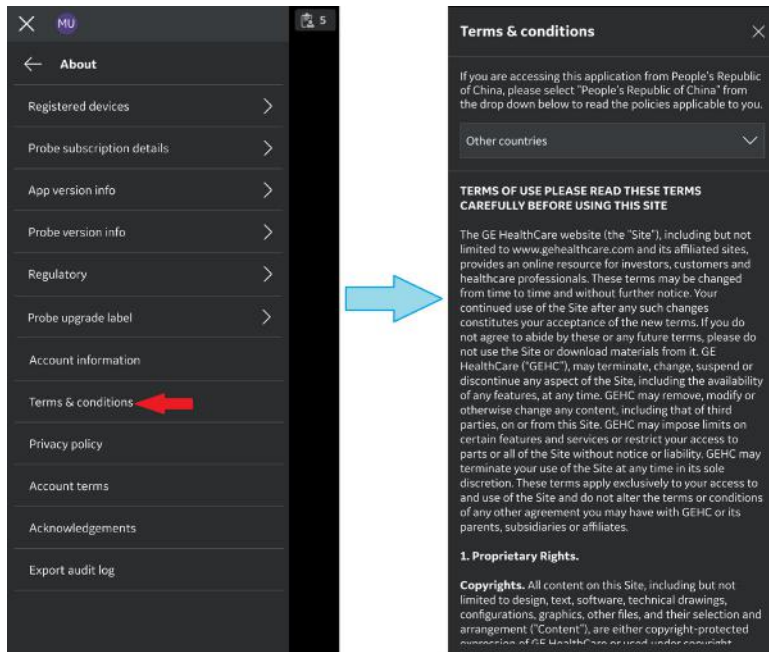
Figure 4-83.   Terms & Conditions

About (continued)

- • **Privacy policy - Displays privacy policy**
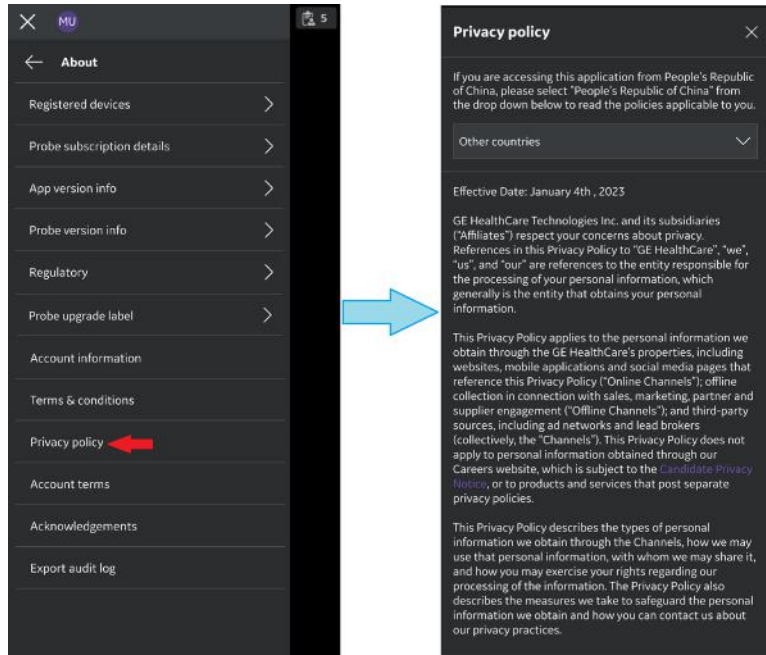
Figure 4-84.   Privacy policy

About (continued)

- **Account terms - Displays account terms**
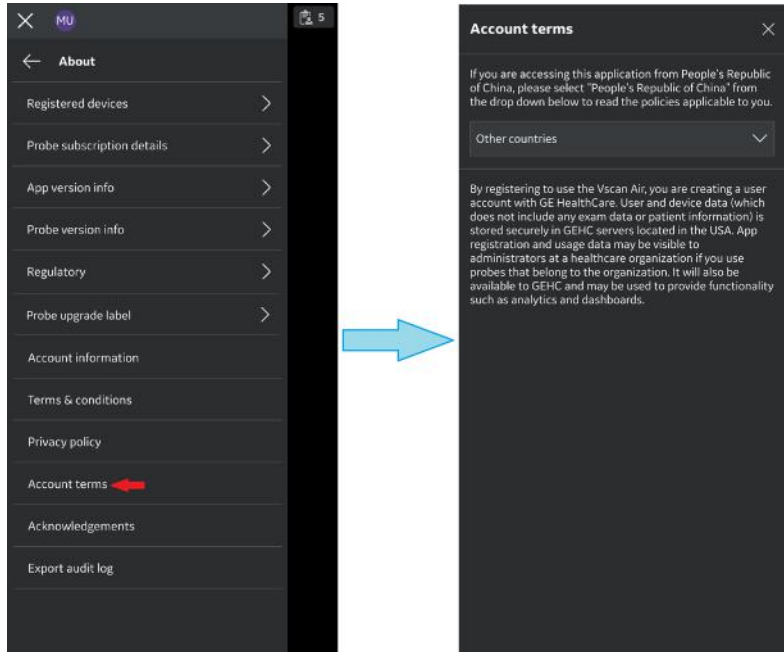
Figure 4-85.   Account terms

About (continued)

> • **Acknowledgements** - Displays the third party software licence.
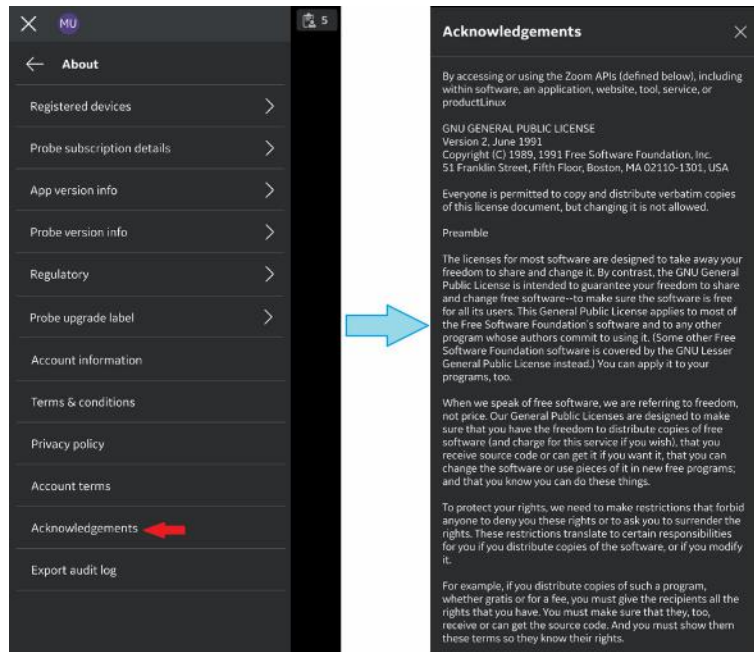
Figure 4-86.   Acknowledgements

About (continued)

- • **Export audit logs** - Audit log data can be stored to an internal storage destination. Refer the 'Audit logs' on *page 5-102*.
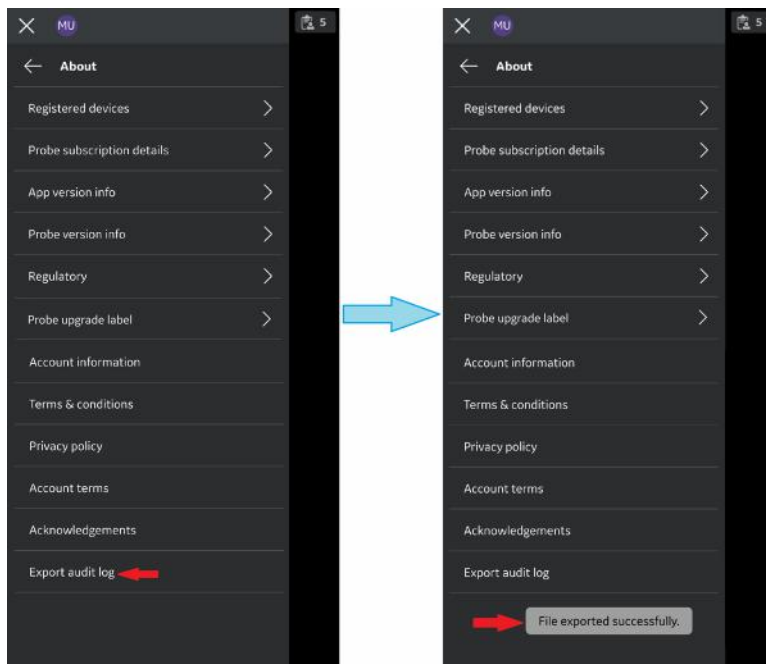
Figure 4-87.   Export audit logs

Chapter 5

Using Vscan Air

Contents:

Display features

Left panel

Swipe left to right or tap on the Vscan Air probe icon on left hand top corner to access presets and menu options.
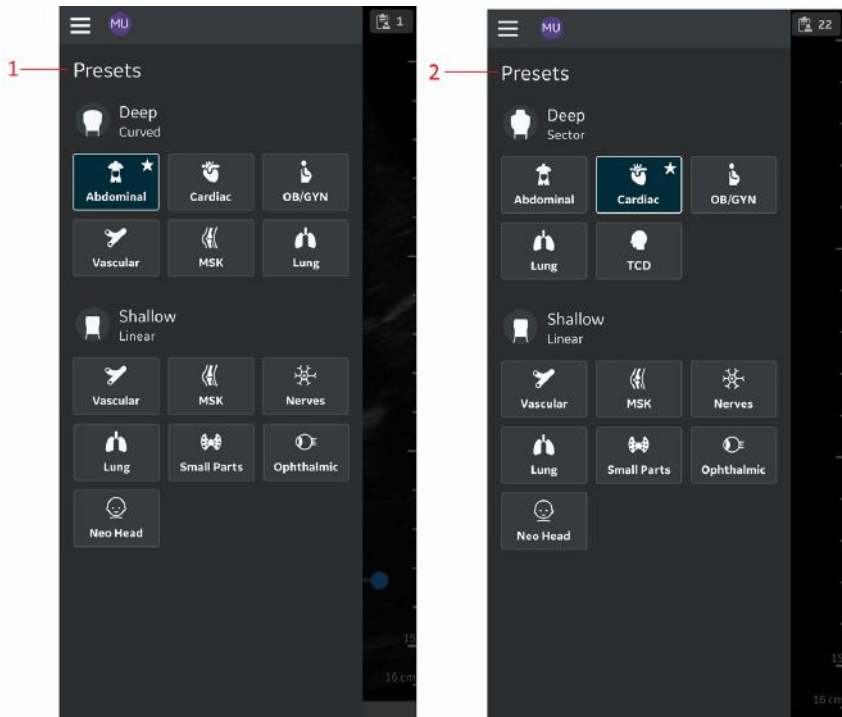
1. Vscan Air CL Presets
2. Vscan Air SL Presets
3. Menu

Figure 5-1.   Left panel

See 'Probe and Presets' on *page 5-15 for more information.*

Right panel

Swipe right to left or tap on the **Exam** icon on the right hand side top corner to create a new exam, access current exam and data from previously saved exams.

1. Start new exam
2. Current exam
3. Previous exams

Figure 5-2.   Right panel

• Start a new exam - Press **New Exam** on right corner at the bottom of the screen to start a new exam.

Right panel (continued)

- The favorite preset will be selected when a **New Exam** is created.
- Current exam - Displays the current exam number
- Exams - Displays a list of previously saved exams that can be selected to access stored images and videos.
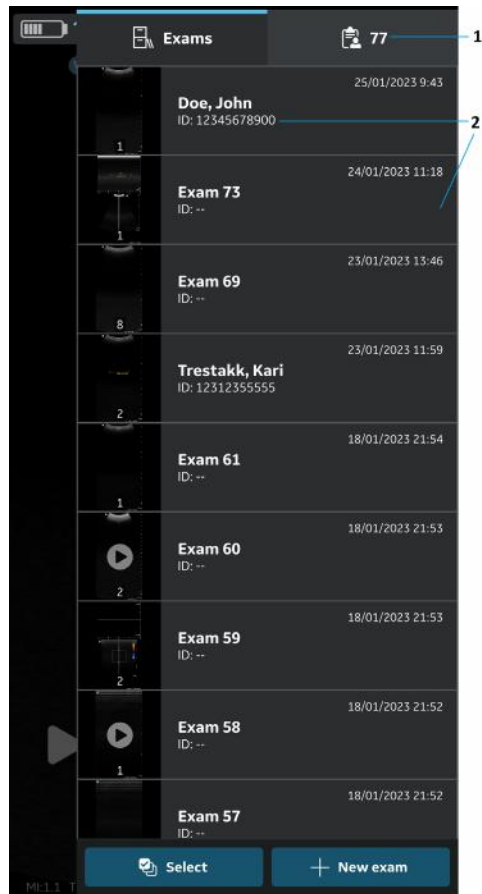
1. Current exam
2. List of saved exams

Figure 5-3.   Exam ID

Scanning

General scanning recommendations

Before each use:

Inspect the Vscan Air probe (see 'Inspection' on *page 6-3*).

After Each Use

- Inspect the Vscan Air probe (see 'Inspection' on *page 6-3*)
- Clean the Vscan Air probe (see 'Cleaning and disinfection' on *page 6-6*).
- If required, disinfect the Vscan Air probe (see 'Cleaning and disinfection' on *page 6-6*).

Ensure that the Vscan Air probe is properly cleaned and disinfected after each use and before storing in the protective case.

WARNING If any damage is found on the Vscan Air probe, do not use it. Contact GEHC service.

Use of Gel

In order to ensure optimal transmission of energy from the transducer to the patient, a conductive gel must be applied on the transducer lens.

CAUTION If the gel comes in contact with the eye, consult the gel manufacturer's instructions.

Use of Gel (continued)

The following gels have been tested to be compatible with the Vscan Air CL and Vscan Air SL probes.

Table 5-1:   Compatible Gels

Aquasonic	Parker Laboratory Inc.
Clear Image	Sonotech Inc.
Scan	Parker Laboratory Inc.
Sonogel	Sonogel Vertriebs GmbH
Wavelength	National Therapy Products Inc.
EcoVue Ultrasound Gel	HR Pharmaceuticals Inc

For more information regarding probe care, refer to the website: https://gehealthcare.com/probecare or https://www.gehealthcare.com/products/ultrasound/ultrasound-transducers

Other recommendations

Like most high frequency computing devices, the electronic components of the Vscan Air probes will generate some heat while operating normally and as intended. Vscan Air probes are equipped with safety mechanisms which will automatically reduce computing speed (frame rate), and ultimately shut down the device, before any risk of overheating occurs. The Vscan Air probes are verified to comply with harmonized safety standards (see 'Conformance Standards' on *page i-4*) under any operating condition described in this user manual (see 'Environmental requirements for Vscan Air probe' on *page 3-7*). To help keeping the Vscan Air probe operating temperature at an optimal functional level, and to ensure longer scanning time with maximum frame rate, it is recommended to hold the Vscan Air probe such that there is good contact between the device and the hand.

⚠ CAUTION For patient and personnel safety, be aware of biological hazards. To avoid the risk of disease transmission:

- Use protective barriers (gloves and transducer sheaths) whenever possible.
- Follow all infection control policies established by your office, department or institution as they apply to personnel and equipment.

Vscan Air probe orientation

Vscan Air probe is provided with an orientation mark on both the transducer heads. This mark is used to identify the side of the Vscan Air probe corresponding to the side of the image having the orientation 'V' mark on the scanning screen.

A steady blue LED light on one end of the Vscan Air probe indicates which transducer head is active.
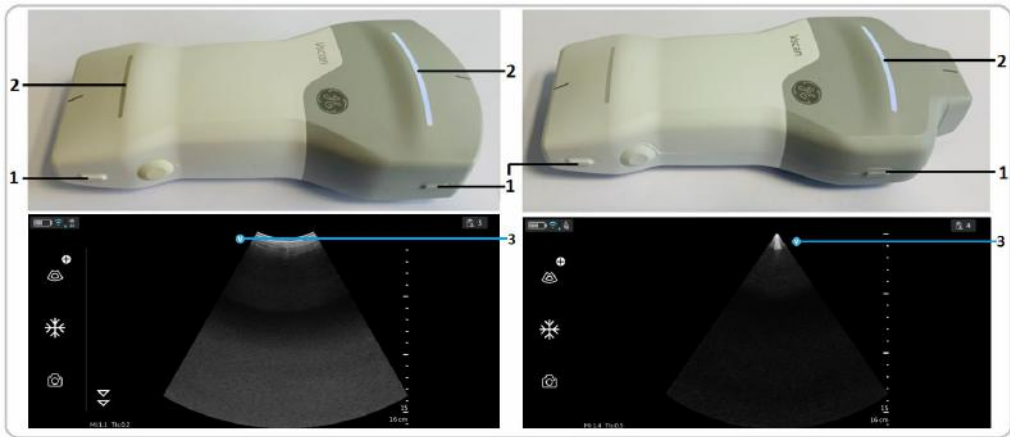
Vscan Air CL Orientation
1. Orientation marking on Vscan Air CL
2. LED light
3. Orientation marking on screen

Vscan Air SL Orientation
1. Orientation marking on Vscan Air SL
2. LED light
3. Orientation marking on screen

Figure 5-4.   Vscan Air probe orientation

Image crop indicator

Vscan Air maximizes the image display on the screen in the portrait mode. As a result, at certain depths, image corresponding to the entire transducer width may not visible on screen in portrait mode. Image crop indicators are displayed in such cases to make the user aware of this.
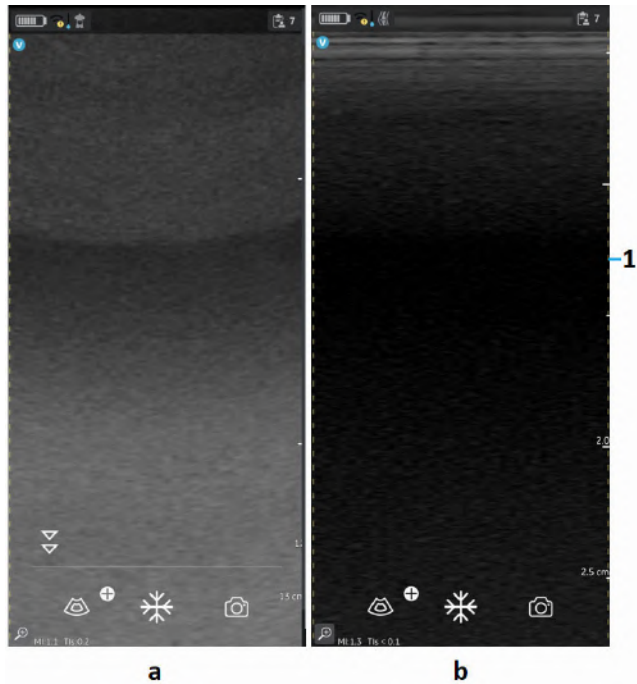
1. Image crop indicator

    a. Curved array (deep scanning) transducer
    b. Linear array (shallow scanning) transducer

Figure 5-5.   Image crop indicator (portrait mode)

Image crop indicator (continued)
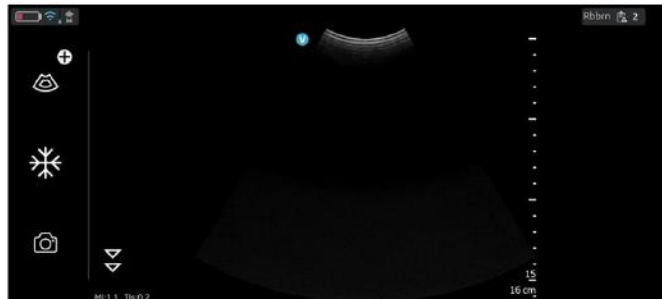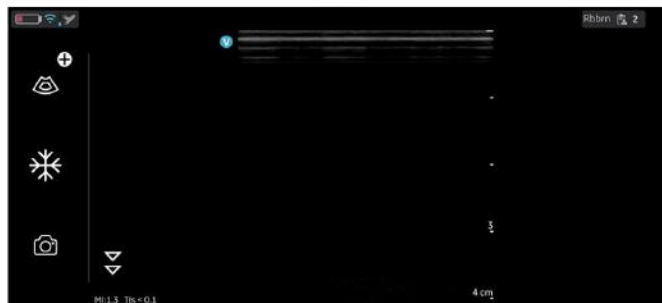
a. Curved array (deep scanning) transducer
b. Linear array (shallow scanning) transducer

Figure 5-6.   Image crop indicator (landscape mode)

Image crop indicator (continued)

If it is important to visualize the entire width, it is possible to do one of the below:

1. Rotate the display device to visualize the image in landscape orientation refer Figure 5-7.

2. If portrait mode is preferred:

    •   The depth can be increased until the whole width is displayed, and image crop indicators no longer appear.

    •   Zoom and pan to visualize the edge of the image on the desired side.
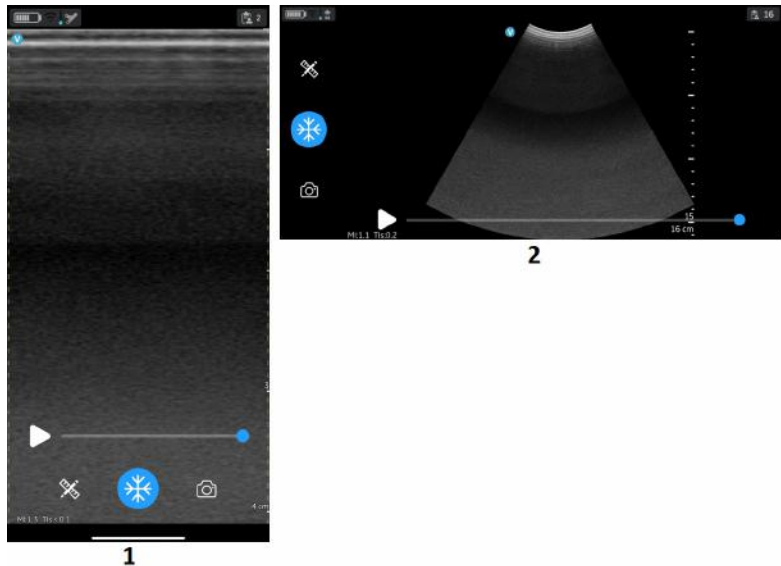
1. FLA Portrait
2. FLA Landscape

Figure 5-7.   Flat Linear Array (FLA)

Image crop and measurements

Rotating the display from portrait to landscape provides one way of moving from viewing a cropped to a not cropped image. Measurements (refer the 'Measurements' on *page 5-77*) can be added and image stored. If adding a measurement close to one of the edges of the image and then rotating the display back to portrait the measurement will be deleted if this measurement extends into the region being cropped in portrait.
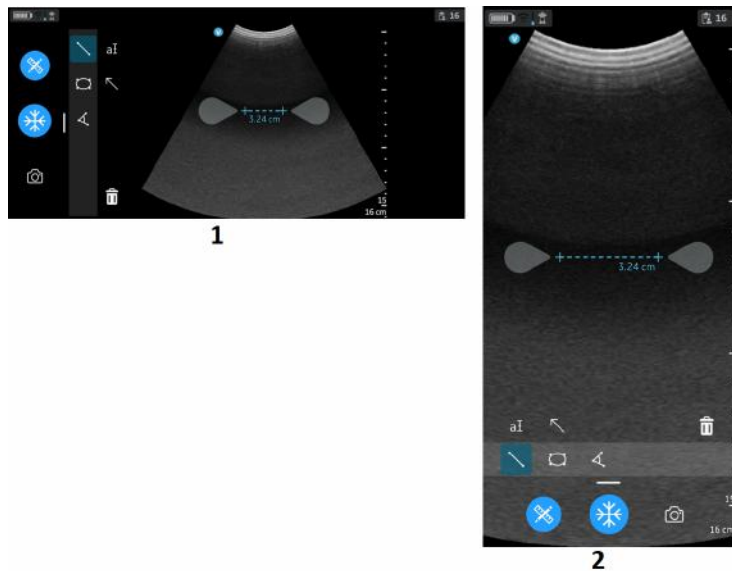
1. FLA Landscape Measure
2. FLA Portrait Measure

Figure 5-8.   FLA Measurements

Patient examination

Creating a new exam

A new exam can be created in two ways:

1. Automatically - A new exam will be created every time the Vscan Air probe pairs successfully with the Vscan Air app and also every time the Vscan Air App is started.

2. Manually - A new exam can be created manually at any time by selecting new exam from the right panel.

   • Swipe from right to left or tap the 'icon' on the right upper corner to bring out the right panel.

   • Press **New Exam** on the bottom right corner of the screen.
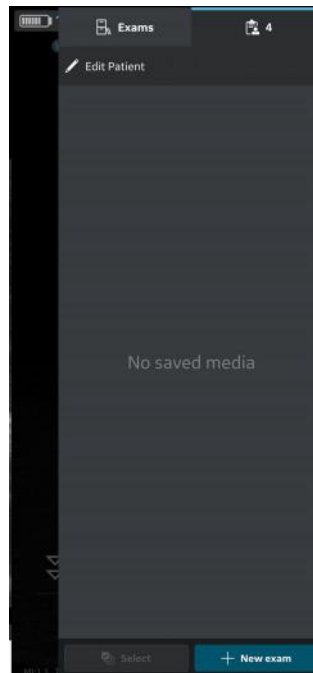
Figure 5-9. New exam

Creating a new exam (continued)

> *NOTE:*   *A new exam also gets created every time a Vscan Air probe connects with the app.*

> *NOTE:*   *An exam will get saved when an image or video is stored for that exam.*

> *NOTE:*   *The maximum number of stored exams is limited to <500. The Vscan Air app will inform the user to export and/or delete exams as needed once the number of stored exams is 480 or higher.*

WARNING   Create a new exam before starting the examination of a new patient to minimize the risk of mixing images from different patients.

Storing an image/video

> Refer to sections 'Storing an image' on *page 5-57* and 'Storing a video' on *page 5-58*.

Probe and Presets

Use of presets

To ensure optimal image quality, the Vscan Air ultrasound system has predefined scanning settings optimized for different applications. Refer to the tables below to select the correct Vscan Air CL or Vscan Air SL transducer and preset combination before scanning.

Table 5-2:   Curved array (deep scanning) transducer presets

Curved array transducer Preset		Optimized for
	Abdominal	• Liver • Gall bladder and biliary tree • Pancreas • Spleen • Kidneys • Urinary Bladder • Prostate • Bowel • Fluid detection
	Cardiac	• Heart • Fluid detection
	MSK	Musculoskeletal (conventional) • Joint • Long bones • Muscles, large tendons • Deeper soft tissue structures

	OB-GYN	• Obstetrics
		   • Uterus
		   • Fetus
		   • Placenta
		   • Amniotic fluid
		• Gynecology
		   • Uterus including cervix
		   • Ovaries and adnexa

	Vascular	• Abdominal aorta • IVC • Other veins and arteries
	Lung	• Thoracic/Pleural motion • Lung tissue • Fluid detection
OB-GYN: Obstetrics and gynaecology, MSK: Musculoskeletal		

Use of presets (continued)

Table 5-3:   Linear array (shallow scanning) transducer presets

Linear array transducer Preset	Optimized for
Vascular	• Veins • Arteries
Nerves	Peripheral nerves
Small Parts	• Small organs • Pediatric (recommended minimum weight: 4 kg) • Soft tissue
MSK	Musculoskeletal superficial • Joints • Long bones • Muscles • Tendons • Ligaments
Lung	• Thoracic/Pleural motion • Fluid detection
Neo Head	Neonatal cephalic
Ophthalmic	Ophthalmic

Use of presets (continued)

Table 5-4:   Sector array (deep scanning) transducer presets

Sector array transducer Preset		Optimized for
	Abdominal	• Liver • Gall bladder and biliary tree • Pancreas • Spleen • Kidneys • Urinary Bladder • Prostate • Bowel • Fluid detection • Abdominal aorta • IVC
	Cardiac	• Heart • Fluid detection

	OB-GYN	• Obstetrics
		    • Uterus
		    • Fetus
		    • Placenta
		    • Amniotic fluid
		• Gynecology
		    • Uterus including cervix
		    • Ovaries and adnexa

	Lung	• Thoracic/Pleural motion • Lung tissue • Fluid detection
	TCD	Cranial vascularity
TCD: Transcranial Doppler		

NOTE: Ophthalmic is not cleared for use in Japan and China.

To change the preset and probe

1. Slide from left to right or tap the preset icon on the leftmost top corner of the scan screen.

   All presets available for the Vscan Air CL or the Vscan Air SL are displayed.

   Presets are grouped according to the deep scanning (Curved array/Sector Array) and the shallow scanning (Linear array) ability of the Vscan Air probes.
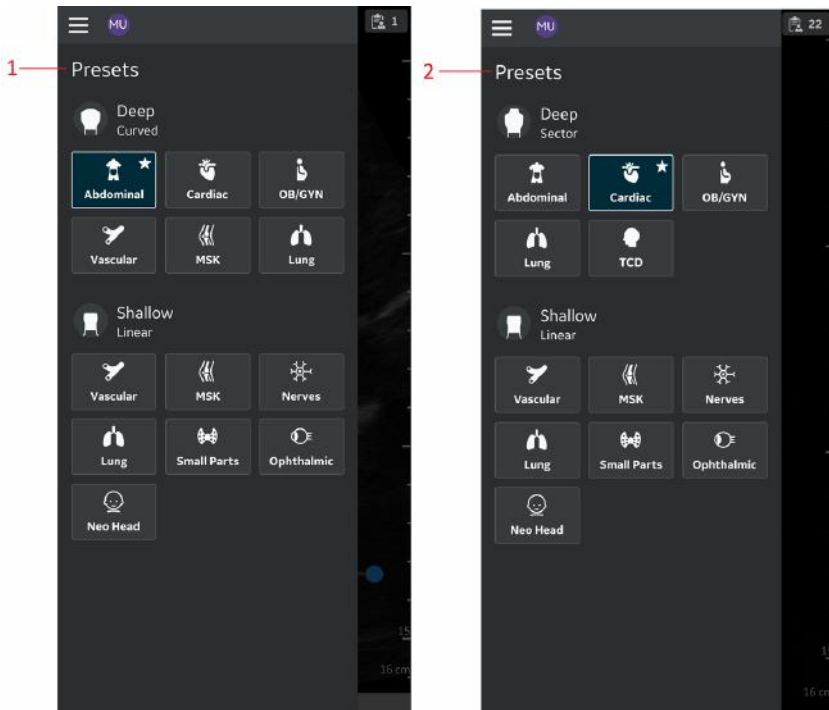
1. Preset menu Vscan Air CL
2. Preset menu Vscan Air SL

Figure 5-10.   Preset menu Vscan Air probe

2. Select the desired preset.

   The preset selected automatically activates the transducer for that preset.

3. To change the preset, swipe from left to right again. Choose the desired preset.

4. Selected preset is highlighted.

Select a favorite preset

Press and hold the preset which needs to be selected as a favorite preset.

A star mark displays to indicate the favorite preset selected.
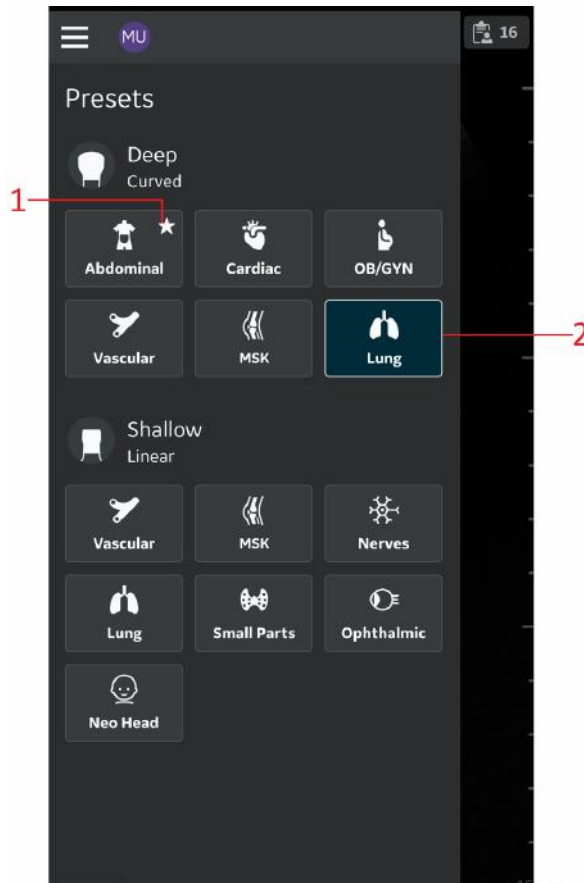
1. Favorite preset
2. Selected preset

Figure 5-11.   Preset as default

NOTE: *The favorite preset indicated when installing the Vscan Air app is the factory default setting.*

Black/white imaging (B-mode)

NOTE: *Scanning does not start if the Vscan Air probe is not connected to a Vscan Air app.*

Black and white imaging is intended to provide two-dimensional images and measurement capabilities concerning the anatomical structure of soft tissue.

Black and white imaging is the default scanning mode.
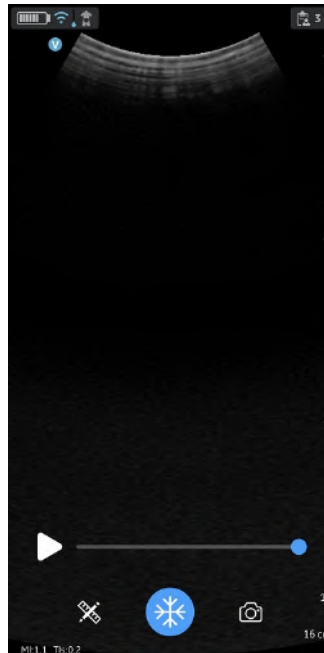
Figure 5-12.   Black/ white (B-mode) scan screen

NOTE: *As a safety precaution, scanning is not possible when charging the Vscan Air probe.*

Black and white imaging adjustments

Gain

Black and white gain increases or decreases the amount of echo information displayed in an image. It may have the effect of brightening or darkening the image if sufficient echo information is generated.

1. Swipe at least half a centimeter from the left or right on the scan screen to initiate a gain change.
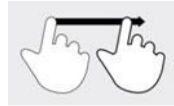
Figure 5-13.   Drag

NOTE: *Small movements will be ignored to avoid unintentional activation of the gain control.*

2. Move your finger to the right or left to increase or decrease gain.
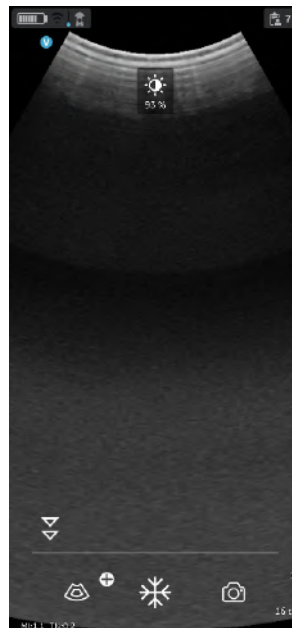
Figure 5-14.   Gain

The adjusted gain value is seen with the icon on the top of the screen.

Time Gain Compensation (TGC)

TGC amplifies returning signals to correct for the attenuation caused by tissues at increasing depths.

TGC sliders are spaced proportionately to the depth. The area each slider amplifies varies as well.

Turn ON or OFF the TGC Controls from the Menu screen.

The TGC controls are displayed on the scan screen as soon as you start adjusting gain by sliding your finger on any part of the image.

Adjust individual TGC sliders to adjust the intensity of echoes in a particular depth of the image.

The TGC sliders will disappear from screen after a timeout period.
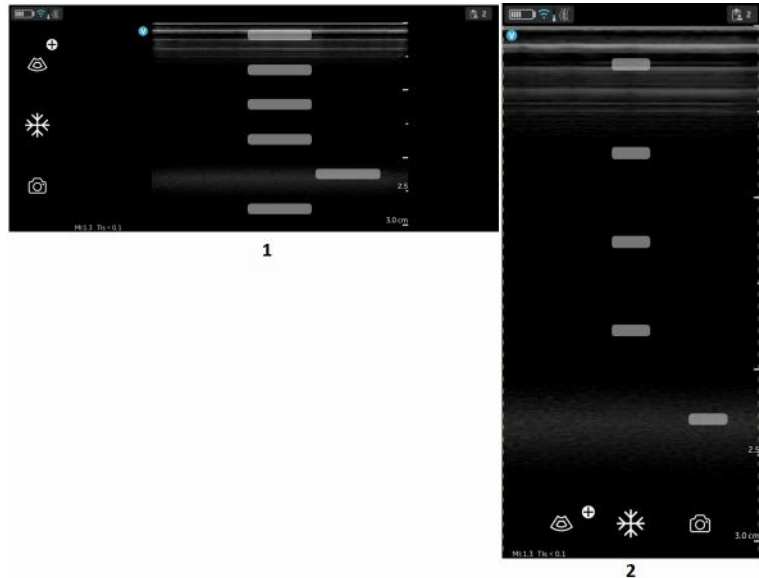
1. Landscape mode
2. Portrait mode

Figure 5-15.   TGC

NOTE: *The Gain control is disabled as long as the TGC controls are active.*

Depth

Depth adjusts the field of view. It increases the field of view to look at larger or deeper structures; it decreases the field of view to look at structures near the skin line.

1. Swipe your finger up/down on the screen at least half a centimeter to initiate depth.
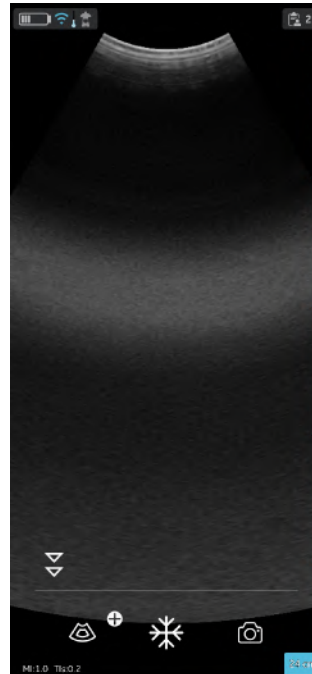
Figure 5-16.   Depth adjustment

NOTE: *Small movements will be ignored to avoid unintentional activation of the Depth control.*

At the start of the swipe, the depth indicator shows the depth change.

2. Change depth per cm from 5-24 cm.

    OR

    Change depth per 0.5 cm from 2-5 cm.

NOTE: *When the screen is rotated from portrait to landscape, depth remains unchanged.*

Zoom and pan

Pinch on the image with two fingers to zoom.

To pan or move the zoomed area, slide your finger on the image in the direction where you want the zoomed area to move.
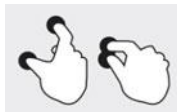
Figure 5-17.   Pinch

An indicator will be displayed on the image whenever Zoom is activated to help recognize a zoomed image easily.

Zooming will be disabled if clicking the on screen Zoom indicator when in Zoom.
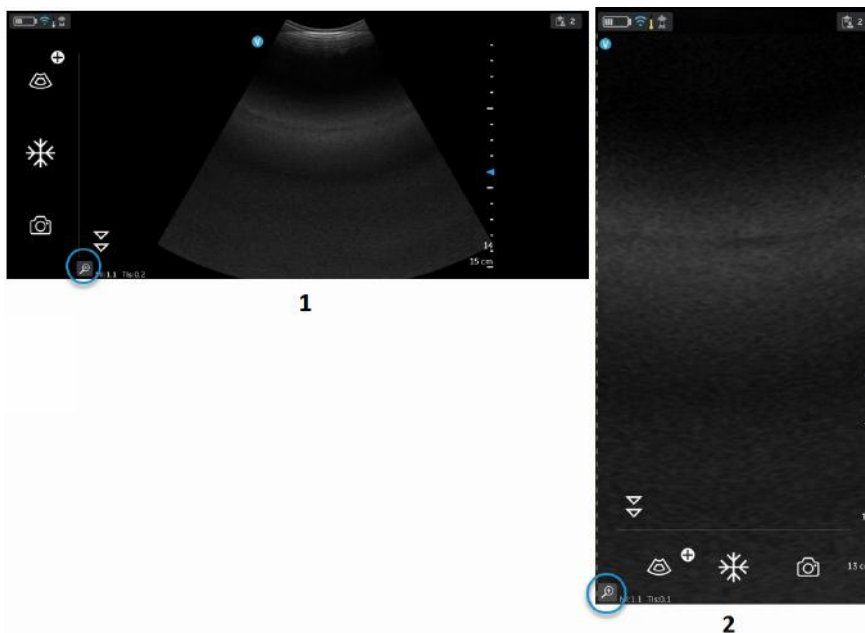
1.   Landscape mode
2.   Portrait mode

Figure 5-18.   Zoom indicator

NOTE: *The images can be zoomed only before saving. The zoom level applied at the time of storing a video is used for the length of the video being stored. This applies even if the zoom level has been changed during the time captured by the video.*

Zoom and pan (continued)

> *NOTE:* *While zooming, one or both edges of the image may go out of the field of view on the screen. In such cases, you will see 'Image crop indicators' appear on the sides where the image edge is not visualized (Refer 'Image crop indicator' on page 5-9).*
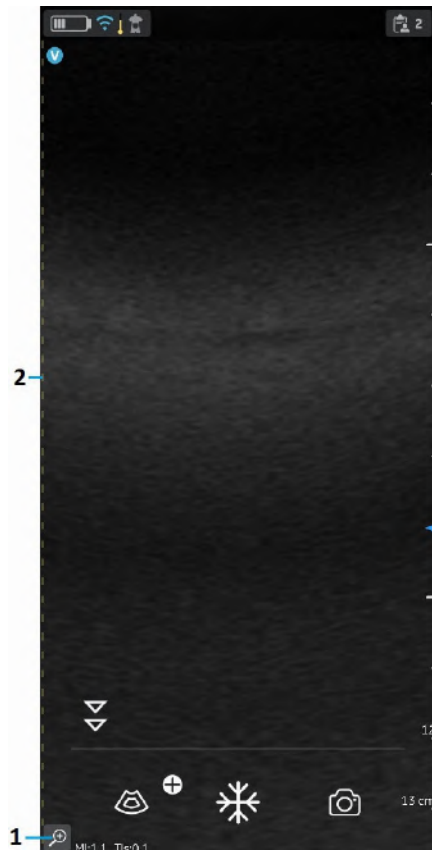
1. Zoom indicator
2. Crop indicator

Figure 5-19.   Curved array transducer

Resolution and Penetration setting

For a few presets, there is a control available in the black and white mode for alternating between **Resolution** and **Penetration** settings.

Resolution setting is the default setting optimized for high resolution imaging balancing adequate penetration for average sized patients.

Penetration setting is useful for imaging at greater depths by optimizing visualization of structures in the far-field in larger than average or difficult to scan patients. An increase in penetration is obtained at the expense of decreased resolution.

The presets that support selection of Penetration setting are listed below.

Curved array	Sector array	Linear array
Abdominal	Abdominal	Vascular
Cardiac		

Resolution and Penetration setting (continued)

To switch between the 'Resolution' (default) and 'Penetration' settings, tap on the ⊻. The ⊻ icon indicates that the 'Penetration' setting is selected and ⊻ icon indicates default or 'Resolution' setting is selected. Depth is maintained while alternating between the two settings.

1. Resolution setting (default)
2. Penetration setting

Figure 5-20.   Resolution and penetration setting

Color flow (Color Doppler)

The Color flow (Color Doppler) mode is adding color coded qualitative information concerning the relative velocity (in m/s) and direction of fluid motion within the black and white image.

1. Press the Color icon.

   A color flow area displays on top of the black and white image.
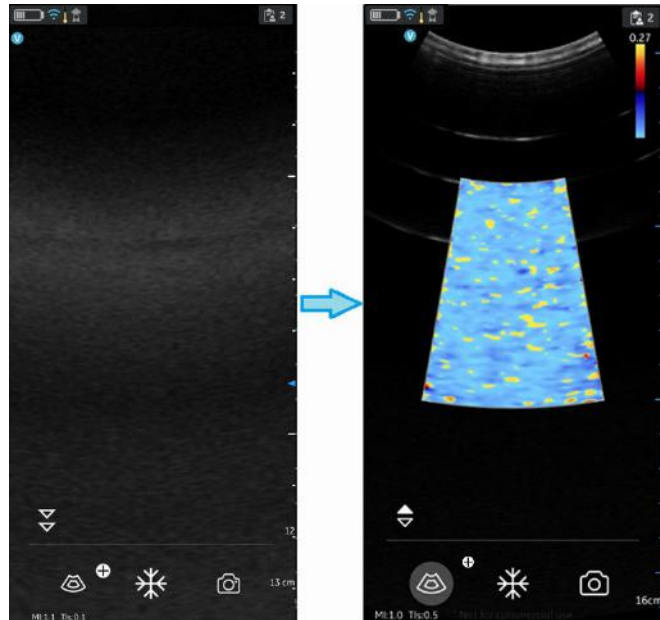
Figure 5-21.   Color icon

2. Drag the color Region of Interest (ROI) to the desired area. The color ROI outline becomes blue when active.

Color imaging scanning adjustments

> *NOTE:*   *The color images can be zoomed by pinching the images with two fingers.*

> *NOTE:*   *The active gain control is disabled as long as the TGC controls are active.*

Color gain

Color gain amplifies the overall strength of echoes processed in the color area.

1. Swipe at least half a centimeter from the left or right on the scan screen to initiate gain.

> *NOTE:*   *Small movements will be ignored to avoid unintentional activation of the color gain control.*

2. Move your finger to the right or left outside the color ROI to increase or decrease color gain.

Position and resize ROI

The size of the Region of Interest (ROI) has an effect on the frame rate. The width of the ROI has a significant effect on frame rate even more than the height of the ROI. Keep the box sized just to the anatomy of interest and as close to center as possible.

Drag your finger inside the ROI to move and position. The box turns blue indicating that the controls for adjusting the ROI are activated. Use the controls on the corners to adjust size.
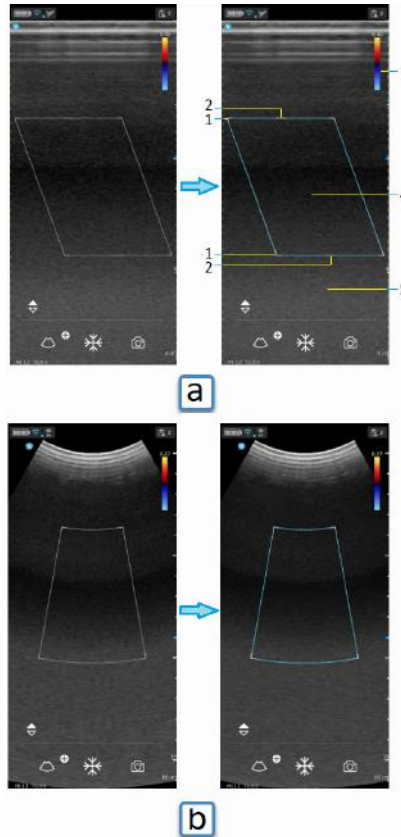
a. FLA color flow
b. Curved linear array (CLA) color flow

1. Resize ROI
2. Steer ROI
3. Nyquist/velocity bar
4. Move ROI
5. Color flow gain (left/right gesture)

Figure 5-22. Position and resize ROI

Color steer

Slant the ROI (Region of Interest) of the Color Flow linear image left or right to get more information without moving the Vscan Air probe.

Use the controls on the center top and bottom to steer the angle.

NOTE: *Color steer applies only when using the linear array transducer of the Vscan Air probe.*

Color aliasing

If the blood flow velocity exceeds the Nyquist limit indicated by the number displayed with the velocity bar aliasing may occur.

⚠ CAUTION

When blood flow velocity exceeds the max velocity range covered by the device, color aliasing may occur, which results in incorrect velocity estimates.

Aliasing appears as a shift in color from the color representing positive velocity to color representing negative velocity or visa versa.

Positive velocity indicates flow towards the transducer and negative indicating flow away from the transducer.

The maximum velocity or Nyquist limit is displayed on top of the velocity bar.

Fast and slow flow (High and low velocity scale)

For a few presets, there is a control available in the color flow mode for alternating between high and low velocity scales. A higher velocity scale is needed to avoid aliasing while imaging of faster (arterial) flow. A lower velocity scale optimizes the imaging of slow flow (venous).

The presets that support selection between high and low velocity scale are the following:

Curved array	Sector array	Linear array
Abdominal	Abdominal	Vascular
OB-GYN	OB-GYN	MSK
Vascular	Cardiac	Small Parts
Cardiac	TCD	
	Cardiac guidance*	
* Cardiac guidance only available if that AI tool option has been purchased.		

Fast and slow flow (High and low velocity scale) (continued)

To change the velocity scale, tap on the ⬍ to alternate between the velocity scales. The ⬍ indicates that the higher velocity scale is selected and ⬍ indicating the lower scale. The velocity setting corresponding to both scales can be seen at the top of the velocity bar ▮.
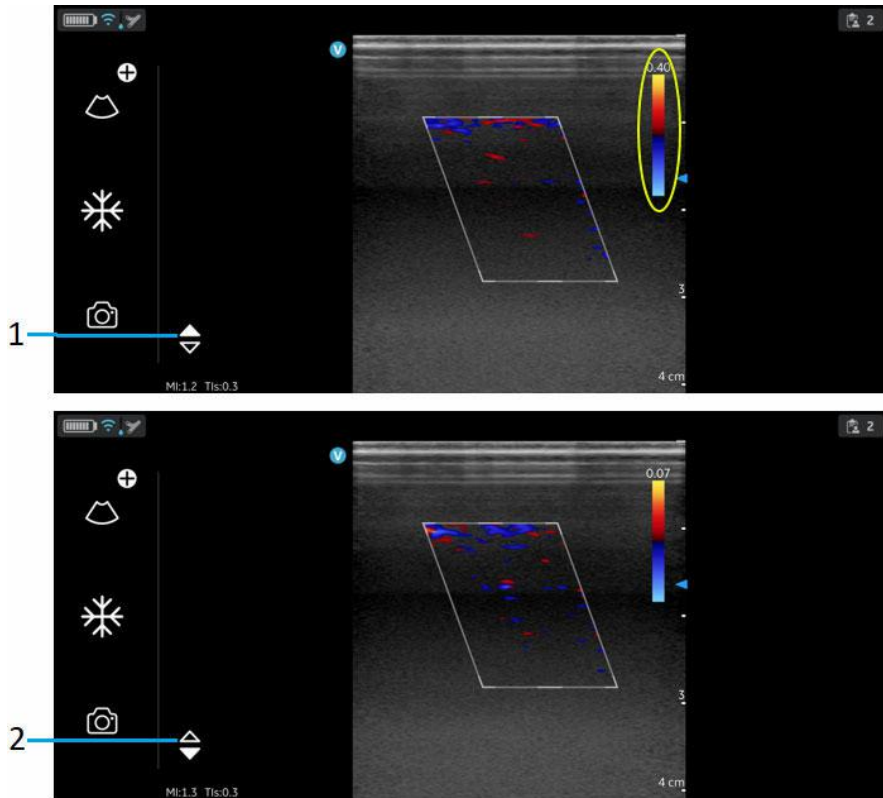
1.   High velocity setting
2.   Low velocity setting

Figure 5-23.   Fast and slow flow

Freeze

To freeze an image:

Press the Freeze button.

Figure 5-24.   Tap or press

When in freeze mode, you can store an image or review frames in the available video buffer.

To reactivate the image:

Press Freeze icon again.

Video buffer

Video buffer displays with an ability to scroll, play and pause the frames in the video buffer.

The indicator is placed on the last frame.

To jump frames:

1. Tap on the video buffer bar to view any frame.
2. Scroll to jump multiple frames.

Auto freeze

If Vscan Air probe is idle for a period of time, the device enters freeze mode to minimize risk of overheating and battery drainage. Press the display to unfreeze the image and continue scanning.

Pulsed wave (PW) spectral doppler

PW Doppler is typically used for displaying the speed, direction, and spectral content of blood flow. This allows the user to perform measurements concerning the velocity of moving fluids. PW Doppler lets you examine blood flow data selectively from a small region called the sample volume.

Typical use - PW doppler

In Pulsed Wave Doppler (PW) mode, energy is transmitted from the ultrasound probe into the patient, as in B-mode. However, the received echoes are processed to extract the difference in frequency between the transmitted and received signals. Differences in frequencies can be caused by moving objects in the path of the ultrasound signal, such as moving blood cells. The resultant signals are presented graphically on the system display. The X-axis of the graph represents time while the Y-axis represents velocity in either a forward or reverse direction.

PW Doppler is typically used for displaying the speed, direction, and spectral content of blood flow at selected anatomical sites.

The site where PW Doppler data is derived (Sample Volume Gate) appears graphically on the B+ Color image. The sample volume gate can be moved anywhere within the B-mode image.

Spectral Doppler display

When PW doppler is enabled it starts updating from the left side of the screen. The baseline of the graph (representing zero velocity, zero frequency shift), appears as a solid line running horizontally across the display. By convention, movement toward the probe is positive and movement away from the probe is negative. Positive frequencies or velocities appear above the baseline. Negative frequencies or velocities appear below the baseline. Typically, blood flow is not uniform but is composed of a mix of blood cells moving at different velocities and in different directions. Strong signals are displayed as bright while weak signals are displayed as less bright.

Typical exam protocol

Using PW Doppler mode might proceed as follows:

1. Select the preset and probe to be used.

2. Locate the anatomy to be examined. Get a good B-mode image. Enable color to help locate the vessel you wish to examine.

3. Press ⊕ icon to access the additional modes to enter PW. The PW-mode is then activated and the PW cursor appears on the frozen B+ Color image.
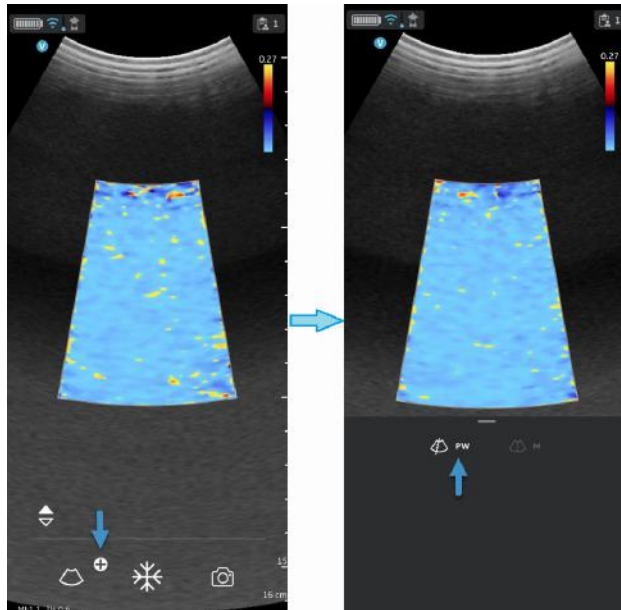
Figure 5-25.   PW-mode activation

4. Position the PW cursor as necessary.

Typical exam protocol (continued)

5. To change the sample volume position touch anywhere in the B+color display area to activate positioning of the PW sample gate.
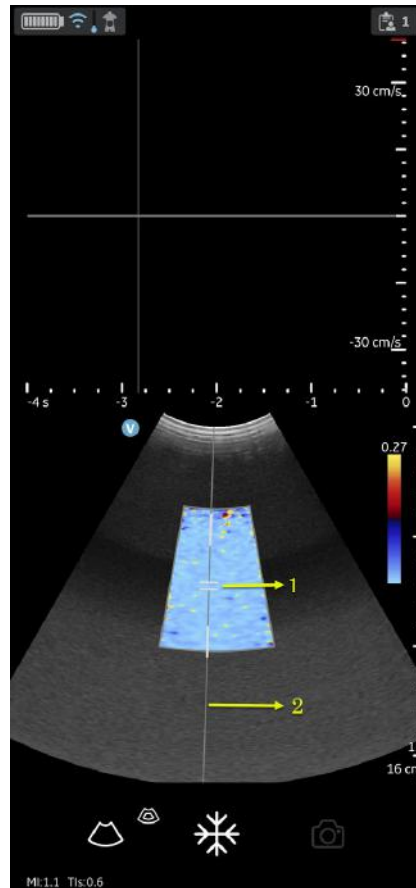
1. PW Sample volume/Sample gate
2. PW cursor

Figure 5-26.   Sample volume positioning

Typical exam protocol (continued)

6. Adjust angle correct (AC) by touching one of the ends of the angle correct line passing through the sample volume gate.
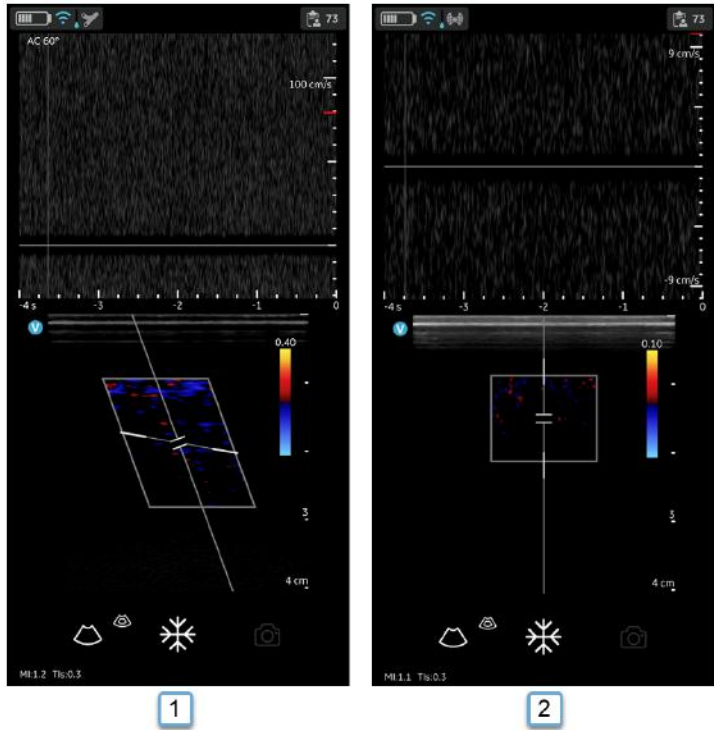
1. AC 60 degree
2. AC 0 degree

Figure 5-27.   Angle correct value

Angle correct defaults to 60 degree for Vascular presets and to 0 degree for all other presets.

The angle correct value displayed in the upper left corner of the PW spectrum is different from 0 degree.

Typical exam protocol (continued)

7. The PW Doppler spectrum appears, and the system operates in Doppler mode.
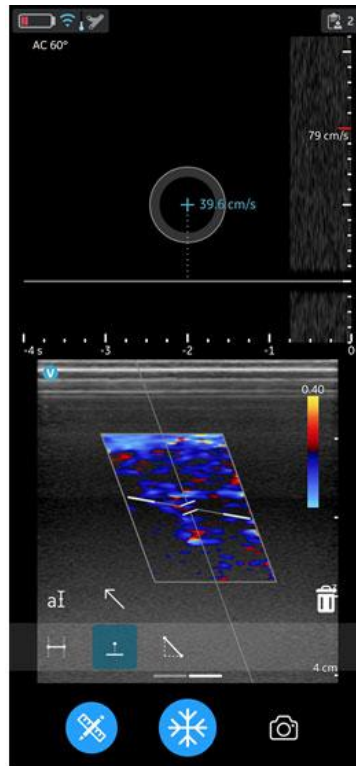
Figure 5-28.   PW Doppler spectrum

Typical exam protocol (continued)

8. Optimize the PW Doppler spectrum, as necessary. Refer ''Optimizing the Image' on *page 5-42* section of this chapter for more information.
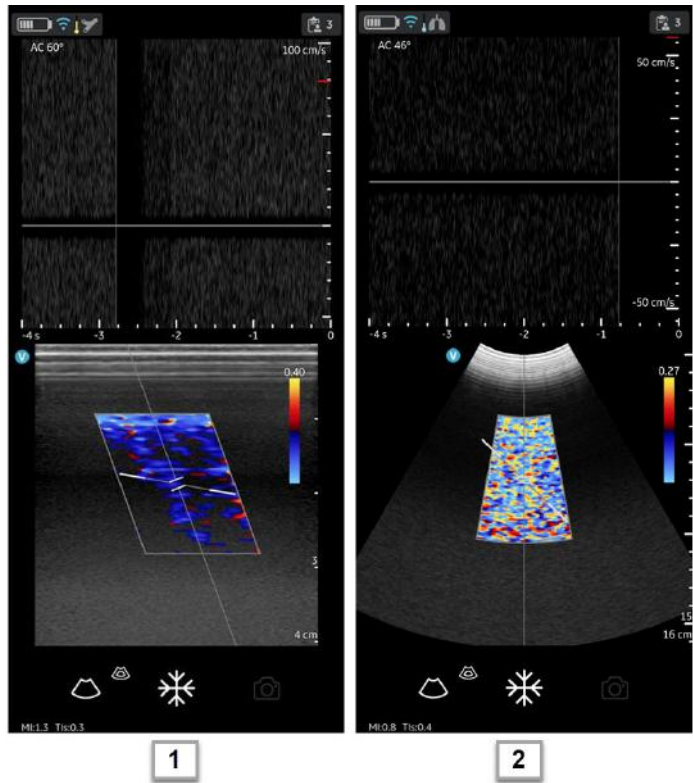
1. Linear array preset
2. Curved array preset

Figure 5-29.   PW Doppler Optimization

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Typical exam protocol (continued)

9. To exit PW Doppler and return to B-mode press the ⬤ icon. To exit PW Doppler and return to B+Color mode press the ⬤ icon to exit PW Doppler.
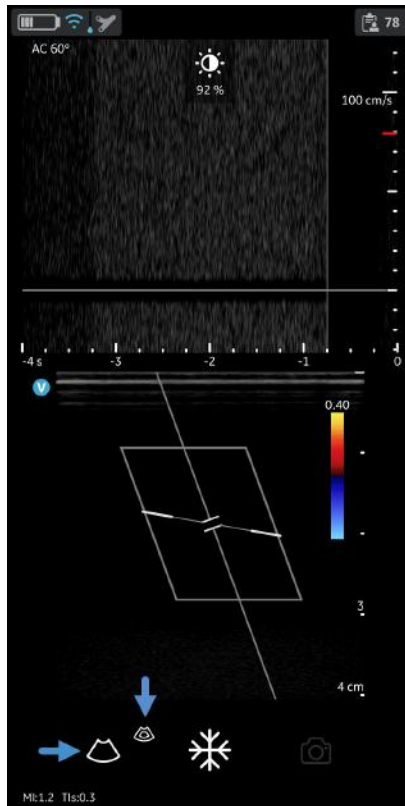
Figure 5-30.   PW gain

Optimizing the Image

1. **Doppler gain**

   Move your finger to the right or left to in the PW doppler display area to increase or decrease gain. Refer Figure 5-30 *on page 5-41*.

2. **Toggling**

   • Toggle between live Doppler (color-mode frozen) and live color-mode (Doppler spectrum frozen) is available in PW modes.

   • Freeze icon can freeze both color-mode and Doppler spectrum simultaneously.

3. **Doppler sample volume gate position**

   • Move the sample volume gate on the color-mode cursor. The gate is positioned over a specific position within the vessel.

   • To move sample volume gate position, tap the cursor then move it in any direction until it is positioned inside the vessel of interest.

Optimizing the Image (continued)

4. **Velocity scale**

- Scale adjusts the velocity scale to accommodate faster/ slower blood flow velocities.

- To increase or decrease velocity swipe your finger up/ down on or close to the on screen velocity ruler. Swipe at least half a centimeter to initiate velocity scale adjustments. The display updates the velocity scale after adjusting.
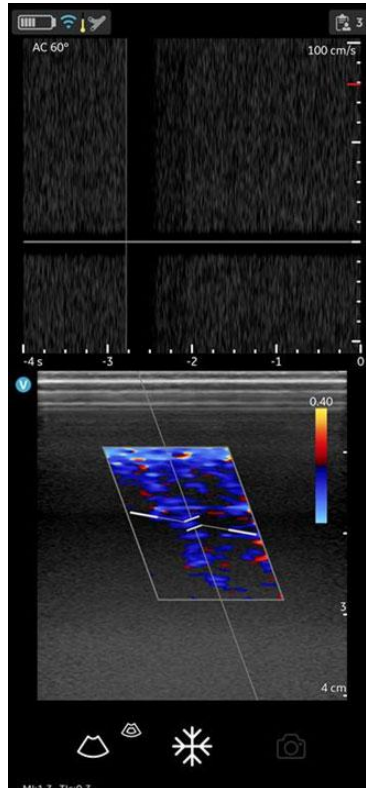
Figure 5-31.   Velocity scale

Optimizing the Image (continued)

5. **Sweep speed (time scale)**

- Sweep speed adjusts the time scale to optimize the display (time) resolution.

- To increase or decrease sweep speed swipe your finger left/right on or close to the on time scale ruler. Swipe at least half a centimeter to initiate Sweep speed adjustments. The display updates Sweep speed after adjusting.
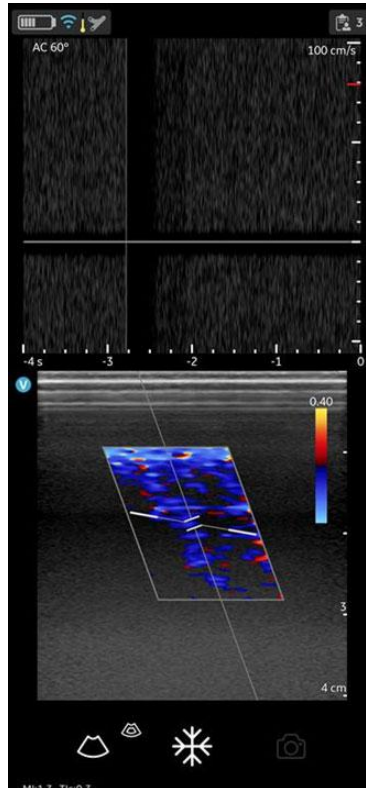
Figure 5-32.   Sweep speed

Optimizing the Image (continued)

6. **Angle Correct**

   Angle correct represents angle in degrees between the PW-mode cursor and angle correct indicator.

NOTE: *When the Doppler mode cursor and angle correct indicator are aligned (the angle is 0), the angle correct indicator as a blue line on top of PW cursor line can be seen.*

NOTE: *The angle correct number in degrees displays as long as the angle correct is not set to zero (0).*

NOTE: *The Doppler Angle displays in red when the angle exceeds 60°. Angle correct values are limited to 80° since values greater than 80° are not accepted by the Vscan Air app.*

7. **Baseline**

   • Baseline rearranges the velocity scale without changing the velocity scale. Readjusts the positive and negative velocities limit without changing the total velocity range.

   • Baseline adjusts the point in the spectrum where the velocity is zero. To shift the baseline, drag Baseline up down directly on the spectral image.

8. **PW Cursor**

   • PW cursor displays the Doppler mode cursor on the live color-mode image.

   • Drag the cursor on the image to position it over the desired target before you activate the Doppler spectrum. The cursor can also be adjusted on the live color-mode image when spectral display is frozen.

9. **Steer**

   The PW Cursor steer will align to the color steer. Color steer is only available for the linear transducer. If needing to change the PW cursor steer, then leave PW-mode, adjust color steer as desired and return to PW.

Screen layout PW doppler
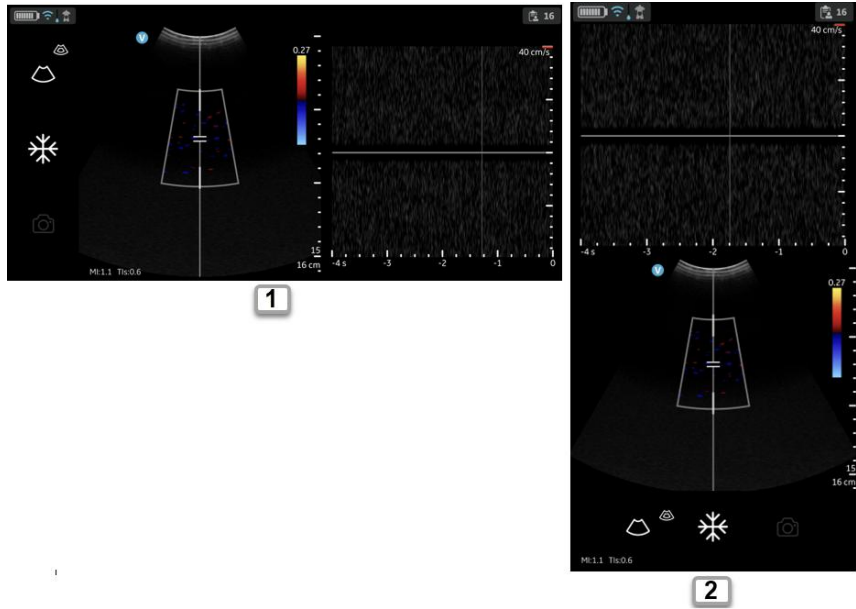
1. PW Landscape
2. PW Portrait

Figure 5-33.   PW layout

NOTE: *If selecting to use landscape when the display device (tablet) is being 7.3 inch (diagonal) or larger, the over/under layout (as in portrait) will be used instead of the side/side layout indicated in Figure 5-33.*

PW-mode measurements

The following basic measurements can be made in Doppler mode:

- Velocity
- Time interval
- Slope

Velocity

To measure velocity:

1. On a frozen image, press **Measure**.
2. The measurement display 'Velocity' being activated by default.
3. Position the velocity caliper.
4. The system displays the velocity measurement.
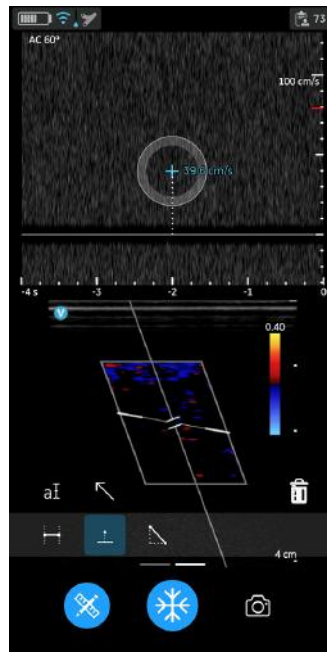
Figure 5-34.   Velocity measurement

5. To store the image with a measurement, press **store**.

For more information refer 'Measurements' on *page 5-77*

PW-mode measurements (continued)

Time Interval on PW-mode

To measure a time interval:

1.   On a frozen image, press **Measure**.

2.   Select the Time measurement tool.

3.   Position the calipers on the PW doppler waveform to measure the desired time interval.

4.   The system displays the time measurement and the corresponding calculated heart rate. The number of beats used for the heart rate calculation is listed with the calculated heart rate. Example 60 bpm (2) refer Figure 5-35
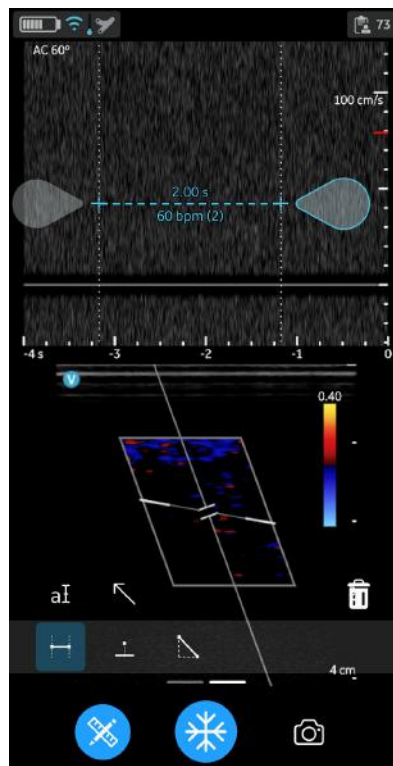
Figure 5-35.   Time interval - PW-mode

5.   To store the image with a measurement, press **store**.

For more information refer 'Measurements' on *page 5-77*

Slope on PW-mode

To measure slope between two points:

1. On a frozen image, press Measure.
2. Select the Slope measurement tool.
3. Drag to position the calipers.
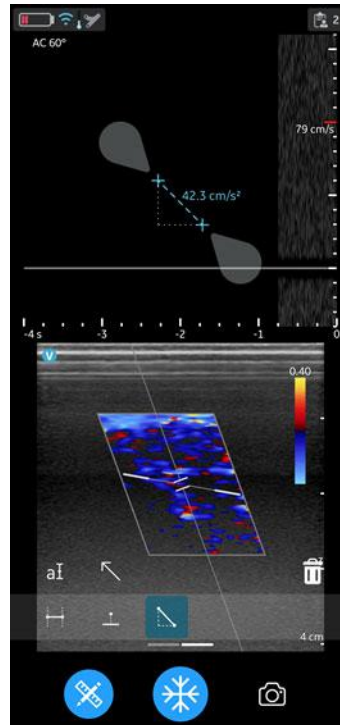
Figure 5-36.   Slope measurement

4. The system displays the slope measurement result.
5. To store the image with a measurement, press **store**.

For more information refer 'Measurements' on *page 5-77*

M-mode (Motion mode)

M-mode (Motion mode) provides a display format and measurement capability that represents tissue motion occurring over time. Data is acquired along one direction indicated by the M-mode cursor.

It is used to determine patterns of motion for objects within the ultrasound beam. The most common use is for viewing motion patterns of the heart.

Typical exam protocol

Using M-mode might proceed as follows:

1. Select the preset and probe to be used.
2. Select a good B-mode image. Survey the anatomy and place the area of interest near the center of the B-mode image.
3. Press ⊕ icon to access entry to M-mode and tap M-mode. M-mode is then active with the cursor appearing on the frozen B-mode image.
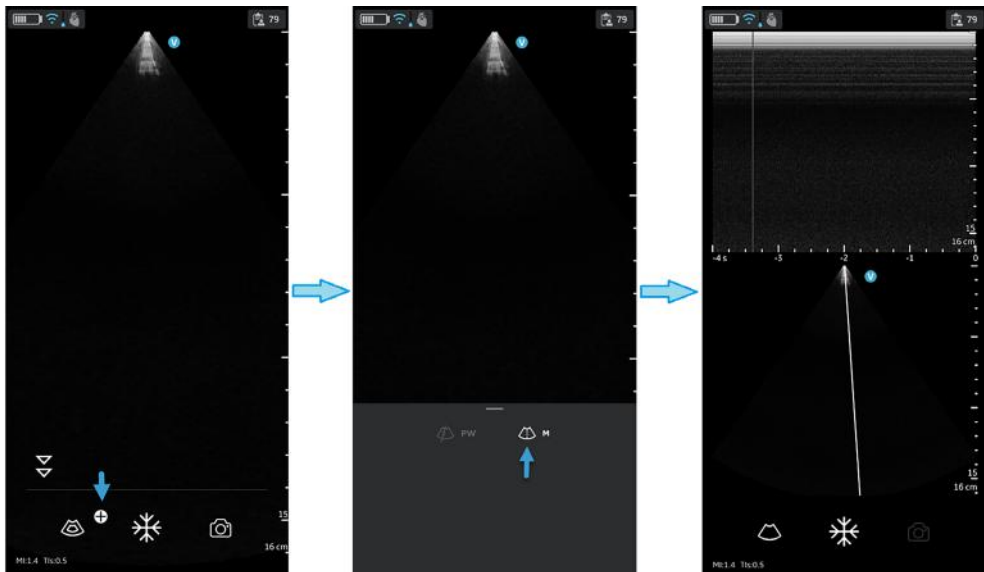
Figure 5-37.   M-mode activation

4. To optimize the M-mode cursor position on the B-mode image touch anywhere in the B-mode display area to activate positioning of the M-mode cursor.

Typical exam protocol (continued)

5. Adjust the sweep speed and gain as needed.

6. Press **Freeze** to freeze the M-mode.

7. Tap **Store** to save image to image gallery.

8. Press **Freeze** to continue imaging.

9. To exit M-mode, press the ⬔ icon to exit M-mode and enter B-mode.
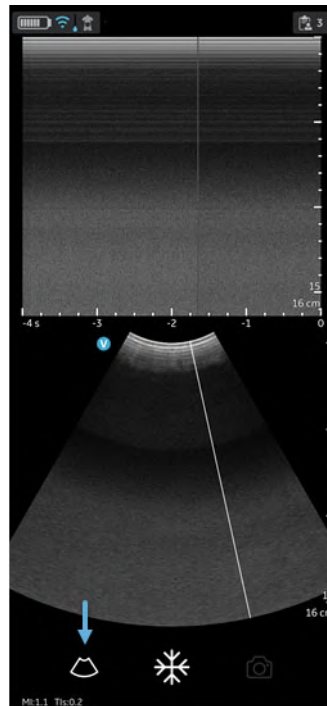
Figure 5-38.   Exit M-mode

M-mode Display & Controls

M Cursor

To position the M-mode cursor, touch the M cursor with your finger and drag it right or left to reach proper position.

Gain

M-mode gain increases or decreases the amount of echo information displayed in an image. It may have the effect of brightening or darkening the image if sufficient echo information is generated.

To increase or decrease gain swipe your finger left/right in the M-mode display area.

NOTE: *Changing the M-mode gain while in live M-mode and frozen B-mode does not affect the B-mode image gain.*

Sweep Speed

Sweep speed changes the speed at which the timeline is swept.

To increase or decrease sweep speed swipe your finger left/right on or close to the on time scale ruler. Swipe at least half a centimeter to initiate Sweep speed adjustments. The display updates Sweep speed after adjusting.

Screen layout M-mode
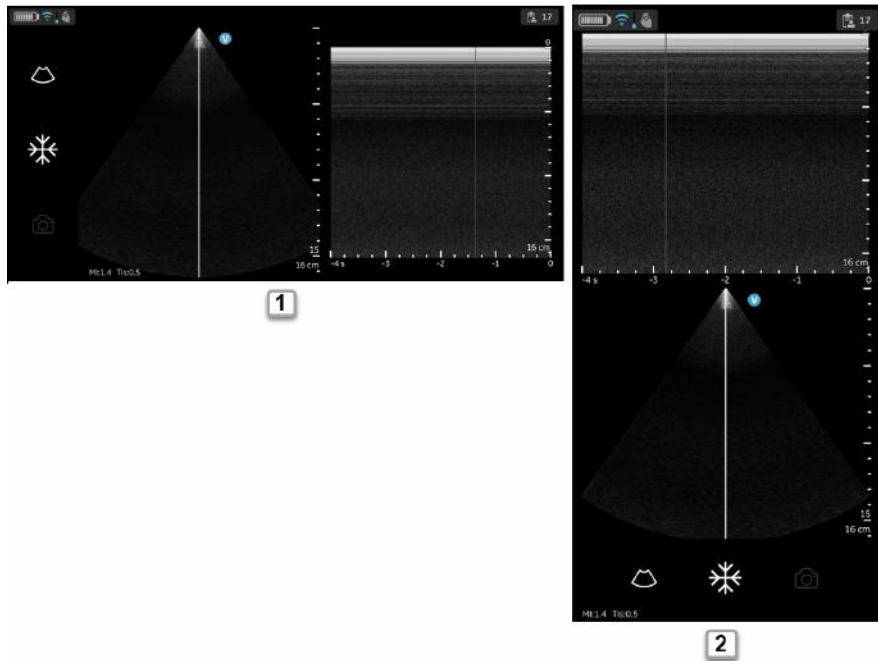
1. M-mode Landscape
2. M-mode Portrait

Figure 5-39.   M-mode layout

NOTE: *If selecting to use landscape when the display device (tablet) is being 7.3 inch (diagonal) or larger, the over/under layout (as in portrait) will be used instead of the side/side layout indicated in Figure 5-39.*

M-mode measurements

Basic measurements that can be taken in the M-mode portion of the display are:

- Distance
- Time Interval
- Slope

NOTE: *The following instructions to be performed:*

1. Scan the anatomy of interest in live B-mode.
2. Activate live M-mode.
3. Position the M-mode cursor over the tissue of interest.
4. Press **freeze**.

Distance on M-mode

Distance measurements in M-mode is vertical distance from one caliper point to the next caliper point.

1. On a frozen image, press **Measure**.
2. Select Vertical distance.
3. Position the calipers.
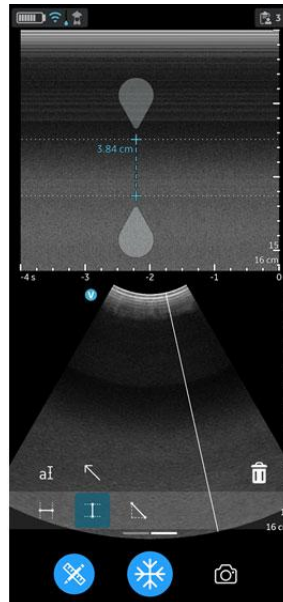
Figure 5-40.   Positioning Calipers

4. The system displays the vertical distance.
5. To store the image with a measurement, press **store**.

Time interval on M-mode

To measure a horizontal time interval:

1. On a frozen image, press **Measure**.
2. Select the Time measurement tool.
3. Position the calipers in the M-mode window to measure the desired time interval.
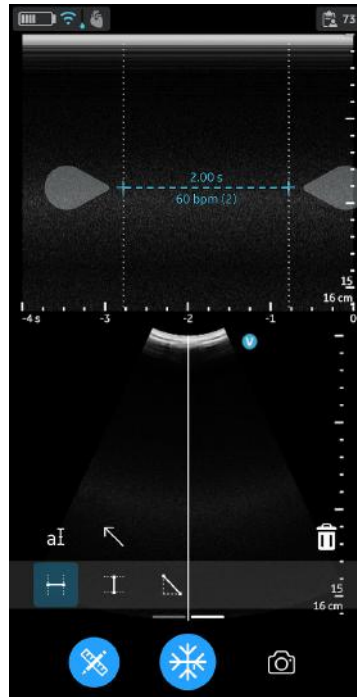
Figure 5-41.   Time interval - M-mode

4. The system displays the time measurement and the corresponding calculated heart rate. The number of beats used for the heart rate calculation is listed with the calculated heart rate. Example 60 bpm (2) refer the Figure 5-41
5. To store the image with a measurement, press **store**.

Slope on M-mode

To measure slope between two points:

1. On a frozen image, press **Measure**.
2. Select slope measurement.
3. Position the calipers to measure slope.
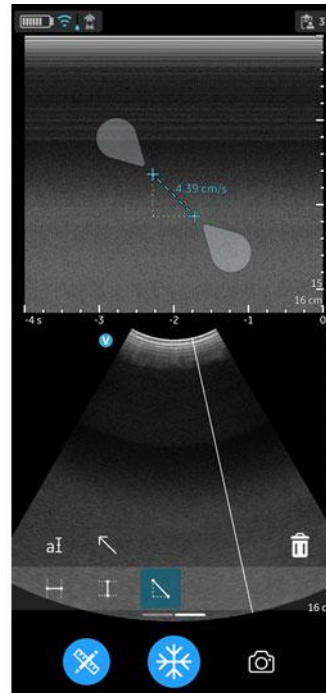
Figure 5-42. Positioning Calipers

4. The system displays the slope measurement result.
5. To store the image with a measurement, press store.

Storing an image

Press **Store** button on the scan screen when the image is frozen to store a still image.
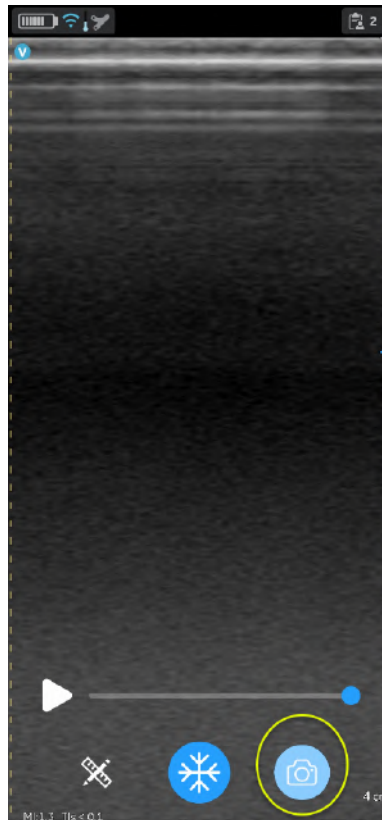
Figure 5-43.   Store still image

Storing a video

To store a video:

1. Press the '**Store**' button on the scan screen when the image is live.

    OR

2. Play the video buffer by using the '**Play**' button on the video scroll bar and then press **Store**.

    Press **Store** button on the scan screen to store a video.

Figure 5-44.   Store video

Protected Health Information

Protected Health Information is the data that helps in identifying a patient. It is possible to either manually enter patient details/ patient data in the Vscan Air application or assign patient/Study information from a scheduled exam retrieved from the Modality Worklist Server.

Assign Patient data manually to the current exam

To assign patient details manually to the current exam in Vscan Air application, follow the procedure below.

1. Swipe from right to left.

   OR

   Press **Exam** icon on the top right corner.
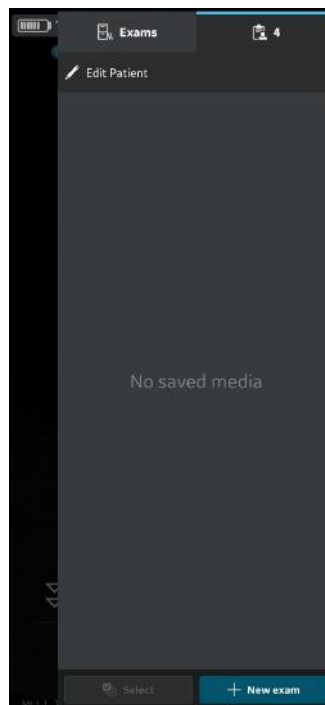
Figure 5-45.   Exam icon

NOTE: *Patient data can be assigned to an individual exam only.*
             The Patient data cannot be assigned to more than one
             exam simultaneously.

Assign Patient data manually to the current exam (continued)

2. Press "**Edit Patient**" and enter the required exam information in the respective fields. The Study Description field is editable and has a 64-character limit. Press "**Save**" button to assign data to the current exam. After saving data successfully the application takes you to the scan screen.
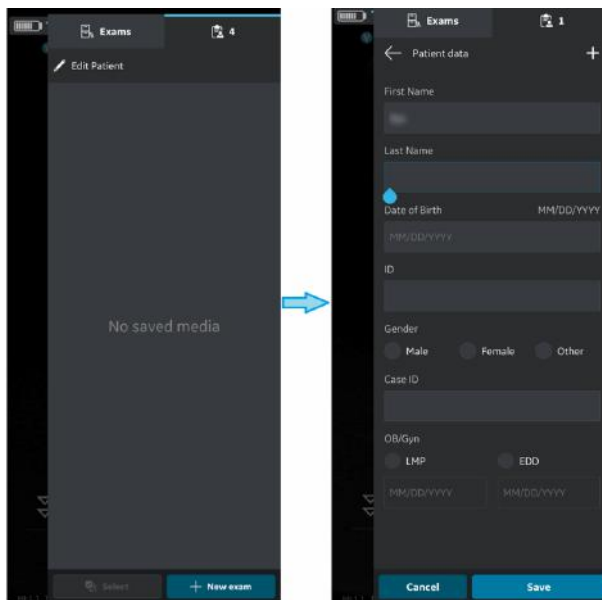
Figure 5-46.   Edit Patient

NOTE: *Be aware that the Operator's Name field is filled with the text before the @ symbol of the email ID of the logged in user as the default value.*

NOTE: *Once an export of exam images/videos has been initiated, the patient details assigned to that particular exam can not be edited in the app.*

Assign Patient data manually to the current exam (continued)

> 3. Patient's Last Name, First Name and ID are shown on the scan screen header.

1. Patient last name and first name
2. Patient ID

Figure 5-47.   Scan screen with patient data

> 4. Press **Exam** icon to view the images/videos under current exam.

Assign Patient data manually to an existing Exam

To assign patient details manually to an existing exam in Vscan Air application, follow the procedure below.

1. Swipe from right to left.

   OR

   Press **Exam** icon on the top right corner.
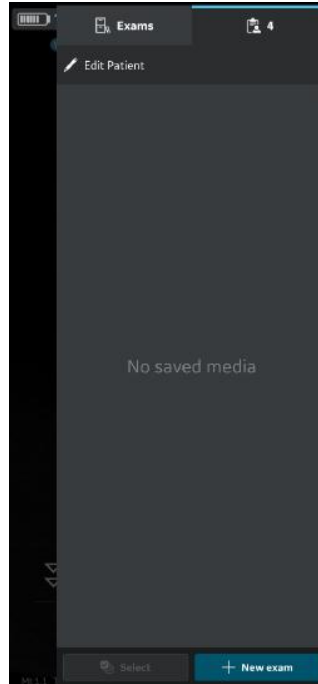
Figure 5-48.   Exam icon

Assign Patient data manually to an existing Exam (continued)

2. Press **Exam** tab.

Press the desired Exam for which you wish to assign Patient data.

Figure 5-49.   Exam Tab

NOTE: *Patient data can be assigned to an individual exam only. The Patient data cannot be assigned to more than one exam simultaneously.*

Assign Patient data manually to an existing Exam (continued)

3. Press "**Edit Patient**" button at top right corner and enter the required information in the respective fields under "Patient data" screen. The Study Description field has a 64-character limit.

Press "**Update**" button to assign Patient data to the existing exam. After successful assignment of Patient data, application takes you to the scan screen.
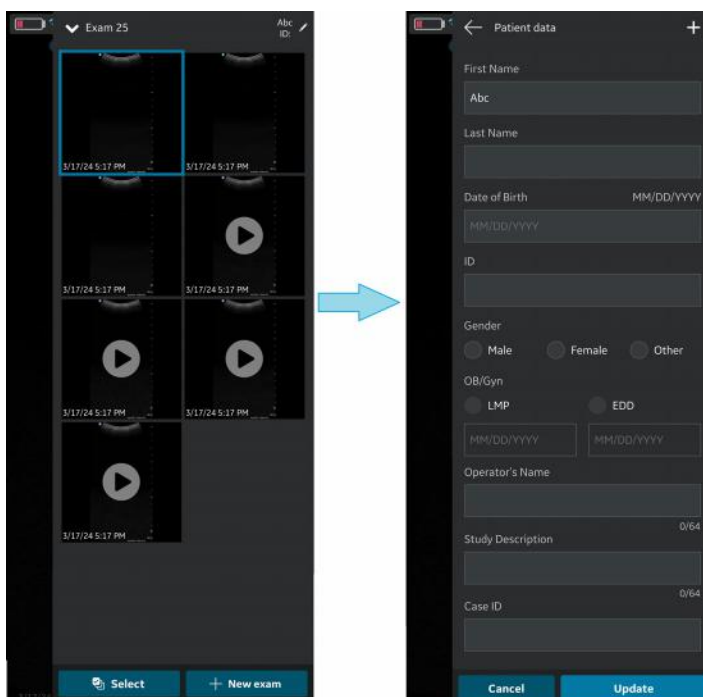
Figure 5-50.   Edit exam

NOTE: *Be aware that the Operator's Name field is filled with the text before the @ symbol of the email ID of the logged in user as the default value.*

NOTE: *Once an export of exam images/videos has been initiated, the patient details assigned to that particular exam can not be edited in the app.*

Assign Patient data manually to an existing Exam (continued)

4. Patient's Last Name, First Name and ID are shown on the top of the scan screen.
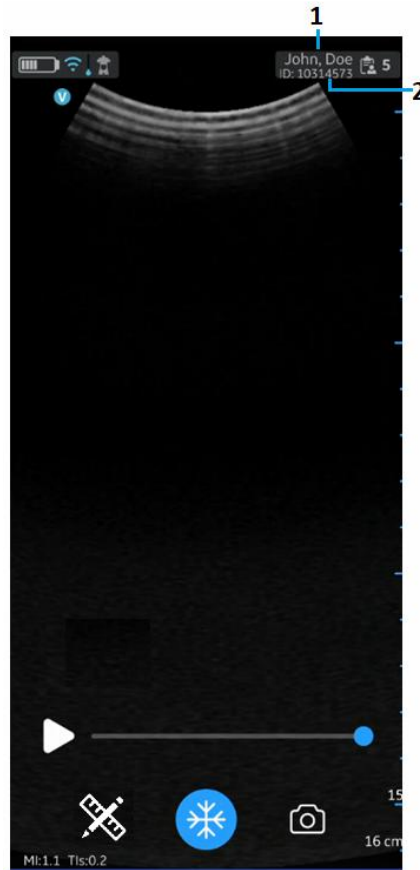
1. Patient Last name and first name
2. Patient ID

Figure 5-51.   Scan screen with Patient data

5. Press **Exam** icon to view the images/videos under the existing exam.

Assign Patient data from Modality Worklist Server to the current exam

Vscan Air can download and refresh a DICOM modality worklist. An exam can be linked to an existing patient pulled from the worklist, prior to exporting to the DICOM image server.

To assign Patient data from a modality worklist server to the current exam in the Vscan Air application, follow the procedure below.

1. Swipe from right to left.

   OR

   Press **Exam** icon on the top right corner.
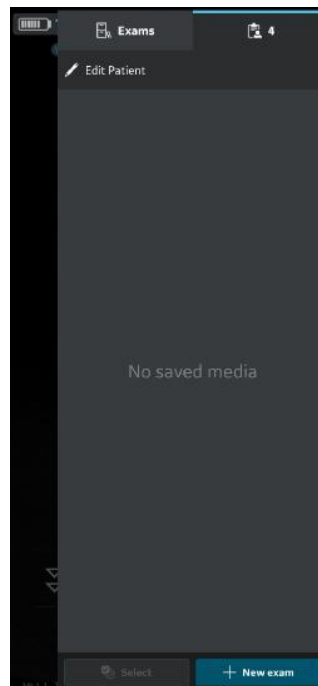
Figure 5-52.   Exam Icon

NOTE: *Patient data can be assigned to an individual exam only. The Patient data cannot be assigned to more than one exam simultaneously.*

Assign Patient data from Modality Worklist Server to the current exam (continued)

2. Press "**Edit Patient**" and then Press the ➕ symbol at top right corner of "**Patient data**" screen.
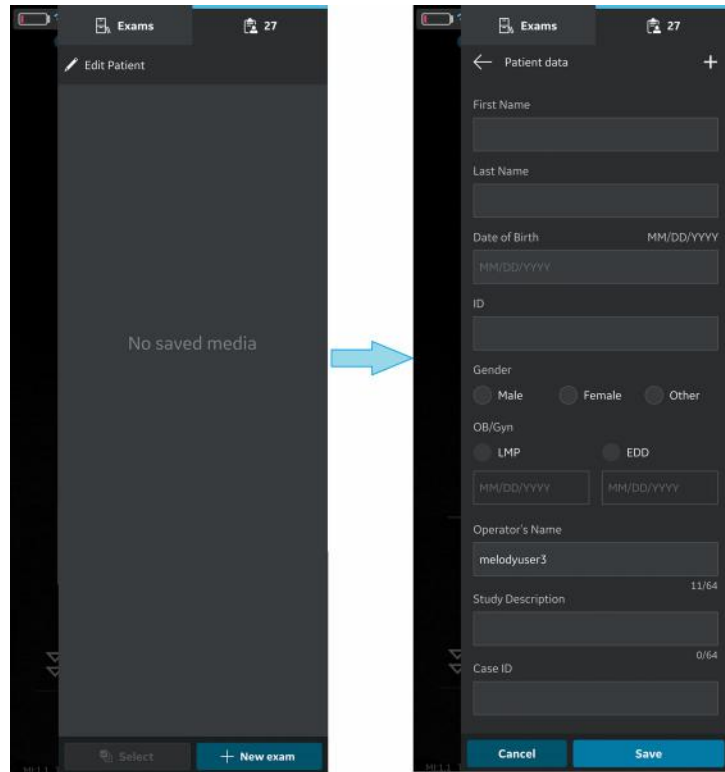
Figure 5-53.   Edit Patient

NOTE: *Be aware that the Operator's Name field is filled with the text before the @ symbol of the email ID of the logged in user as the default value.*

Assign Patient data from Modality Worklist Server to the current exam (continued)

3. Press the refresh button on the "Worklist" screen to import the list of patients from Modality Worklist Server. Patient data can be added to current exam in one of the following ways:

   a. Tap on the desired Patient Name / Patient ID from the imported list of patients OR

   b. Make a local search to find the details of a particular patient from the imported list of patients - by entering Patient Name / Patient ID in the "Filter" field on the screen OR

   c. Make a remote search to find the details of a particular patient from selected Modality Worklist Server – by entering Patient ID in the "Patient Query" field on the screen.
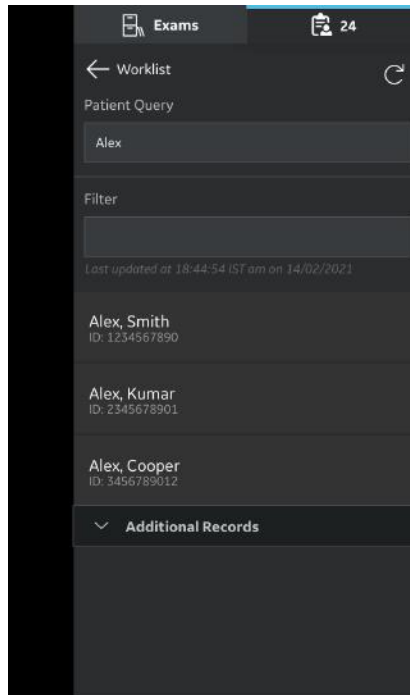
Figure 5-54.   Search Patient

Assign Patient data from Modality Worklist Server to the current exam (continued)

NOTE: *When a remote search is initiated, only the records matching the search criteria will be displayed on the screen. If user moves away from the worklist screen and comes back, the worklist screen will display the imported list of records and clears the remote search results.*
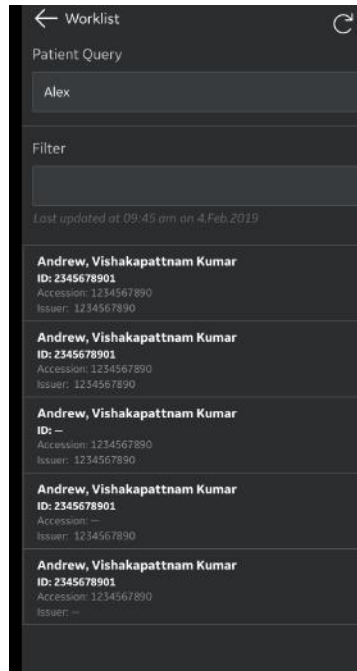
Figure 5-55.   Worklist

NOTE: *Make sure that the display device hosting Vscan Air app and the PC in which server is configured are connected to same network.*

NOTE: *When you refresh the patient details in "worklist" screen, the connection between Vscan Air Probe and display device may be temporarily interrupted.*

NOTE: *For any patient, if details are missing in Modality Worklist server, import of those patient records will be rejected in the application and it will be displayed in the patient list as "Rejected".*

Assign Patient data from Modality Worklist Server to the current exam (continued)

4. Press "**Save**" button to assign Patient data to the current exam. After successful assignment of Patient data, application takes you to the scan screen. The Study Description field is editable and has a 64-character limit.

    Patient's Last Name, First Name and ID are shown on the top of the scan screen.
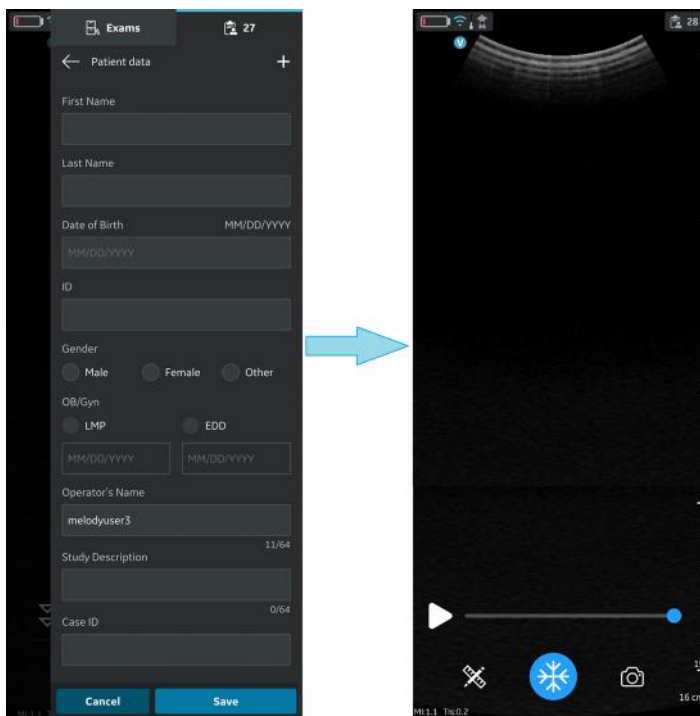
Figure 5-56.   Add patient

5. Press **Exam** icon to view the images/videos under current exam.

NOTE: *Be aware that the Operator's Name field is filled with the text before the @ symbol of the email ID of the logged in user as the default value.*

NOTE: *Once the patient from the Modality Worklist server is assigned to an exam, the patient details assigned to that particular exam can not be edited in the app.*

Assign Patient data from Modality Worklist Server to an existing exam

Vscan Air can download and refresh a DICOM modality worklist. An exam can be linked to an existing patient pulled from the worklist, prior to exporting to the DICOM image server.

To assign Patient data from a modality worklist server to an existing exam in the Vscan Air application, follow the procedure below.

1. Swipe from right to left.

   OR

   Press **Exam** icon on the top right corner.
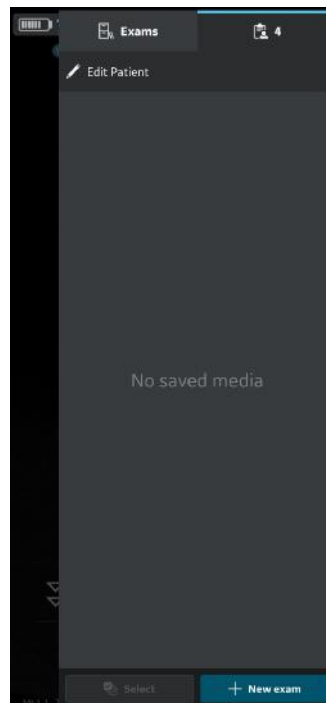
Figure 5-57.   Exam Icon

NOTE: *Patient data can be assigned to an individual exam only. The Patient data cannot be assigned to more than one exam simultaneously.*

Assign Patient data from Modality Worklist Server to an existing exam (continued)

2. Press **Exams** tab.

   Press the desired Exam for which you wish to assign Patient data.
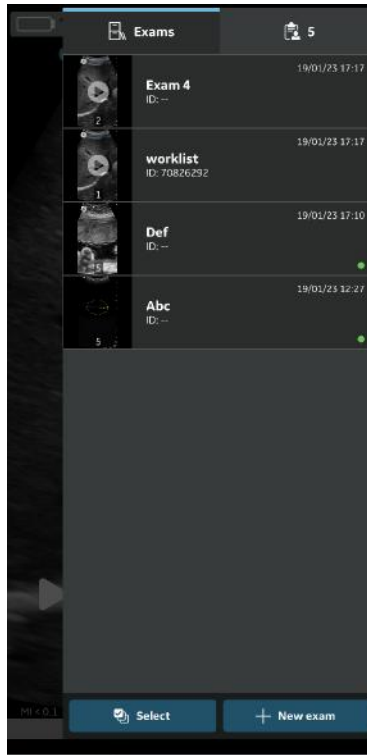
Figure 5-58.   Exam tab

Assign Patient data from Modality Worklist Server to an existing exam (continued)

3. Press "**Edit Patient**" button at top right corner.

Press the ➕ symbol on "**Patient data**" screen.
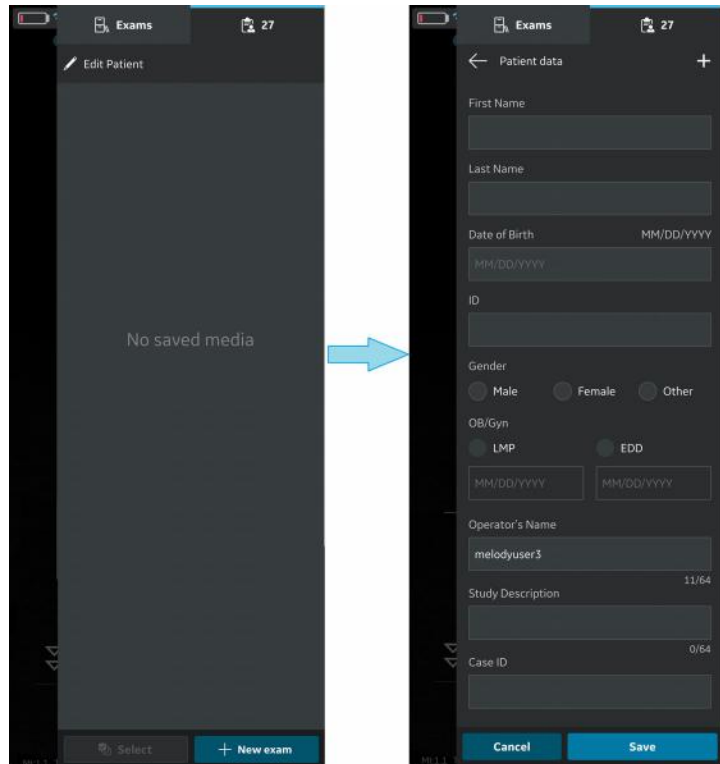
Figure 5-59.   Edit Patient

NOTE: *Be aware that the Operator's Name field is filled with the text before the @ symbol of the email ID of the logged in user as the default value.*

Assign Patient data from Modality Worklist Server to an existing exam (continued)

4. Press the refresh button on the "Worklist" screen to import the list of patients from Modality Worklist Server. Patient data can be added to current exam in one of the following ways:

   a. Tap on the desired Patient Name / Patient ID from the imported list of patients OR

   b. Make a local search to find the details of a particular patient from the imported list of patients - by entering Patient Name / Patient ID in the "Filter" field on the screen OR

   c. Make a remote search to find the details of a particular patient from selected Modality Worklist Server – by entering Patient ID in the "Patient Query" field on the screen.
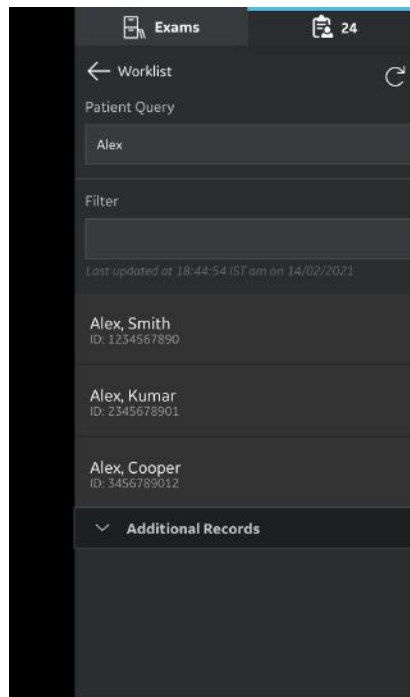
Figure 5-60.   Search patient

Assign Patient data from Modality Worklist Server to an existing exam (continued)

> *NOTE:*   *When a remote search is initiated, only the records matching the search criteria will be displayed on the screen. If user moves away from the worklist screen and comes back, the worklist screen will display the imported list of records and clears the remote search results.*
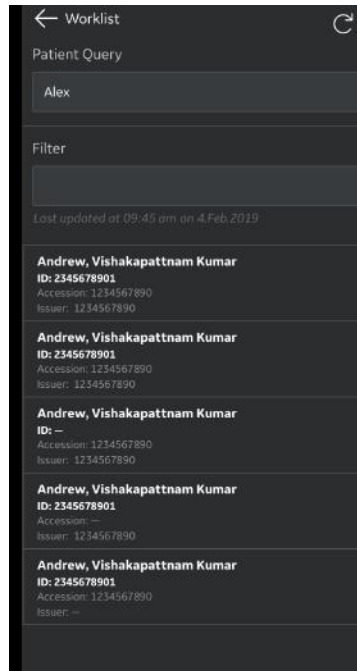
Figure 5-61.   Worklist

> *NOTE:*   *Make sure that the display device hosting Vscan Air app and the PC in which server is configured are connected to same network.*

> *NOTE:*   *When you refresh the patient details in "worklist" screen, the connection between Vscan Air Probe and display device may be temporarily interrupted.*

> *NOTE:*   *For any patient, if details are missing in Modality Worklist server, import of those patient records will be rejected in the application and it will be displayed in the patient list as "Rejected".*

Assign Patient data from Modality Worklist Server to an existing exam (continued)

5. Press "**Update**" button to assign Patient data to the existing exam. After successful assignment of Patient data, application takes you to the scan screen. The Study Description field is editable and has a 64-character limit.

   Patient's Last Name, First Name and ID are shown on the top of the scan screen.
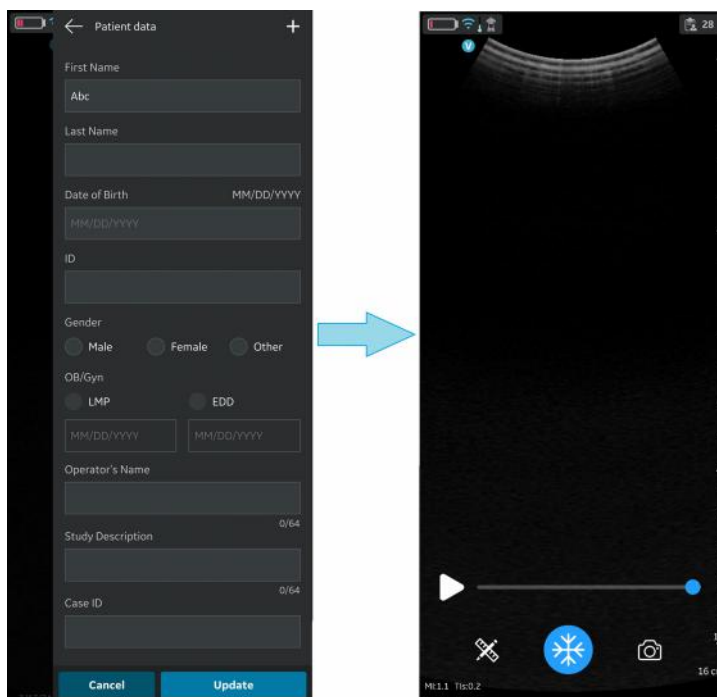
Figure 5-62.   Add patient

6. Press **Exam** icon to view the images/videos under the existing exam.

NOTE: *Be aware that the Operator's Name field is filled with the text before the @ symbol of the email ID of the logged in user as the default value.*

NOTE: *Once the patient from the Modality Worklist server is assigned to an exam, the patient details assigned to that particular exam can not be edited in the app.*

Measurements

Taking measurements

The Vscan Air app enables distance, time, velocity, angle, and ellipse circumference measurements. Measurements can be made during image review or on images recalled from the gallery.

To perform a distance measurement:

1. On a frozen image, press the **Measure/Annotate** button.

    The '**Distance**', '**Ellipse**' and '**Angle**' measurements options are available with distance being activated.
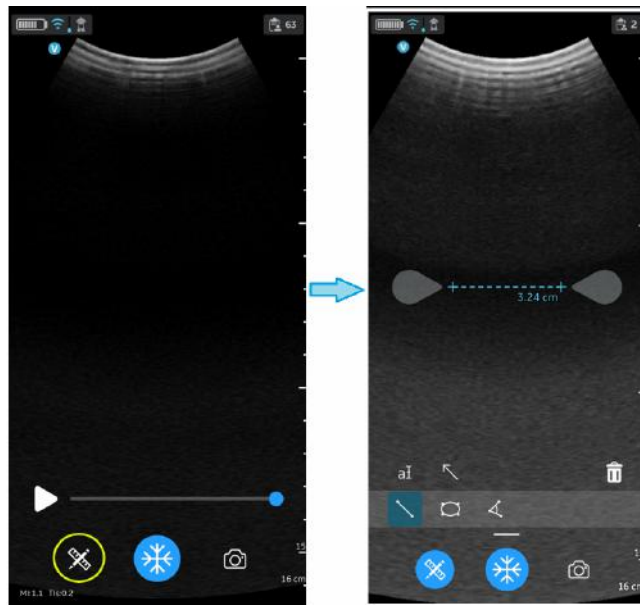
Figure 5-63.   Select measurement

Taking measurements (continued)

2. Drag to position the calipers to obtain the desired distance measurement.

3. To store the image with a measurement, press **store**.

To make additional measurements:

1. Press the distance measurement icon again to make additional measurements on the displayed image.

To delete a distance measurement:

1. Select the measurement you wish to delete.

2. Press '**Bin**' icon to delete the selected measurement.

To perform an ellipse measurement:

1. On a frozen image, press the **Measure/Annotate** button. The ellipse measurement tool displays.
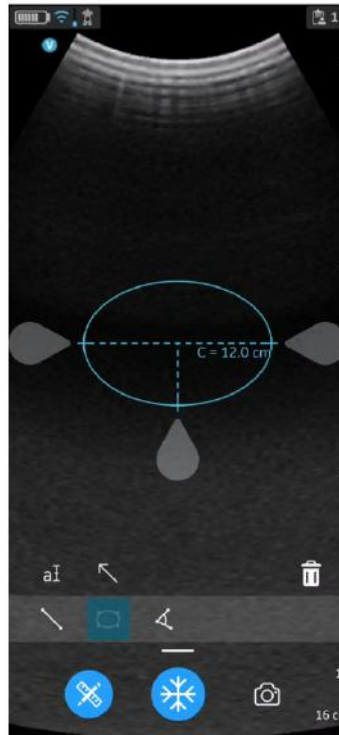
Figure 5-64.   Select Ellipse measurement

Taking measurements (continued)

2. Drag to position the calipers to obtain the desired ellipse circumference measurement.

3. To store the image with a measurement, press **store**.

NOTE: *Only a single ellipse measurement can be performed on the displayed image.*

To delete an ellipse measurement:

1. Select the measurement.

2. Press the '**Bin'** icon to delete the selected measurement.

To perform an angle measurement:

1. On a frozen image, press the Measure/Annotate button. The 'Distance', 'Ellipse' and 'Angle' measurements options are available with distance being activated.

2. Select Angle.
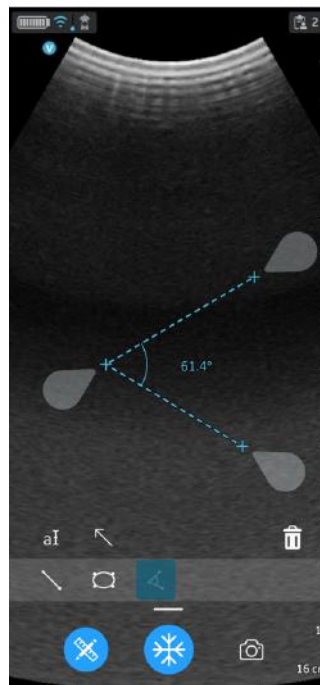
Figure 5-65.   Select Angle measurement

Taking measurements (continued)

3. Drag to position the calipers to obtain the desired Angle measurement.

4. Press the store button to store the result if needed.

To delete an angle measurement:

1. Select the measurement.

2. Press the '**Bin**' icon to delete the selected measurement.

To exit the **Measure** mode select the '**Measure**' icon or press '**Freeze**' icon or switch frame with Video buffer slider.

OB (Obstetric) measurement

Obstetric measurements are available on images obtained using the OB preset. The following OB measurements are supported:

•   BPD, FL, CRL

•   HC, AC

•   Amniotic Fluid Index (AFI)

•   Deepest Vertical Pocket

•   Angle of Progression (AOP)

NOTE: *The Vscan Air obstetric measurements module supports measurements and reporting for one fetus per exam. If you need to measure and report on a case of multiple gestations, a separate Exam will need to be created for measuring and reporting each of the fetuses.*

OB Distance measurement

Biparietal Diameter (BPD), Femur Length (FL) and Crown Rump Length (CRL) are among the basic distance measurements used to assess fetal size.

1. Navigate to OB measurement screen by clicking the measurement tool while in the OB preset. Select the BPD, FL or CRL measurement tool.

2. Make a distance measurement. The system displays the BPD, FL or CRL measurement value.

3. Press the store button to store the result in the OB worksheet.
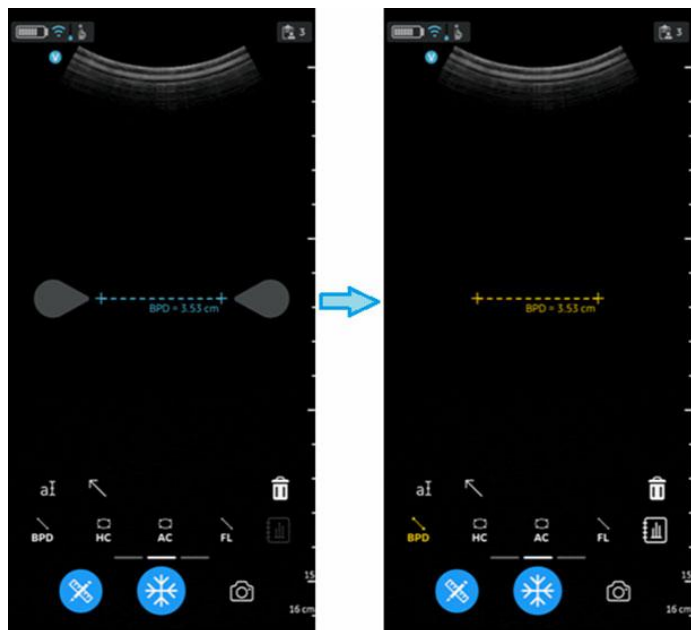
Figure 5-66.   Biparietal diameter value

OB Ellipse measurement

Abdominal Circumference (AC) and Head Circumference (HC) are among the basic parameters used to assess fetal size.

1. Navigate to the OB measurement screen, and select HC or AC.

2. Make an ellipse measurement. The system displays the HC or AC circumference value.

3. Press the store button to store the result in the OB worksheet.
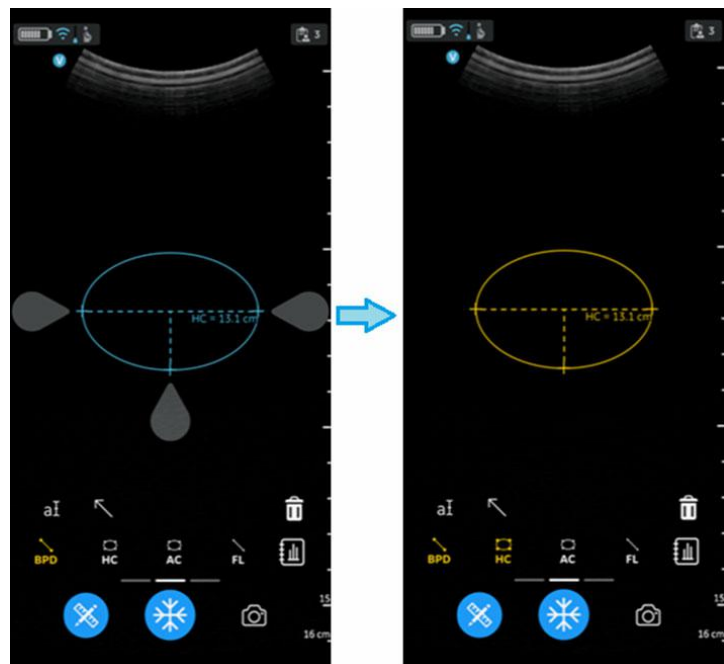
Figure 5-67.   Head circumference

AFI – Amniotic Fluid Index

AFI is the sum of deepest depth of amniotic fluid in each quadrant of ultrasound images. Here, Q1, Q2, Q3, and Q4 indicate each quadrant.

To calculate the amniotic fluid index, make one or four distance measurements.

To make a AFI (Q1, Q2, Q3, and Q4 Caliper) measurement:

- Navigate to OB measurement screen, and select AFI for the required quadrant (Q1, Q2, Q3, and Q4 Caliper).
- Make a distance measurement. The system displays the measured value against the respective quadrant value in the results window as shown in the below Figure 5-68.
- Select the **>0<** button to set a particular quadrant to zero.
- The AFI value is calculated from the various quadrant values measured.
- Press the store button to store the result in the OB worksheet.
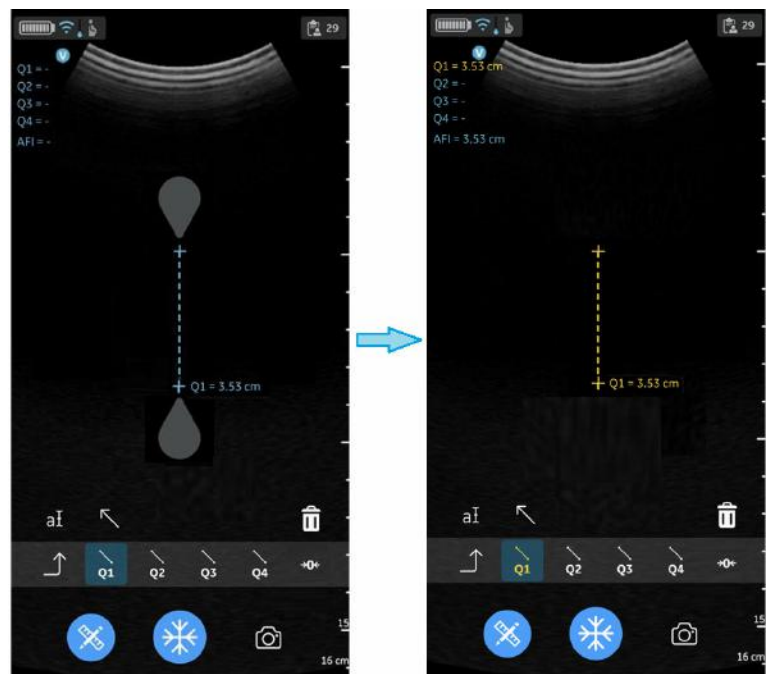
Figure 5-68.   AFI Q1 Caliper

Set >0<

Select the **>0<** button to set the current quadrant value to zero.
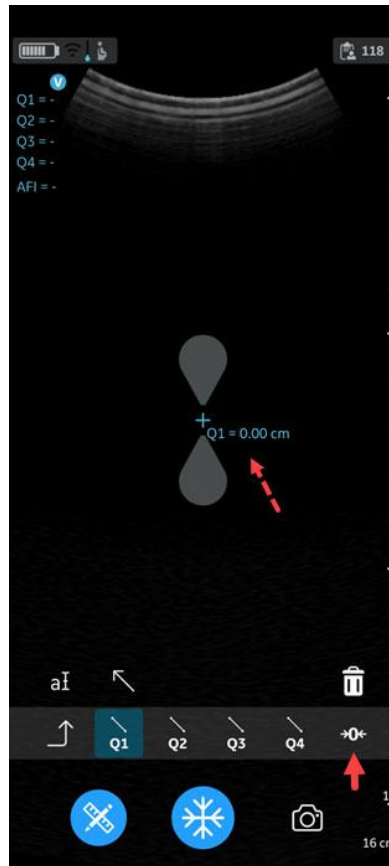
Figure 5-69.   Set >0<

DVP - Deepest Vertical Pocket

User can measure DVP using a pre-assigned measurement caliper. The deepest (maximal) vertical pocket depth is considered a reliable method for assessing amniotic fluid volume on ultrasound. It is performed by assessing a pocket of a maximal depth of amniotic fluid which is free of an umbilical cord and fetal parts.

1. Navigate to OB measurement screen, and select DVP.
2. Make a distance measurement. The system displays the DVP value.
3. Press the store button to store the result in the OB worksheet.
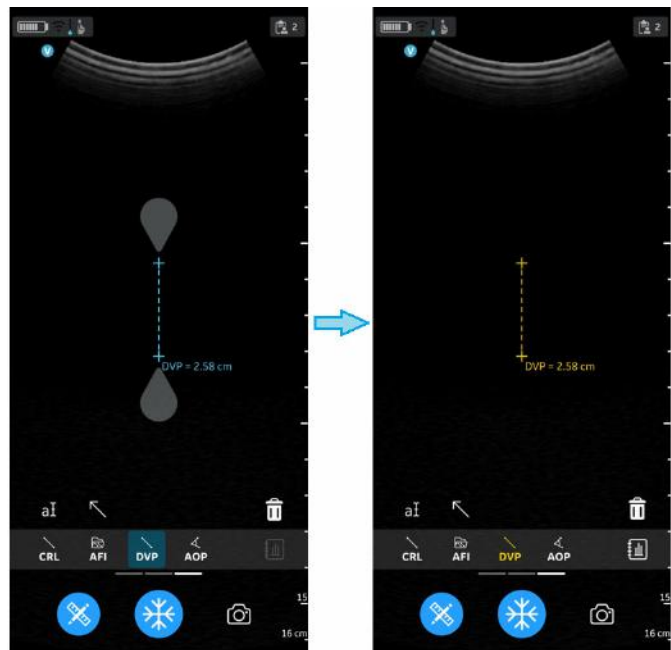
Figure 5-70.   Deepest vertical pocket

AOP- Angle of Progression

The AOP is a simple and reliable ultrasound parameter for the assessment of the descent of the fetal head.

1. Navigate to the OB measurement screen, select AOP.
2. Drag the calipers to the appropriate location based on position of the fetal head on the image.
3. The system displays the AOP value.
4. Press the store button to store the result in the OB worksheet.
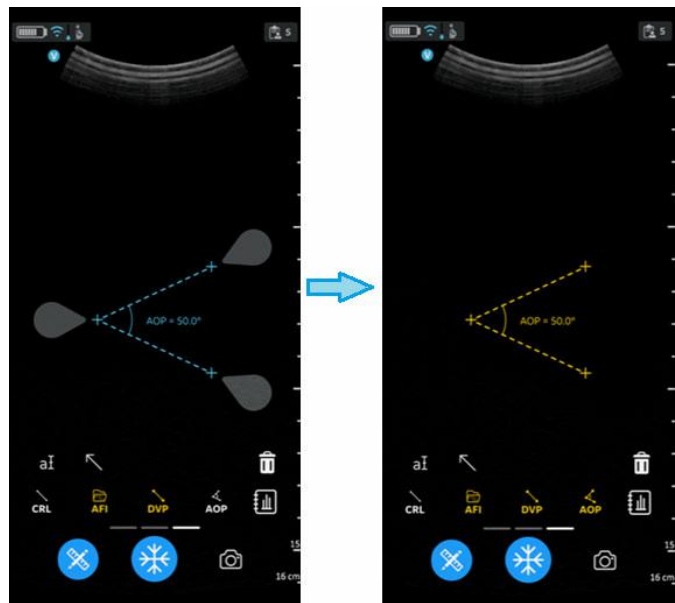
Figure 5-71.   Angle of progression

EFW – Estimated Fetal Weight

Fetal weight is estimated using the selected table (e.g. Hadlock) based on the different measurements that have been made for an exam. The supported options include:

- EFW (AC, BPD)
- EFW (AC, FL)
- EFW (BPD, AC, FL)
- EFW (HC, AC, FL)
- EFW (BPD, HC, AC, FL)

The system displays each measurement and the estimated fetal weight in the OB report.

OB Worksheet/Report

View and store Worksheet/Report

To review the OB measurement results and their corresponding calculation results, select the Worksheet icon available in the OB measurement menu. The Worksheet icon is not active until a measurement has been stored. See Figure 5-66 *on page 5-81*.

A report will be generated on the Report Button Clicked which will show the measurements taken, Gestational age (GA) calculated values, Average Ultrasound Age (AUA), Estimated Fetal Weight (EFW), Last Menstrual Period (LMP) or Estimated Date of Delivery (EDD) from the patient information.

View and store Worksheet/Report (continued)

Fetal biometry measurement results and calculations are available in the OB worksheet/report.

1. To view the OB worksheet/report tap the worksheet/report icon as illustrated in Figure 5-72

2. To save the OB worksheet/report tap the Save button in the OB worksheet/report as illustrated in Figure 5-72
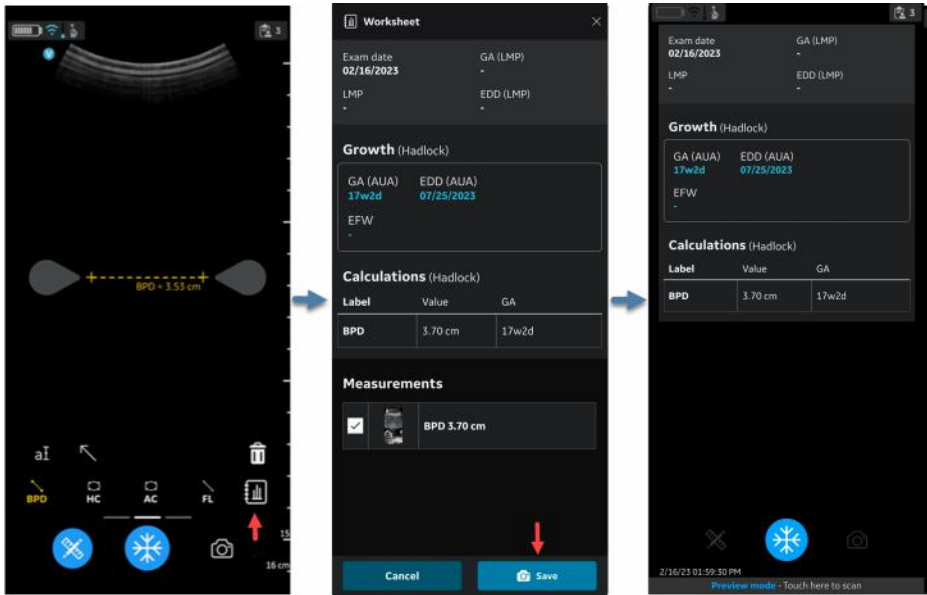
Figure 5-72. OB worksheet/report

NOTE: *Be aware that the selected preset (see Figure 3-8) needs to be the OB/GYN preset to enable OB measurements also when reviewing images stored to the image gallery.*

Measurement out of range

If a measurement used for calculating fetal age is outside the range accepted as input for the calculation, meaning that the measurement is either less than or greater than the range allowed, a 'hyphen' will be shown as the Gestational Age (GA) result. See Figure 5-73.
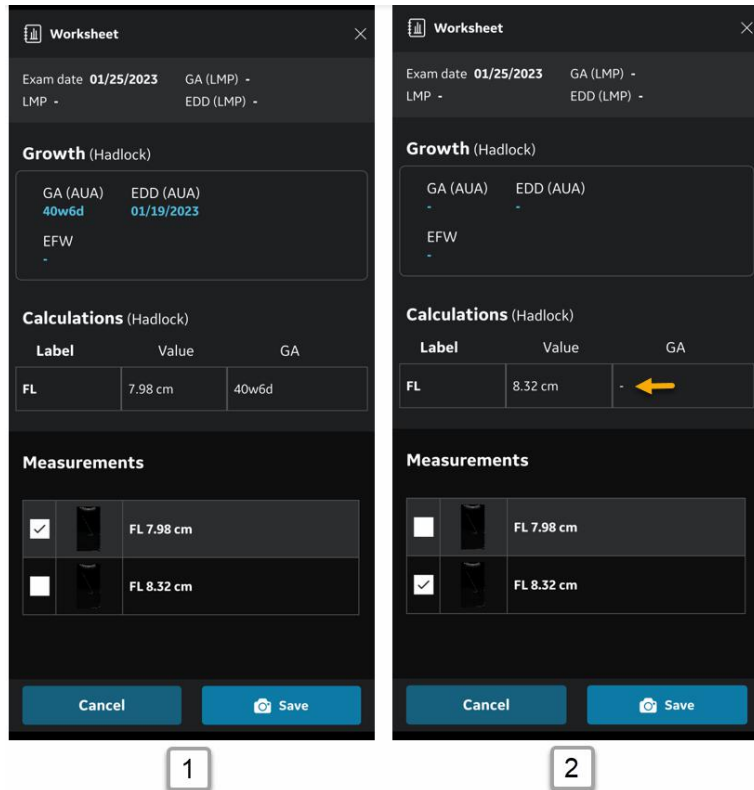
1. FL (Hadlock) < 8.2cm
2. FL (Hadlock) > 8.2cm

Figure 5-73.   FL (Hadlock)

Annotations

Introduction

The Annotation function provides the capability to type comments of free text and/or add pointer(s)/arrow(s).

Text annotations may be inserted anywhere in the image area.

- Annotation features are available for all presets and modes for both CL and SL probes.
- Annotation features are available in Freeze and for data recalled for review.
- The Vscan Air app supports a maximum of 5 annotation texts on a frozen or recalled image.

To add annotations on an image, activate the mode by clicking ▣ button which is available in the Tool bar.

Annotating an image

1. Select the desired preset and tap Annotation aI icon.
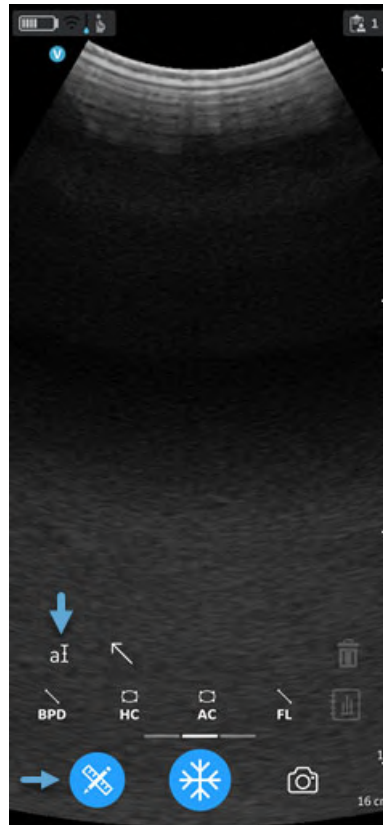
Figure 5-74.   Tap annotation icon

Annotating an image (continued)

2.   Use the keyboard to type the desired text and press done.
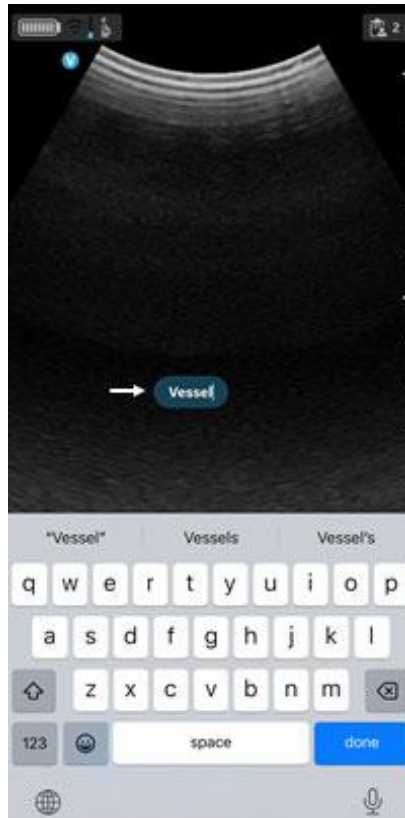
Figure 5-75.   Text annotation

Default position for annotations text box is illustrated in
Figure 5-75.

Annotating an image (continued)

3. Move the annotation box to the desired location and tap outside the annotation text field to exit annotation edit mode.
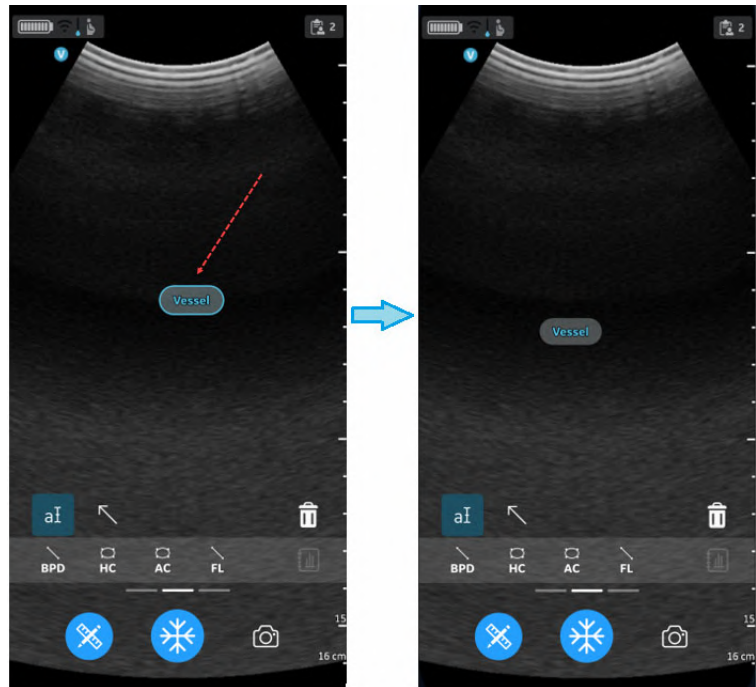
Figure 5-76.   Edit or clear annotation

NOTE: *A maximum of five arrows and five text annotations can be added to a frozen or a recalled image.*

Annotations states
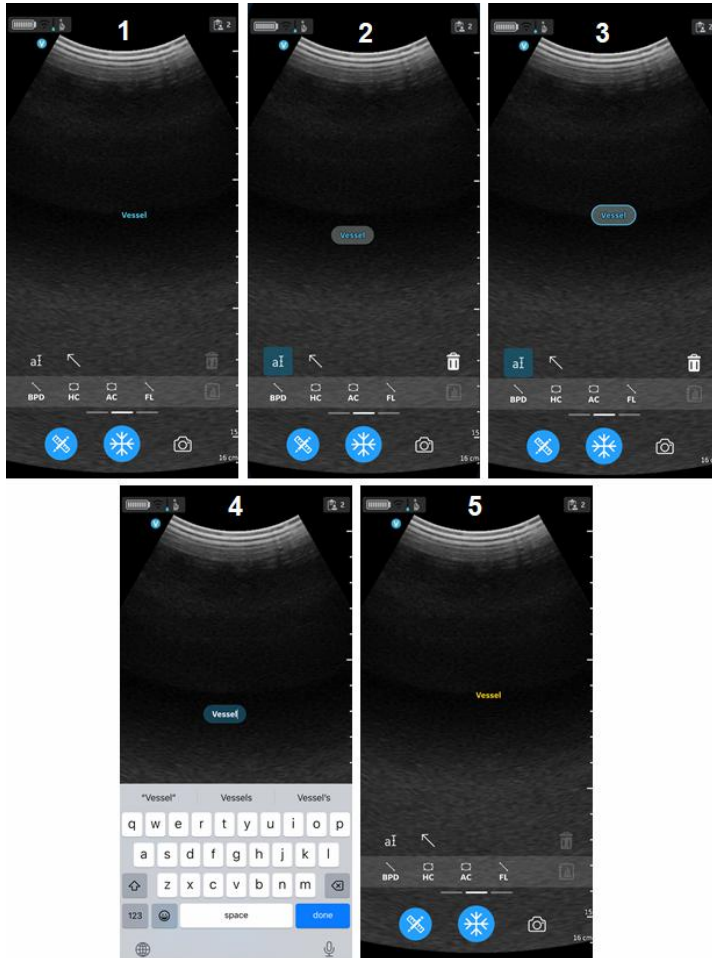
1. Inactive
2. Selected
3. Interactive
4. Editing
5. Stored

Figure 5-77.   Annotations states

Edit an Annotation

Tap the annotation text field to select the text and tap again to enable editing. Press '**done**' on the keyboard and tap outside the annotation text field to exit annotation edit mode.
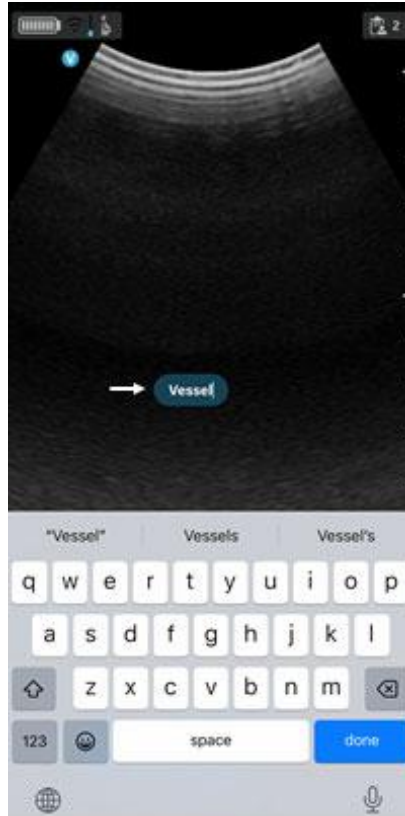
Figure 5-78.   Edit annotation

Reposition an Annotation

Select Annotation, tap the annotation text and drag to position it elsewhere. Tap outside the annotation text field or select another tool to exit annotation edit mode.

NOTE: *User can position the annotations anywhere on the image.*
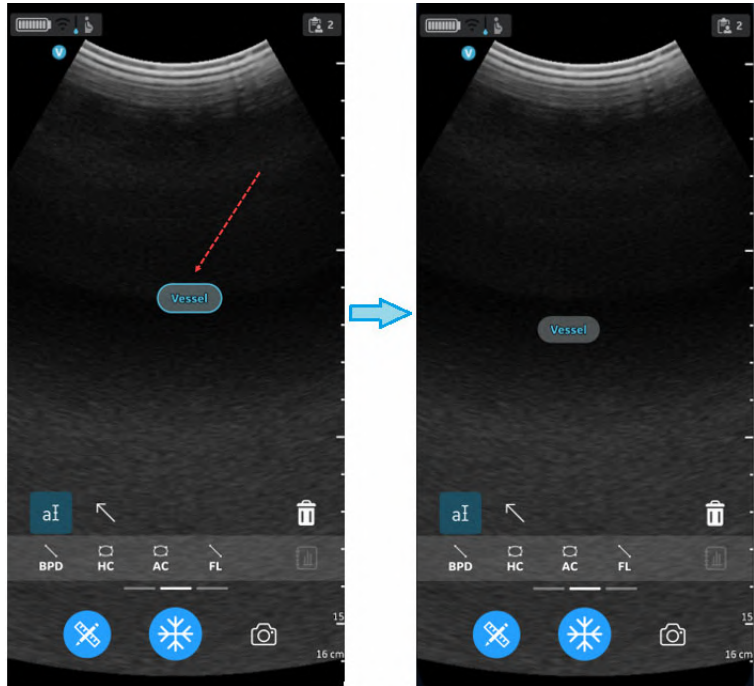
Figure 5-79.   Repositioning annotation

Delete Annotation

1. Select Annotation and single tap to enter selected mode.
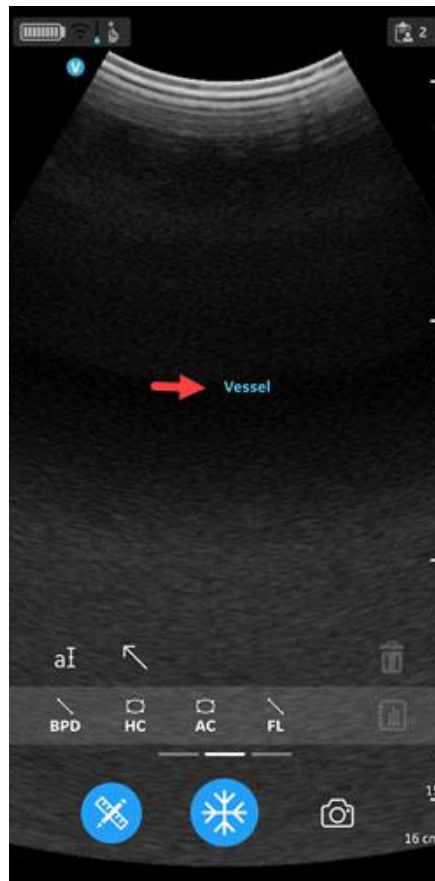
Figure 5-80.   Select annotation

Delete Annotation (continued)

2. Tap the 🗑 icon to delete. When the Bin icon is tapped, the selected item is deleted, and any previous entered annotation is selected. The last in first out principle applies to annotations, measurements, and arrows.
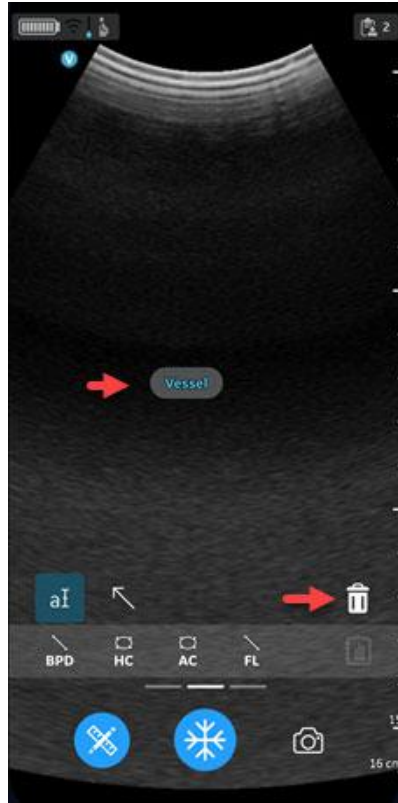
Figure 5-81.   Deleting annotation

Arrow Pointer

1. Tap **Comment** and select **Arrow**.
2. Select the desired arrow pointer and move it to the target position on the screen.

NOTE: *The length of the arrow pointers can be changed by moving the teardrop ends.*

3. Press anywhere on the scanning screen to set the arrow pointer or press to delete it.

   User can lengthen, position or rotate the arrow pointer anywhere on the image.

   The Vscan Air app supports a maximum of 5 pointers/ arrows on a frozen or recalled image.

Arrow states
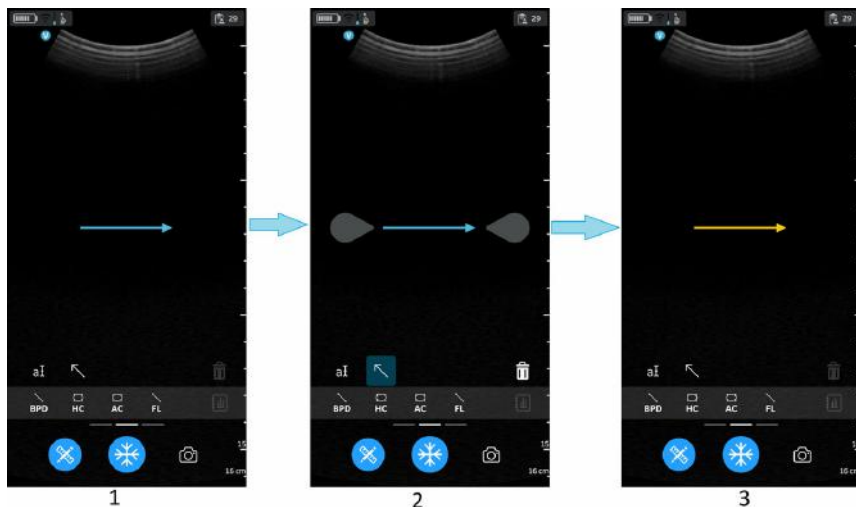
1. Inactive
2. Selected and interacting mode
3. Stored

Figure 5-82.   Arrow states

Review and recall of stored data

Review Current Exam

1. Swipe from right to left.

   OR

   Tap on **Exam** icon on the top right corner.

   Images and video loops captured in current exam is shown.

2. Select to activate and review stored images.
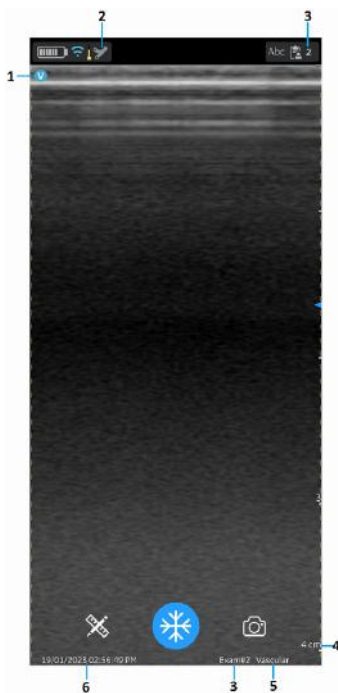
1. Image orientation marker
2. Recalled image preset icon
3. Recalled image exam number
4. Recalled image depth
5. Recalled image preset
6. Recalled image date and time

Figure 5-83.   Recalled stored image

Review Saved Exams

1. Swipe from right to left.

    OR

    Tap on **Exam** icon on the top right corner.

2. Tap **Exams** on top tab.

    Saved exams will be shown in a list. Most recent exams are shown on top.

NOTE: *When accessing Exam list, select the desired image to go to the viewer. The viewer opens with selected image and the Exam list closes. The freeze button becomes active. You can unfreeze to continue scanning using the current exam.*

Delete images/videos

You can delete images or videos individually or from an exam list.

Delete images/videos from an exam list

The steps describe deleting entire exams from the list.

1. Open **Exam** List.
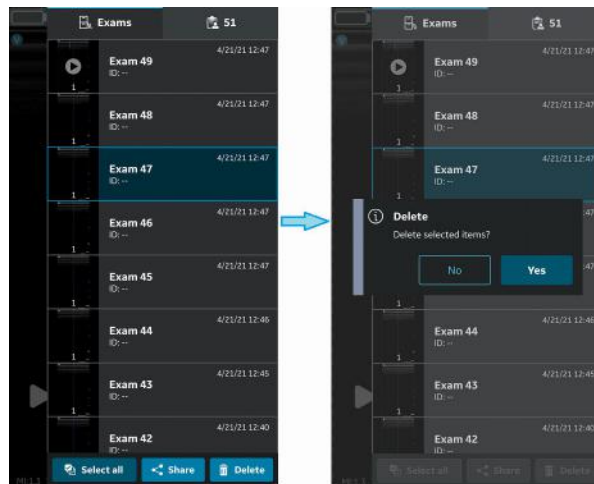
Figure 5-84.   Delete image or video

2. Select the desired Exam you wish to delete.

3. Press **Select** or Press and hold.

4. Press the '**Bin**' icon to delete.

Delete individual images/videos

1. Press **Select**.
2. Tap Select box on the image/video.
3. Press the '**Bin**' icon to delete.

Clear selection

1. Press **Select All**.
2. Press **Clear all** to clear the selection if you do not wish to delete.

NOTE: *If deleting the Vscan Air App from the display device, the App data, including all exam data including the images and videos will be deleted.*

Audit logs

An audit log is essentially a record of events and changes. Audit logs typically capture events by recording who performed an activity, what activity was performed, and how the system responded.

Audit logs are anonymous with regards to patient details. The Audit log captures the user ID (email).

Examples: Logging events related to Exam Data as for instance Add, Delete, Date/Time of data access.

In addition there are DICOM events being logged.

For exporting the audit log for review select «About | Export audit log».

The Audit log will then be available as a text file stored internally on the display device as the shown below.

- Internal storage:/Documents/AuditLog.txt (Android 12).

- Files/On my iPad/Vscan Air/AuditLog.txt (iOS 14 on iPad).

Audit logs (continued)
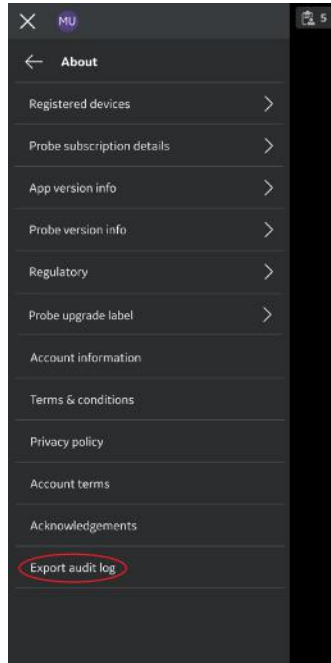
Figure 5-85.   Export audit log

Audit logs (continued)

> *NOTE:* *When storing the audit log file using an Android device the user will be given the option to choose the path and edit the file name before storing the file. This can be utilized to avoid overwriting the old audit log file.*
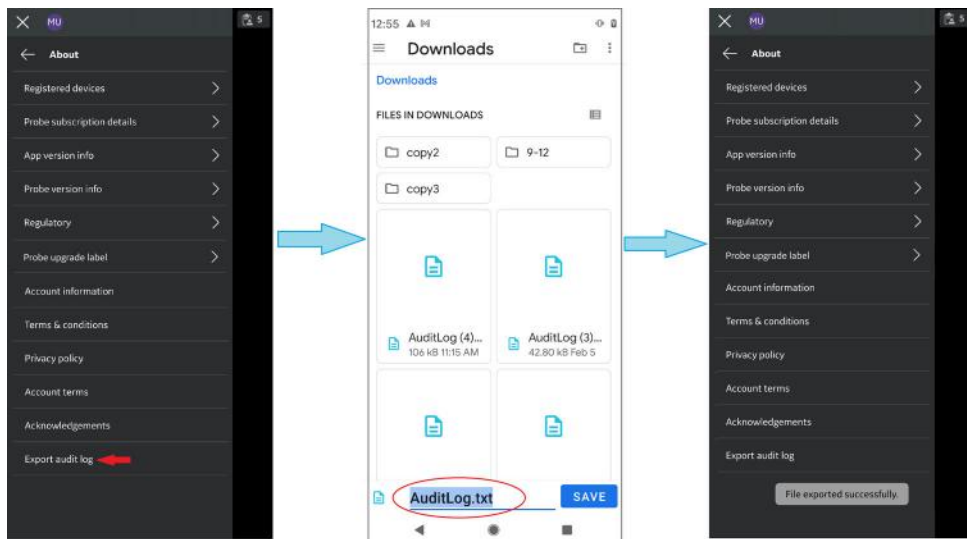
Figure 5-86.   Android audit log export

Audit logs (continued)

> *NOTE:*   *When storing the audit log file using an iOS device (iPhone or iPad) it will replace any already stored audit log file. If the audit log file or the Vscan folder is kept open in the background, the new file appears as another file with same file name. When the folder is refreshed (closed and opened again) the latest file will be displayed.*
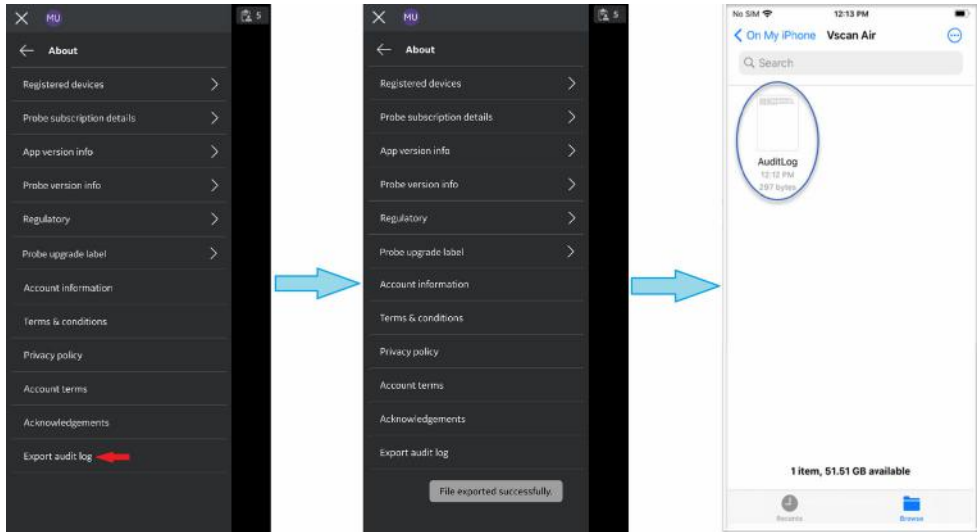
Figure 5-87.   iOS audit log export

Export data

The Vscan Air is regarded an imaging acquisition device and not an image storage device or image archive.

The maximum number of stored exams is limited to <500. The Vscan Air app will inform the user to export and/or delete exams as needed once the number of stored exams are 480 or higher.

The user should make sure to export images, videos (loops) or exams to an external storage device via the share function or the export to DICOM functionality available in the Vscan Air app.

Disclaimer: *When sharing data from the Vscan Air app, data can be shared to other apps including anonymized images and movies/loops.*

Use the Share function on the display device to share data.

Share individual images/videos

1. Swipe from right to left.

   OR

   Press **Exam** icon button on the top right corner.

   A list of stored images or videos for the current exam display.

Figure 5-88. Current exam images/videos

Share individual images/videos (continued)

2. Select the desired exam or video you wish to share.
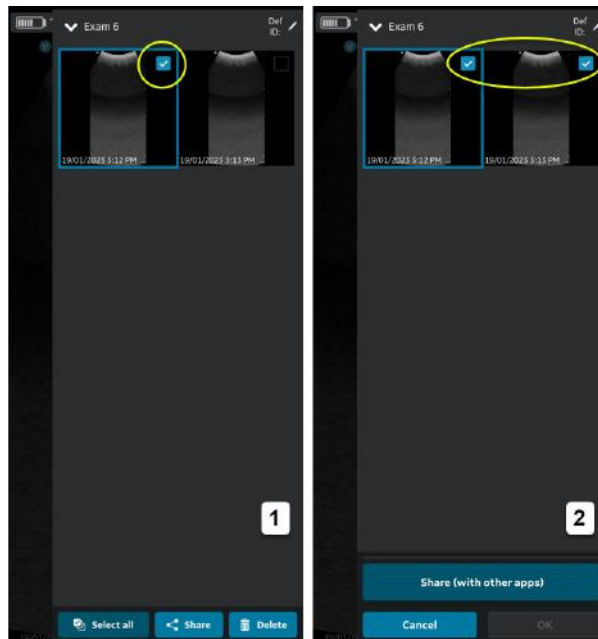
1. Select one OR
2. Select all

Figure 5-89. Select desired Exam

Share individual images/videos (continued)

3.   Press **Share** icon.

Figure 5-90.   Share with other apps

Share individual images/videos (continued)

4. Choose the Share function on your display device to share the images/videos.
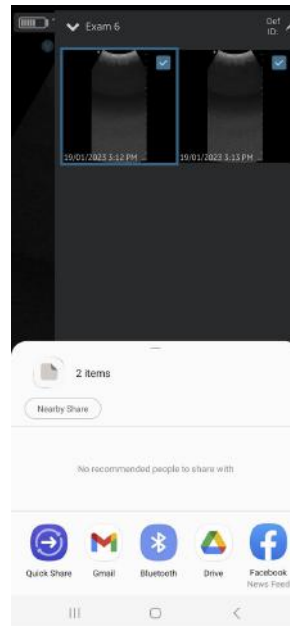
Figure 5-91.   Select app

Share all images/videos from an exam

In the same way as illustrated in the Share individual images/ videos section it is also possible to select and share Exams.

1. Press **Exams** tab on the right panel.
2. Select the desired exam from which you wish to share images/videos.
3. Press **Select**.
4. Press **Select All**.
   OR
   Press **Clear all** if you wish to clear the selection.
5. Press **Share** icon.
6. Choose the **Share** function on your display device to share the Exams.

Share Exams

1. Press **Exams** tab on the right panel.
2. Select the desired single/multiple Exam/Exams from the Exams list.
3. Press **Share** icon.
4. Choose the Share function on your display device to share the entire single/multiple Exams.

Export data to the DICOM Image Server

To export images/videos/exams from Vscan Air application to a configured DICOM image server, follow the procedure below.

1. Swipe from right to left.

    OR

    Press **Exam** icon on the top right corner.
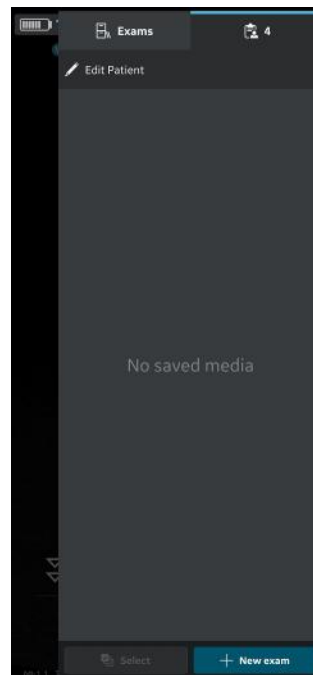
Figure 5-92.   Exam icon

Export data to the DICOM Image Server (continued)

2. Press "**Exams**" tab and select the desired Exam from which you wish to share images/videos.
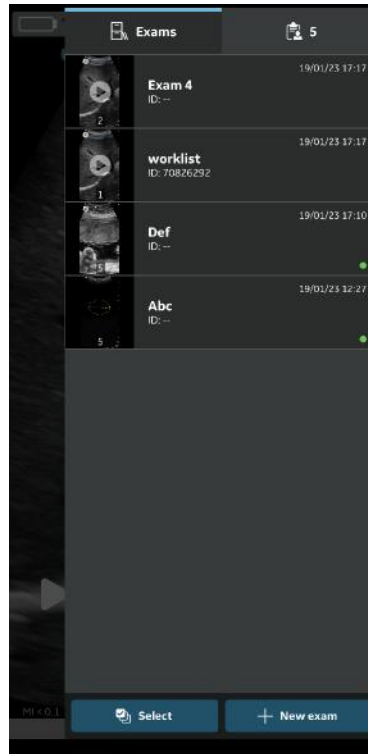
Figure 5-93.   Exams Tab

Export data to the DICOM Image Server (continued)

3. Select the desired image or video you wish to export and Press the Share icon. See 'Share individual images/videos' on *page 5-107* for more information.

OR

Select all images or videos you wish to export and Press the Share icon. See 'Share all images/videos from an exam' on *page 5-110* for more information.

OR

Select the desired single/multiple exams you wish to export from Exams list and Press the Share icon. See 'Share Exams' on *page 5-111* for more information.
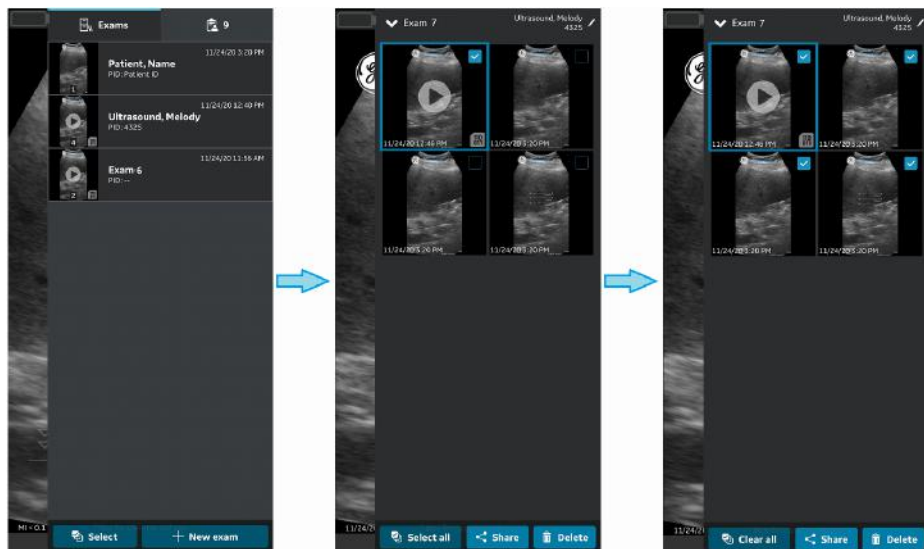
Figure 5-94.   Select Images/Videos

Export data to the DICOM Image Server (continued)

4. Select the DICOM Image Server as storage destination and Press OK button to initiate the export.

    If there is more than one DICOM Image server, select the desired DICOM Image Server as storage destination.
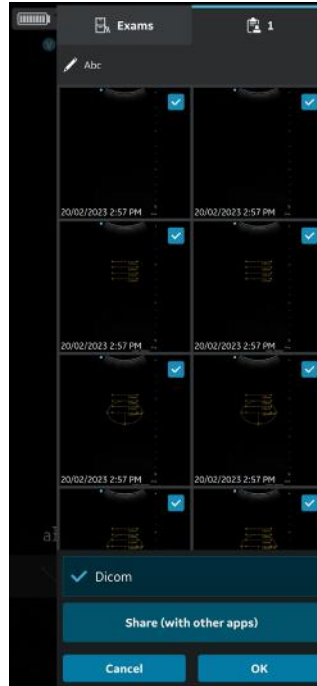
Figure 5-95.   Share Images/Videos

NOTE: *You can also select all the configured servers simultaneously, if you wish to share the data with all the servers that supports data export.*

NOTE: *To export Images/videos/Exam to a DICOM Image Server, you need to assign Patient information to that particular Exam.*

Export data to the DICOM Image Server (continued)

5. You can see the image queue at the bottom with items remaining to be exported.

In addition to image queue you can also view export status for each image/video/ exam, where a green dot indicates it is successfully exported and a red dot indicates the export is failed.
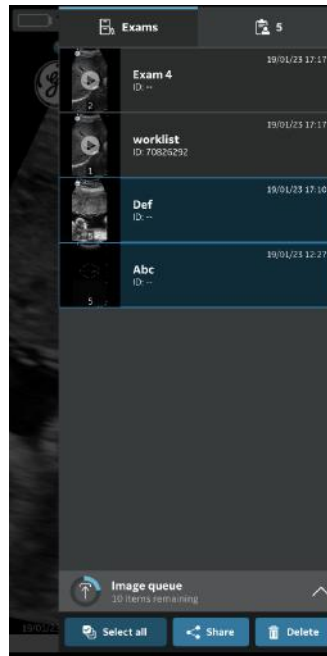
Figure 5-96.   Image Queue

Export data to the DICOM Image Server (continued)

In one attempt you can export maximum of 200 images. When you try to export more than 200 images in a single attempt, application throws the following warning message.

⚠ **Export limit reached maximum**

Export limit has reached to its maximum of 200. Please try sharing after completing existing transfer requests.

Ok
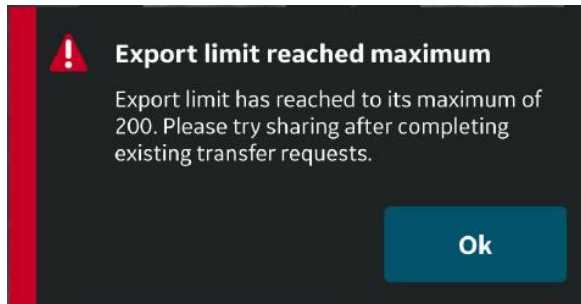
Figure 5-97.   Export limit warning message

NOTE: *The application initiates an Auto Retry in case of a failed export due to various reasons including network interruption.*

NOTE: *Once an export of exam images/videos has been initiated, the patient details assigned to that particular exam can not be edited in the app.*

Secure DICOM

Secure DICOM enables a secure connection between the Vscan Air application and a server over the Internet.

Trusted certificates are typically used to make secure connections. You can get a certificate from your system administrator or download it from sites that require authentication.

To enable Secure DICOM in the Vscan Air app, follow the procedure below:

1. While configuring DICOM Image Server or Modality Worklist Server or MPPS Server, to enable Secure DICOM, select the check box Secure DICOM on "Add New Server" screen.

    See 'Configure DICOM Image Server' on *page 4-24* for more information.

    See 'Configure Modality Worklist Server' on *page 4-19* for more information.

    See 'Configure Modality Performed Procedure Step (MPPS) Server' on *page 4-29* for more information.
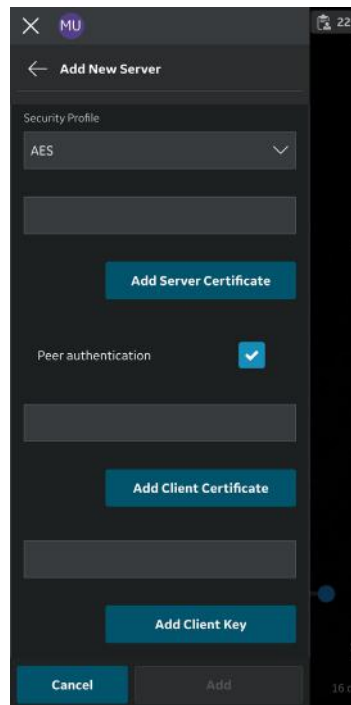
Figure 5-98.   Select secure DICOM

Secure DICOM (continued)

2.   Under Secure DICOM select the desired Security Profile.
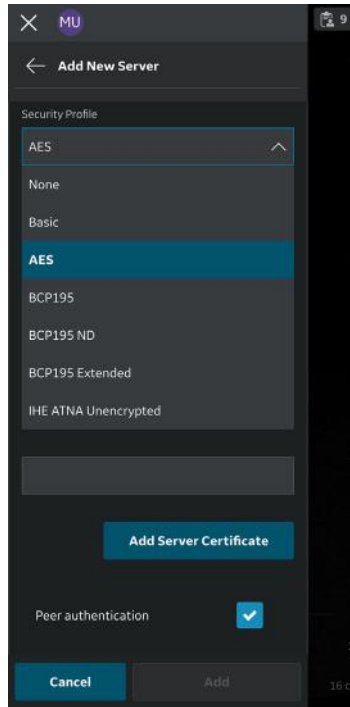
Figure 5-99.   Select security profile

Secure DICOM (continued)

3. Press the **Add Server Certificate** button, to upload the server certificate.
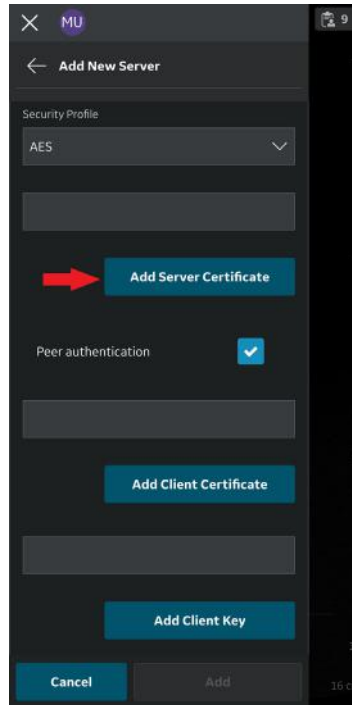
Figure 5-100.   Add server certificate

Secure DICOM (continued)

4. Press the **Add Client Certificate** button, to upload the Client certificate.
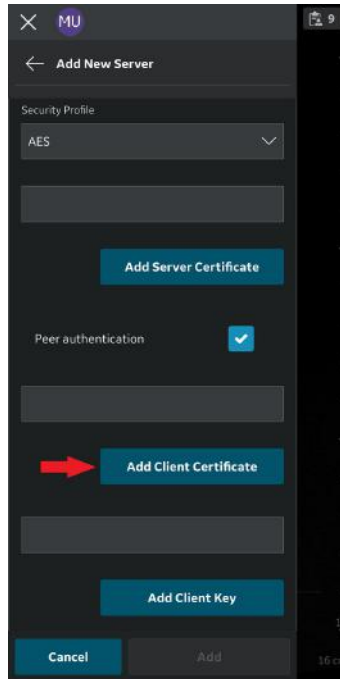
Figure 5-101.   Upload client certificate

Secure DICOM (continued)

5. Press the **Add Client Key** button, to upload the Client Key.
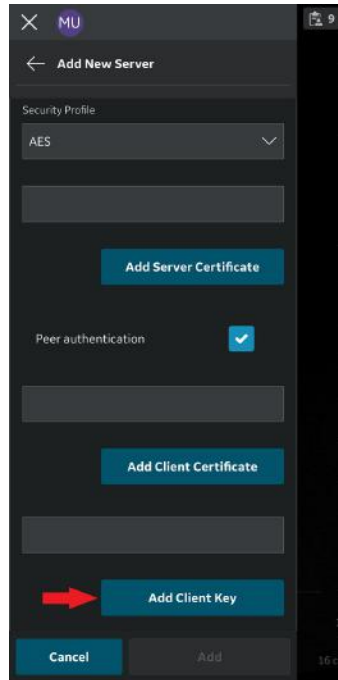
Figure 5-102.   Upload client key

6. After successful uploading of the certificates, you can verify the server.

MPPS Server

To send MPPS events from the Vscan Air app to a configured MPPS server for an exam, follow the procedure below.

1. If not already done by your BioMed or IT support, you will need to have your Modality Worklist Server and MPPS Server added and set as a favorite. See 'Configure Modality Performed Procedure Step (MPPS) Server' on *page 4-29*.

2. Add the patient details to the exam from Modality Worklist Server. See 'Assign Patient data from Modality Worklist Server to the current exam' on *page 5-66*.

3. Once the above conditions are met for saving the exam images, you will see the items being added to the Queue.

4. You can see the MPPS messages getting updated in the queue at the bottom indicating the number of items which will be automatically exported.
   Expand the queue to see the pending items in the MPPS queue and the user can retry to send these messages or delete the same if not required.
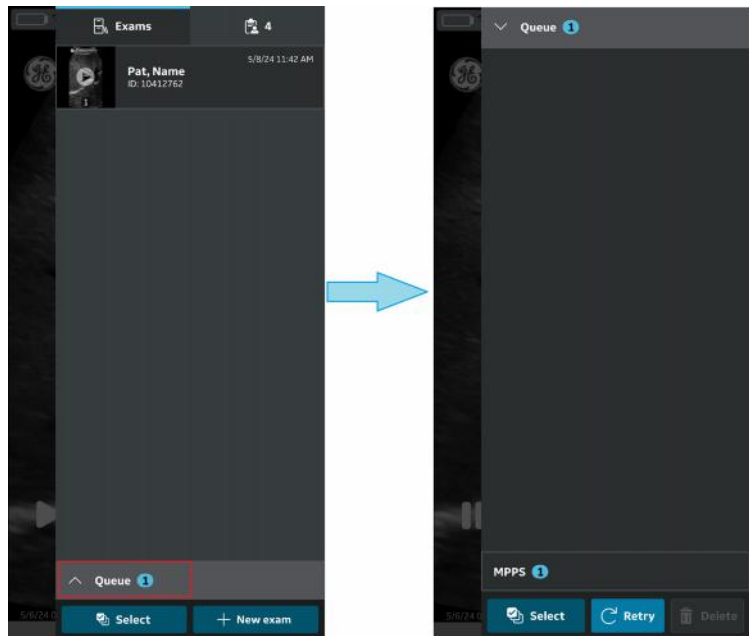
Figure 5-103.   Item in Queue

MPPS Server (continued)

NOTE: *When the first image of an exam is stored, the exam status is updated to 'Started' and sent to the MPPS Server. When "New Exam" is clicked, the current exam is treated as complete and 'Completed' exam status is sent to MPPS Server. If a network connection is not available, the exam status information is maintained in queue for further actions.*

Depending on the display device in use, you may need to disconnect the probe in order to connect to the network and then clear the queue.

Export data to the Network Shared Folder

To export images/videos/exams from Vscan Air application to Network Shared Folder, follow the procedure below.

1. Swipe from right to left.

   OR

   Press **Exam** icon on the top right corner.
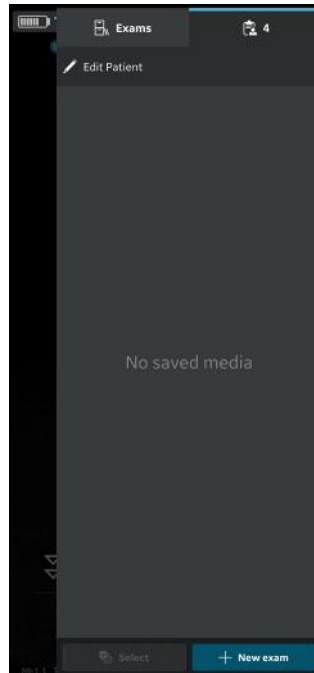
Figure 5-104.   Exam icon

Export data to the Network Shared Folder (continued)

2. Press "**Exams**" tab and select the desired Exam from which you wish to share images/videos.
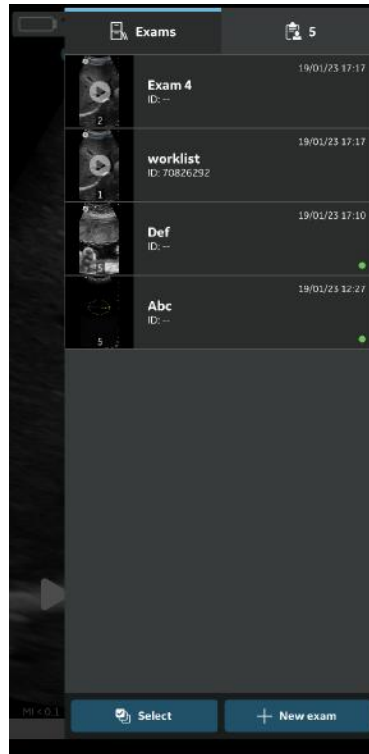
Figure 5-105.   Exams tab

Export data to the Network Shared Folder (continued)

3. Select the desired image or video you wish to export and Press the Share icon. See 'Share individual images/videos' on *page 5-107* for more information.

    OR

    Select all images or videos you wish to export and Press the Share icon. See 'Share all images/videos from an exam' on *page 5-110* for more information.

    OR

    Select the desired single/multiple exams you wish to export from Exams list and Press the Share icon. See 'Share Exams' on *page 5-111* for more information.
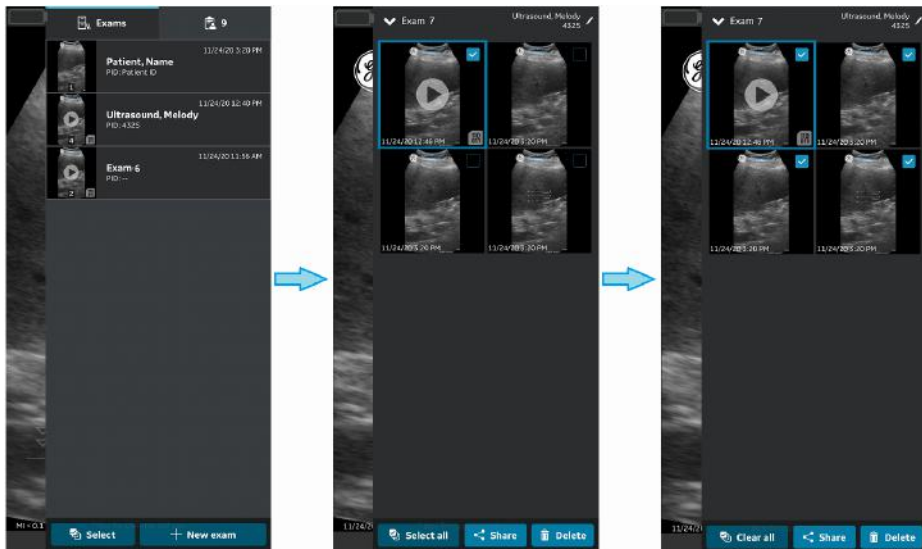
Figure 5-106.   Select images/videos

Export data to the Network Shared Folder (continued)

4. Select the configured Network Shared Folder as storage destination and Press **OK** button to initiate the export.

   If there is more than one configure shared folder, select the desired Network Shared Folder as storage destination.
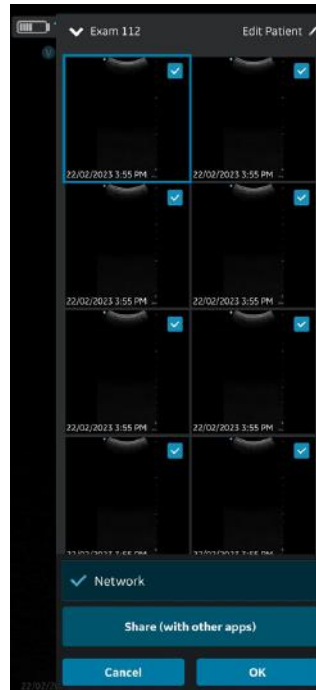
Figure 5-107.   Share images/videos

NOTE: *You can also select all the servers simultaneously, if you wish to share the data with all the servers that supports data exporting.*

NOTE: *You can export images/videos/exams to Network Shared Folder without assigning the patient details.*

5. You will find Image Queue with remaining items in the Queue.

   In addition to image queue you will also find export status of image/video/exam, where a green dot on the image/video/exam indicates it is successfully exported and a red dot indicates the export is failed.

Export data to the Network Shared Folder (continued)
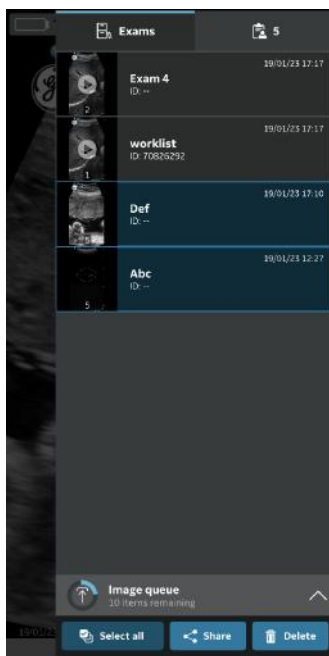
Figure 5-108.   Image queue

In one attempt you can export maximum of 200 images.
When you try to export more than 200 images in a single
attempt, application throws the following warning message.
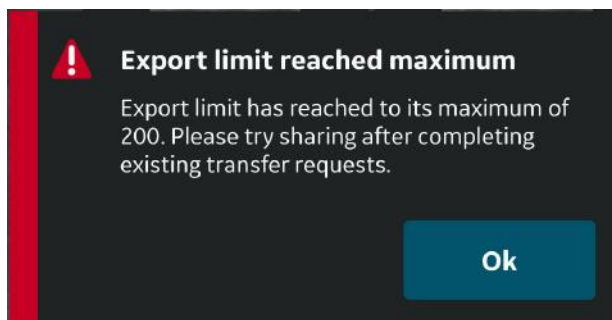
Figure 5-109.   Export limit warning message

NOTE: *Once an export of exam images/videos has been initiated,*
the patient details assigned to that particular exam can not
be edited in the app.

Comprehensive exam info

While configuring network shared folder, you can optionally configure to export the below mentioned exam data along with images and videos. See 'Configure Network Shared Folder' on *page 4-36* for more information.

The exam data that can be exported to network shared folder along with the images and videos is the exam number, the patient's first name, the patient's last name and the patient ID.

Network shared folder structure

Network shared folder structure is as follows in different scenarios:

1. **If only "Patient ID" is assigned to an exam**

   If only "Patient ID" is assigned to an exam, the network shared folder structure appears as below after exporting to your PC. The images and videos are stored in a series of folders.

   Folder: Shared folder created by customer in PC

   Sub Folder: Patient ID

   Sub-sub Folder: Exam creation date and time(YYYYMMDDHHMMSS)

   Image and video file: Image and video creation date and time(YYYYMMDDHHMMSS)

2. **If only "Patient ID" and "First Name" are assigned to an Exam**

   If only "Patient ID" and "First Name" is assigned to an exam, the network shared folder structure appears as below after exporting to your PC. The media files are stored in a series of folders.

   Folder: Shared folder created by customer in PC

   Sub Folder: Patient ID_First Name

   Sub-sub Folder: Exam creation date and time(YYYYMMDDHHMMSS)

   Media file: Media creation date and time(YYYYMMDDHHMMSS)

Network shared folder structure (continued)

3. **If only "Patient ID" and "Last Name" are assigned to an exam**

   If only "Patient ID" and "Last Name" is assigned to an Exam, the Network Shared Folder structure appears as below after exporting to your PC. The media files are stored in a series of folders.

   Folder: Shared Folder created by customer in PC

   Sub Folder: Patient ID_Last Name

   Sub-sub Folder: Exam creation date and time(YYYYMMDDHHMMSS)

   Media file: Media creation date and time(YYYYMMDDHHMMSS)

4. **If "Patient ID", "First Name" and "Last Name" are assigned to an exam**

   If "Patient ID", "First Name" and "Last Name" are assigned to an Exam, the Network Shared Folder structure appears as below after exporting to your PC. The media files are stored in a series of folders.

   Folder: Shared Folder created by customer in PC

   Sub Folder: Patient ID_Last Name_First Name

   Sub-sub Folder: Exam creation date and time(YYYYMMDDHHMMSS)

   Media file: Media creation date and time(YYYYMMDDHHMMSS)

5. **If Patient details are not assigned to an exam**

   If Patient details are not assigned to an Exam, the Network Shared Folder structure appears as below after exporting to your PC. The media files are stored in a series of folders.

   Folder: Shared Folder created by customer in PC

   Sub Folder: Exam number

   Sub-sub Folder: Exam creation date and time(YYYYMMDDHHMMSS)

   Media file: Media creation date and time(YYYYMMDDHHMMSS)

Using Vscan Air

Using Vscan Air in environments where time is critical and disruptions are less tolerated

The Vscan Air system is qualified for use in pre-hospital emergency environments including road- and air ambulances. Vscan Air is also qualified for use in home healthcare and in other environments where time might be critical and disruptions are less tolerated.

A wireless probe has a limited inherent risk of a disrupted connection due to various factors that could lead to loss of real time imaging.

⚠️ WARNING   If a temporary, unexpected disruption to real time imaging is determined to have a severely negative adverse effect on the patient's health outweighing the benefits of using an ergonomic wireless probe in a pre-hospital emergency environment, it is recommended to consider using a wired ultrasound device.

NOTE: *The Vscan Air probe is not certified for being charged inside a road- or air ambulance.*

Configure the device for acute- and emergency environments

The following considerations should be made regarding the configuration of the Vscan Air for use in acute- and emergency environments.

- The *Auto-freeze* time can be adjusted to keep device scanning for a longer period if exam is expected to be performed with no or infrequent user interface interactions but note that freezing the image when image acquisition finishes will reduce battery drainage and minimize device heating when device is not being used. It can be configured from the Menu -> Configuration -> Auto freeze time

- The **probe button** can be configured for additional functionality (Store or Freeze) that can be helpful during an emergency exam to minimize interaction with the display device. It can be configured from the Menu -> Configuration -> Probe button. Note that accidentally pressing the button for 3 seconds or more could lead to an unintentional shut down of the probe.

- To avoid additional delays when starting the Vscan Air probe and app the display unit should if possible be configured to not accept automatic app updates. If an app and/or a probe update is to be performed the availability of the device for scanning might be delayed by up to 3 to 5 minutes. In addition a possible delay must be expected if the probe software needs to be updated and the probe battery is not sufficiently charged (50%) for the software update to start. See 'Upgrades' on *page 6-20*.

- An internet connection will be required for a user to sign in. Be aware that an **automatic sign out** configuration setting will give users an option to control the duration of a signed in session. Configuration is available via Menu -> Configuration -> Automatic sign out. The default value is 24 hours.

When time is critical and charging options are limited or unavailable

The following considerations should be made if the Vscan Air system is used in home healthcare or pre-hospital emergency environments where time is critical and the options to charge the Vscan Air probe or the display devices are unavailable or limited.

General considerations:

• Make sure that both the Vscan Air probe and Vscan Air app selected for use has been registered and are prepared as described in section 3.

• It is recommended for users to get comfortable with handling the Vscan Air prior to taking the device into a home healthcare or pre-hospital emergency environment.

• To help uncover any unexpected challenges with a stable connection between the Vscan Air probe and Vscan Air app, the selected Vscan Air probe and the preferred display device should be tested in an environment as close as possible to the environment where the service is to be provided.

• If an internet connection is not available and/or a user cannot sign in because of other reasons selecting Guest on the Sign in page will give the access to scan and store functionality. Review of images stored while using the guest option is available.

Before taking the device for use in a pre-hospital or home healthcare environment:

• Check the display device charge level, and verify that the charge level is consistent with the charge level needed for the duration the display device is planned to be used. A good advice is to always keep the display device fully charged before taking it to pre-hospital or home healthcare environments.

• Check the Vscan Air probe battery charge level according to the description in the "Vscan Air probe is **OFF**" section, and verify that the probe is fully charged, i.e., both LEDs are green.

NOTE: *Please note if the Vscan Air probe Storage mode is enabled the probe has to be re-activated (see 'Re-activating a probe from Storage mode' on page 5-137) and battery charge level checked before taking the probe for use in pre-hospital or home healthcare environments.*

When time is critical and charging options are limited or unavailable (continued)

After each use in pre-hospital or home healthcare environment:

• Check the display device charge level.

• Check the Vscan Air probe battery status according to the description in the "Vscan Air probe is OFF" section.

• If needed charge the Vscan Air probe to a 90-100% level as described in the "How to charge the Vscan Air probes" section.

• If needed charge the display device to a 90-100% charge level.

Scanning for foreign bodies

Ultrasound can be used for localizing soft tissue foreign bodies. Examinations should be performed with the highest frequency transducer applicable. The area of interest is often feet or hands. The size and the echogenicity of the foreign body is maybe the most important factors regarding detection. Superficial objects may be hard to detect, but using the linear array transducer and a stand-off pad to elevate the transducer can likely help in such situations. A foreign body is likely to appear hyperechoic where wood, glass, and plastic tends to produce shadowing while metal objects tends to produce reverberations, comet tail artifacts and acoustic shadowing.

Be aware that detection of a foreign body can be time consuming. Multiple attempts should be made to visualize the region of interest from as many angles possible. Keeping the probe parallel to the object makes visualization the easiest. To avoid foreshortening the appearance of the foreign body care should be taken to find the true long axis of it. The foreign body surrounding tissue may present hypoechoic often indicating pus or granulation tissue. The degree of the associated inflammation can likely be visualized using color doppler showing vascular in-growth. When scanning for foreign bodies knowledge of regional anatomy is crucial. Distractions when scanning may include gas and proteinaceous of echogenic fluid, also be aware that bony, articular surfaces and scars may appear hyperechoic.

Storing devices in between uses

Storing a Vscan Air probe requires careful consideration of several factors to maximize the lifespan of the probe battery.

Longer term storage - more than one month

If there is a need to store a Vscan Air probe for a longer period it is recommended to utilize 'Storage mode' available via the Vscan Air app Menu.

'Storage Mode' allows the user to keep a probe stored for up to 36 months without significant probe battery degradation. If the probe must be available on short notice, it can easily be removed from 'Storage mode' by placing it onto a Vscan Air charger.

Short term storage

If selecting to store the probe for a short period without utilizing Storage mode it is recommended to:

- Keep the Vscan Air probe OFF when storing it or select to use 'Storage mode' even if storing the probe for less than one month (see 'Putting the probe into Storage mode' on *page 5-136*).

- Store the Vscan Air probe in a cool, dry place. Aim for temperatures between 0°C to 20°C and remember that colder is better, for example: 10°C is better than 20°C.

- Although a Vscan Air probe carrying a fully charged battery can be stored up to 3 months without needing to be recharged, it is recommended to charge the probe on a monthly basis to make sure that it carries enough power for a scan session if there is a sudden need for starting using the probe.

- If a dedicated display device is stored with the probe keep it OFF when storing.

- Re-charge the display device at the intervals required to make sure that the device will be able to keep the Vscan Air app actively running for a minimum of 2 hours. Follow the display device manufacturer recommendations regarding the display device battery, battery charging and battery health.

Putting the probe into Storage mode

To put a probe into Storage mode it needs to be connected to the app. It is advisable to keep the battery partially charged before storage. The recommended battery charge level, before utilizing 'Storage mode', is a battery charge level of 3 bars. Using a higher charge level will be accepted, but keeping the charge level higher than, but close to 3 bars is recommended (refer 'Battery level indicator' on *page 3-23*).

Table 5-5:   Battery level indicator

Icon	Description
	Battery charged 35-50%
	Battery charged 25-35%

With the probe connected to the app navigate to Menu -->Configuration-->Storage Mode -->tap Activate storage mode.

Putting the probe into Storage mode (continued)

NOTE: *If the probe charge level is lower than the recommended 3 bars, an informational message will appear leaving the user with the option to cancel or to continue to enable Storage mode.*

NOTE: *If the probe is placed on the wireless charger while in 'Storage mode' it needs to be removed from the wireless charger for 30 seconds or more to re-enable the probe for use.*
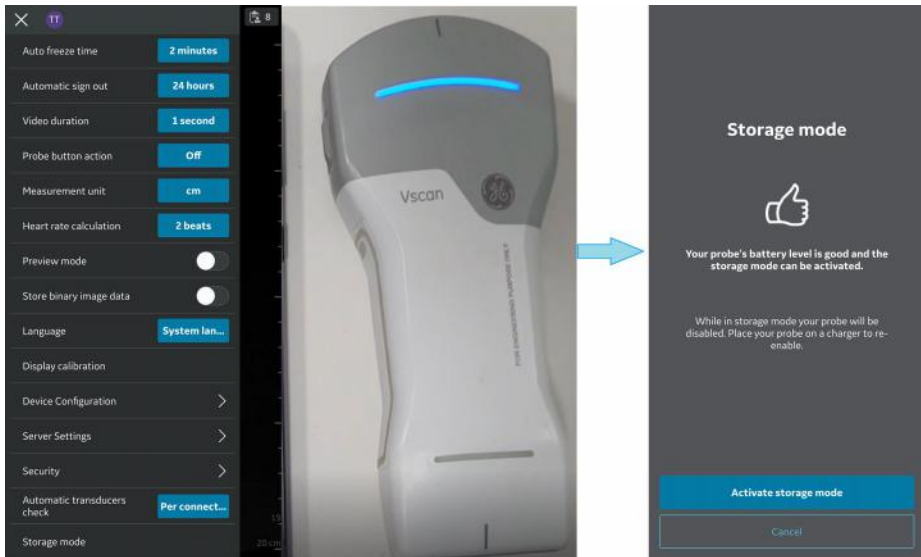
Figure 5-110.   Probe in Storage Mode

Re-activating a probe from Storage mode

To re-activate the probe, place probe on the wireless charger before turning the Vscan Air probe ON. The Vscan Air probe will not start unless a re-activate charging cycle has been initiated.

NOTE: *When purchasing a new Vscan Air probe it arrives with 'Storage mode' enabled, so to activate the probe it needs to be put onto a wireless charger before being powered on as described in the section 'To power ON the Vscan Air probe' on page 3-38.*

Important guidelines to follow for Storage

- Store probe in a cool, dry place. Aim for temperatures between 0°C to 20°C and remember that colder is better, for example: 10°C is better than 20°C.
- Make sure to re-enable probes in 'Storage mode' at least every 36 months to check battery capacity, charge if needed, and put probe back into 'Storage mode' if required.
- If storing multiple probes, it is recommended to practice a first in first out rotation when selecting a probe for use.
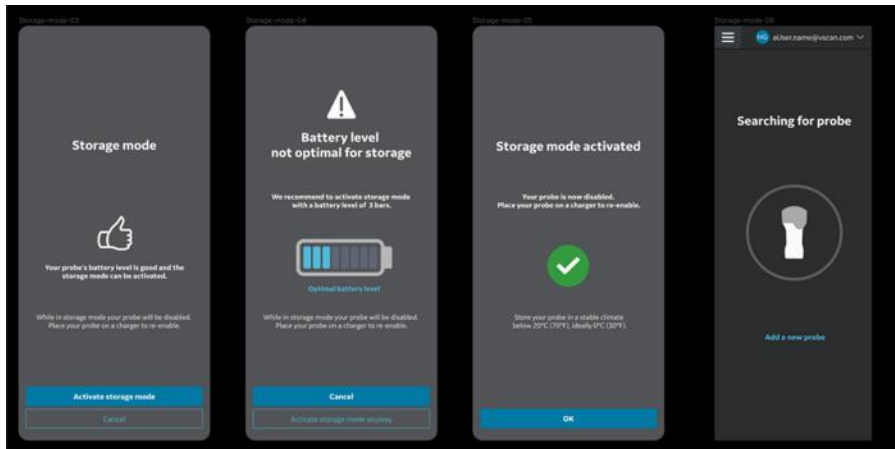
Figure 5-111.   Guidelines for Storage Mode

Preparing for a guided procedure with Vscan Air

A wireless probe has a limited inherent risk of a disrupted connection due to various factors that could lead to loss of real time imaging.

⚠ WARNING If a temporary, unexpected disruption to real time imaging is determined to have a severely negative adverse effect on the patient's health outweighing the benefits of using an ergonomic wireless probe at the point of care, it is recommended to consider using a wired ultrasound device for the specific procedure guidance.

⚠ CAUTION When performing a guided procedure or a freehand biopsy, i.e. without a biopsy guide, it is the user's responsibility to use appropriate equipment. Ensure that the needle (especially the needle tip) is always visible in the ultrasound image during the whole procedure.

⚠ CAUTION Always use only B-mode when performing guided procedures or a freehand biopsy.

Assessing Display Device Wi-Fi Performance with Vscan Air probe

Prior to setting up for a guided procedure, it is recommended to check if the display device being planned for use during the procedure supports a stable connection with the Vscan Air probe, by following the below steps.

Step	Step name	Description
1	Configure app settings	Set the Video duration to 1 second from Menu -> Configuration. This will help to visualize discontinuities in loop playback which indicate lost frames.
2	Connect probe and app	Connect the probe with the app
3	Select preset with color	Select Small Parts from the Shallow (Linear) presets menu. Enter color flow mode by pressing the ROI button. Adjust the color gain to 100% to visualize noise inside the color ROI.
4	Confirm/Verify	Observe the noise pattern inside the color ROI. The randomness of the pattern should not appear to pause occasionally.
5	Review cine	Press freeze. Then press the Play button to the left of the scroll bar.
6	Confirm/Verify	Observe the blue cine position indicator as it moves from left to right along the position indicator. It should move in a consistent fashion from left to right (the distance it moves with each increment appears equal).

If the display device does not pass the above criteria successfully, using an alternate display device is recommended for supporting guided procedures.

General considerations

- There may be differences in the physical characteristics of a wireless probe (shape, design, weight etc.) and the way it might be handled during a scan or a procedure when compared to a probe attached to a console. Hence, it is recommended for users to get comfortable with handling the Vscan Air device prior to performing a procedure to minimize accidental dropping or slipping of the probe during the procedure.

- Wherever possible, prior use of the probe and preferred display device in the network environment where the procedure is expected to be performed will help uncover any unexpected challenges with a stable connection between the probe and app before the actual procedure.

- Make sure to follow the disinfection protocol to prepare the probe and display device for the procedure being performed. More information on cleaning and disinfection methods and approved agents can be found in the 'Cleaning and Disinfection' section of the user manual. Use probe sheaths for procedures where a sterile field needs to be maintained or infection is a concern.

- In order to make the interventional part of the procedure more efficient, and if this is not an emergency procedure, you may want to perform a preliminary scan to familiarize yourself with anatomical landmarks around the target and procedural planning like the anticipated entry point, needle path and tracking method. It might be helpful to mark transducer location, anticipated needle entry point and trajectory, whenever possible and appropriate.

Setting up device for procedure

Please read and follow the below instructions to prepare the device before performing a dynamic ultrasound guided procedure with Vscan Air.

Step	Step name	Description
1	Configure app settings	• If working with a display device for the first time, use an example image to adjust the brightness level for optimal visualization of the image based on the ambient environment where the procedure is expected to be performed. Consider dimming ambient lights for better image visualization, wherever possible. • Adjust/maximize the Auto-freeze time to avoid image freeze during the procedure if there are no user interface interactions. Note that freezing the image when device is not being used will minimize device heating and battery drainage. • Centerline marker can be turned on from the Menu -> Configuration, if desired. Please note that Vscan Air supports only free hand biopsy and needle procedures so the centerline marking should not be confused with biopsy guidelines indicating needle path on the image. • The probe button can be configured for additional functionality (Store or Freeze) that could be helpful during procedure to minimize interaction with the display device. It can be configured from the Menu -> Configuration. Accidental long press (3 secs or more) of this button during scanning can lead to unintentional shut down of the probe. • The video duration should be set to save a video appropriate for documentation requirements.
2	Use a cool probe	Make sure the probe is sufficiently cooled down after any previous scanning. Disruption may occur due to the probe getting warm if a lengthy procedure is anticipated. Leaving the probe on a desk (outside the pocket or the case) after it off will help cooling down faster. It should take about 30-60 minutes to get to a reasonably cool state depending on how warm it was from the previous scan and the ambient temperature. If accelerated cooling of the probe is required, place the probe, while turned off, in front of a fan, run under cold water, or apply cooling pack.

Step	Step name	Description
3	Minimize lost connection between probe and mobile device during scan	The probe without a cable can be very helpful to support sterile procedures. At the same time its use depends on bandwidth and stability of the wireless connection between probe and mobile device. Following are the recommendations for minimizing loss of real time images due to connection instability: 　a. The probe and mobile device should be within 1 m to each other during pairing, and less than 1.5 meters while in use. 　b. Avoid congested Wi-Fi network environments, if possible. 　c. In cases where multiple Vscan Air probes and display devices with the app are available, make sure 　　- the app is closed on all other devices except the one to be used and 　　- all other probes are turned off and moved away from the vicinity of the device.
4	Check battery levels of probe and display device	Ensure that the probe and display device have enough charge before starting a procedure. Charge levels of 50% and above are recommended before starting, and above 30% during procedure. Battery levels of the probe can be checked on the top left corner of imaging screen after connecting with the app. Please refer to the user manual for the detailed description of the battery level indicator bars.
5	Confirm 'Wireless connection quality' and 'Probe temperature'	Ensure that the connection between the probe and app is stable by checking the connection quality indicator on the top left corner of the imaging screen. The probe temperature indicator is also visible in the same place for confirming the use of a cool probe.
6	Select appropriate preset	Choose the correct preset based on the anatomy being visualized and the planned procedure. Details of the presets and the optimized anatomy are available in the user manual.
7	Image crop-guidance / Choose display device orientation	Image size is maximized in the portrait mode. As a result, at certain depths, image corresponding to the entire transducer width may not be visible on the screen. Image crop indicators are displayed on the sides in such cases. It is recommended to rotate the display device to landscape orientation for visualizing the whole image including the edges and needle entry point. Alternatively, 1.　The image can also be zoomed to pan it sidewise if portrait mode is preferred. OR 2.　The depth increased until the crop indicators on the side of the image disappear indicating that the edges are visible in the field of view. Refer 'Image crop indicator' on *page 5-9* for a more detailed description.
8	Position display device	Position the display device in such way that it is comfortable to visualize the image during the procedure (for e.g. Imaging features such as orientation marker is clearly visible, ambient lighting is optimal, display device is in the line of sight and no straining is required). Consider using a cart or stand to mount the display.

Digital tools

Vscan Air supports some digital features which are optional and enabled if purchased. Digital tools are not available in every country.

1. MyDeviceHub

MyDeviceHub is a device management tool for enterprises who have multiple Vscan Air devices and would like to manage them centrally. It is accessed by enterprise administrators via a dedicated web-based portal and provides functionality such as registration for probes, set up of user access lists, DICOM server settings, etc.

MyDeviceHub can be purchased as part of the Vscan Air Fleet digital solution.

NOTE: *Probes with Fleet solution enabled cannot be registered or unregistered by anyone other than an administrator. The administrator can register a probe from the app or the MyDeviceHub portal. Unregister probe option is only available via the app.*

a. User access

Enterprise administrators can restrict usage of Fleet enabled probes to certain named users.

1. MyDeviceHub (continued)

When attempting to connect to a Vscan Air probe, the app checks existing access restrictions. If the signed in user is not authorized to use the connected probe, the following error will be displayed. In this case, the user may choose to use a different Vscan Air probe or contact the Enterprise administrator to update the access control list.
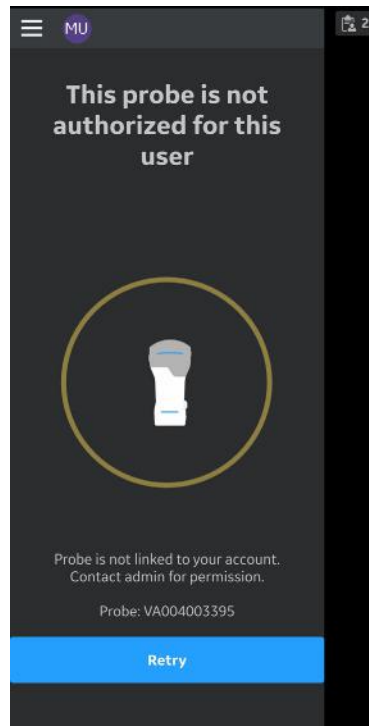
Figure 5-112.   Error message

NOTE: *After access rights for a probe are updated by an administrator, the user must sign out of the app and sign back in for the changes to be reflected in the app.*

1. MyDeviceHub (continued)

b. Importing server configurations

The app is able to import any DICOM server settings that have been entered by the Enterprise administrator via the MyDeviceHub portal. The first time a user connects to a Fleet enabled probe, the app provides the user an option to import these settings as shown below.
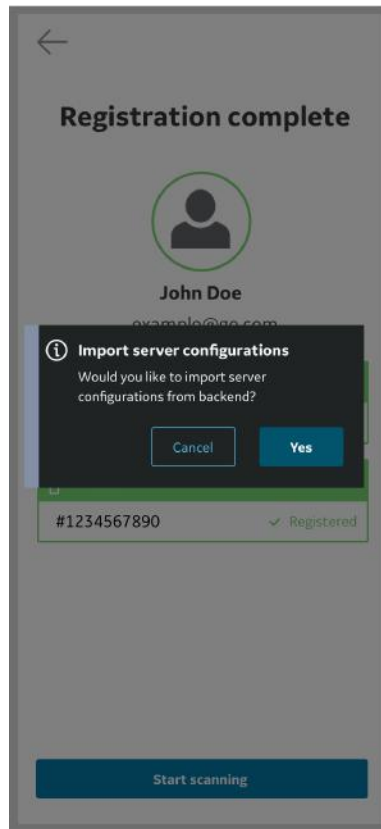
Figure 5-113.   Auto-import of server configuration

1. MyDeviceHub (continued)

User can choose to accept or deny the configuration settings from backend. If user choses to accept the configuration, the server settings will be updated in the application.

The user can also download server configurations from the backend whenever desired from the menu.

Click on the button ⬗, on the Server Settings page to the import settings.
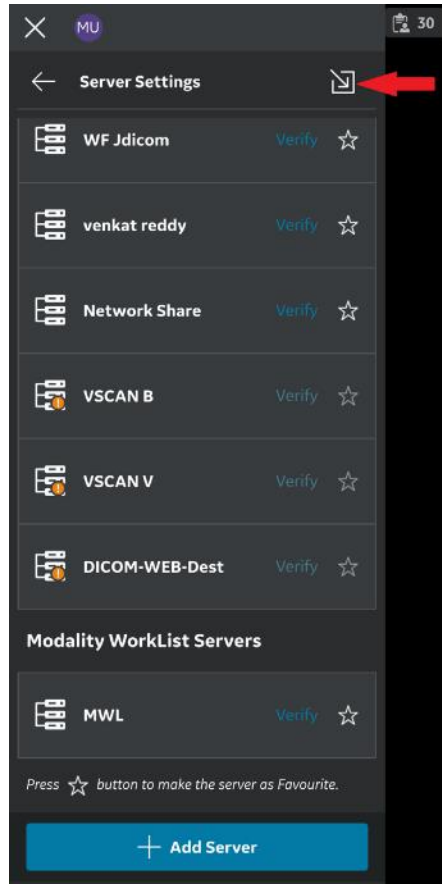
Figure 5-114.   Manual import of server settings

1. MyDeviceHub (continued)

DICOM Server Configuration

If DICOM server configurations are received from the MyDeviceHub, they will be added to Menu -> Configuration -> Server Settings

Mandatory fields for each DICOM server will be displayed as received from backend, but user will need to enter secure information like Username, Password, Certificates & key (if Secure DICOM is enabled) for each received server entry to complete its configuration.
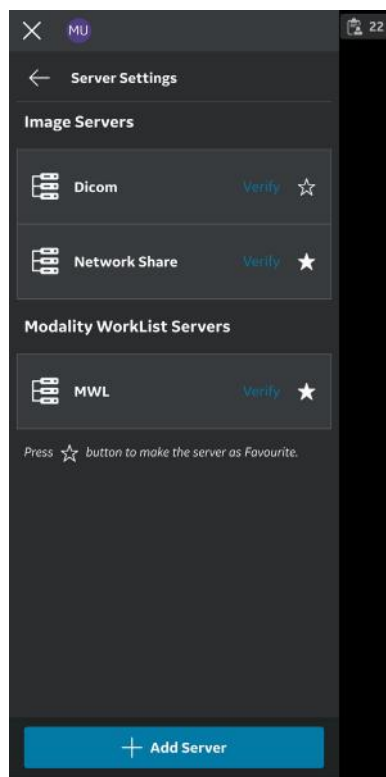
Figure 5-115.   Server configuration complete

DICOM Server Configuration (continued)

If the received configuration is incomplete, then the following indication will be shown to user.
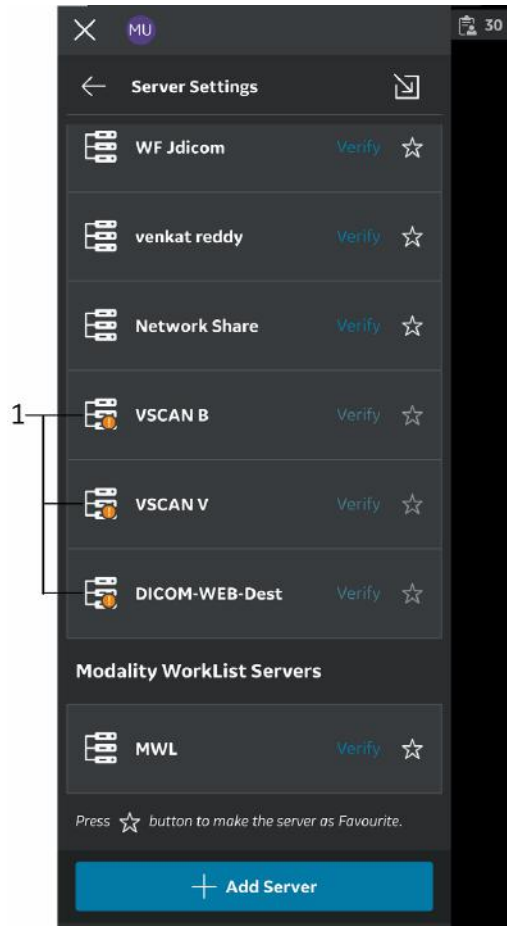
1. Error indicator

Figure 5-116.   Server configuration incomplete

2. MyRemoteShare, powered by Zoom

MyRemoteShare is a tool which enables the Vscan Air user to initiate a collaboration session with one or more remote participants, during which the user can optionally share the scan screen and camera feed from their mobile device and have an audio conversation. This tool is powered by Zoom and utilizes the Zoom for Healthcare application. It is compliant for use in healthcare environments (e.g. HIPAA compliant in USA).

If purchased, this feature will be accessible via the Preset Menu (left panel menu) of the app.

NOTE: *MyRemoteShare is provided for education, training, and support purposes. It is not intended for diagnostic use since the quality of the image feed seen by the remote participant will depend on the user's and participant's network connection as well as the display device used by the participant, and as such cannot be guaranteed.*

NOTE: *The user of the Vscan Air app is responsible for the remote participants selected, the content shared, and for obtaining appropriate patient consents if applicable.*

NOTE: *Since MyRemoteShare uses the secure version of the Zoom platform, remote participants must have the Zoom app installed on their mobile device or computer in order to join a MyRemoteShare session. Participants will not be able to join just via a web browser.*

NOTE: *The MyRemoteShare session is limited to 45 minutes, after which the session will be terminated.*

2. MyRemoteShare, powered by Zoom (continued)

NOTE: *To enable key functionality like screen share, audio and video sharing, during MyRemoteShare sessions, the user must give the following permissions to the Vscan Air app when prompted by their mobile device:*

1.   Access to the microphone and camera.
2.   Permission to overlay (Android only).

NOTE: *Annotation feature for MyRemoteShare feature on Vscan Air is available only on the Android platform. The annotation option needs to be enabled on the host side to ensure that the annotations on the remote participant side are available.*

NOTE: *Please refer to the below link for system and network requirements from ZOOM for MyRemoteShare feature.*

https://support.zoom.us/hc/en-us/articles/ 201179966-System-requirements-for-iOS-iPadOS-and-Android ?__cf_chl_captcha_tk__=Wm.YZcuP4p4zRndl26olRQlCtCJYo.i oil..axXQS_o-1638101273-0-gaNycGzNDT0

NOTE: *iOS devices need to enable cellular data prior to starting the MyRemoteShare session since the Wi-Fi channel will be used for communicating with the probe.*

Usage of MyRemoteShare

1. Press the Menu -> Select "**Start screen share session**" from MyRemoteShare tab on the Preset menu.
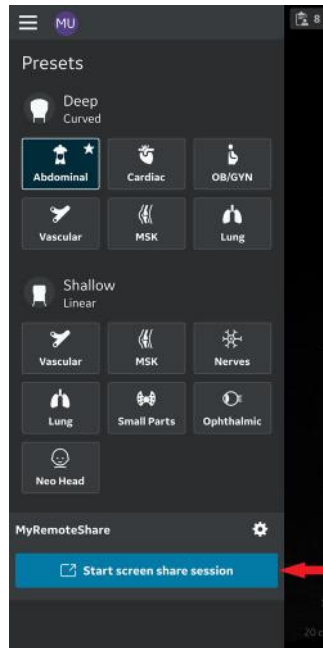
Figure 5-117.   Activate MyRemoteShare

Usage of MyRemoteShare (continued)

2. Click on Start Session -> Warning message will be displayed on the screen stating that the feature is not intended for diagnostic use. The user must confirm to proceed.
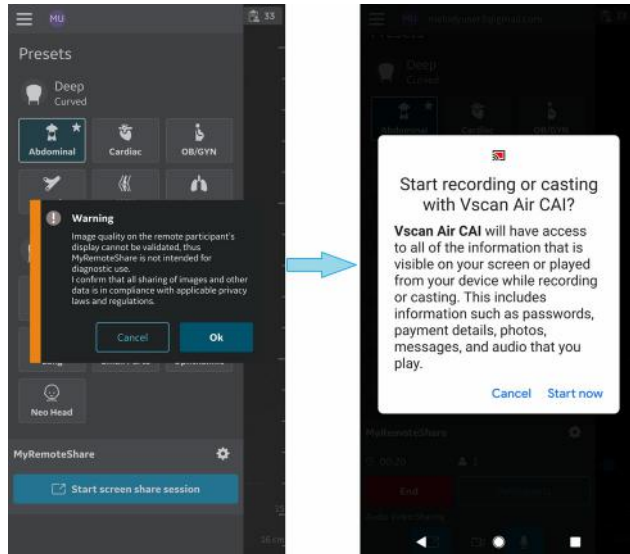
Figure 5-118.   Warning message

Usage of MyRemoteShare (continued)

3. Send the invitation link to one or more desired participants using any third-party messaging apps from the mobile device. There is also an option to copy the link if needed.
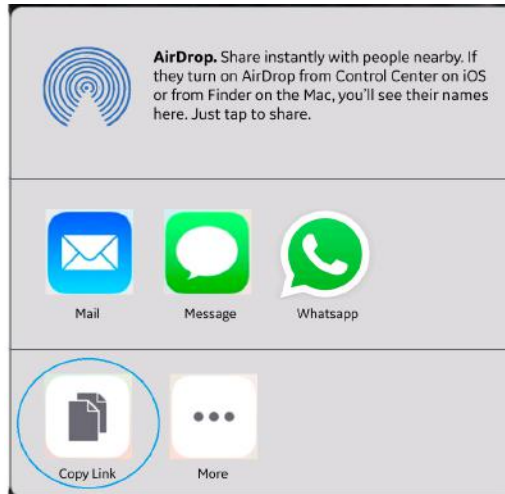
Figure 5-119.   Share/copy link to invite

Usage of MyRemoteShare (continued)

4. During a session, click "**Invite Participants**" and send to
   one or more desired participants using any third-party
   messaging apps via mobile device.
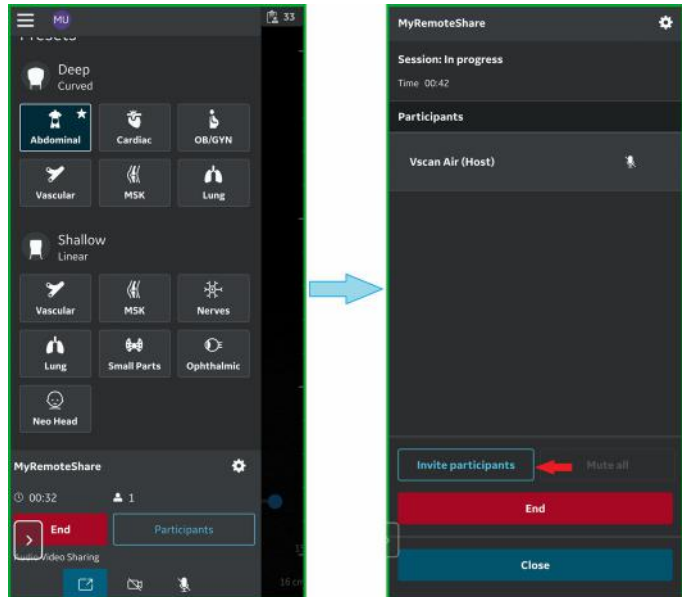
Figure 5-120.   Invite participants

Usage of MyRemoteShare (continued)

5. Invitation is sent to the participant(s).
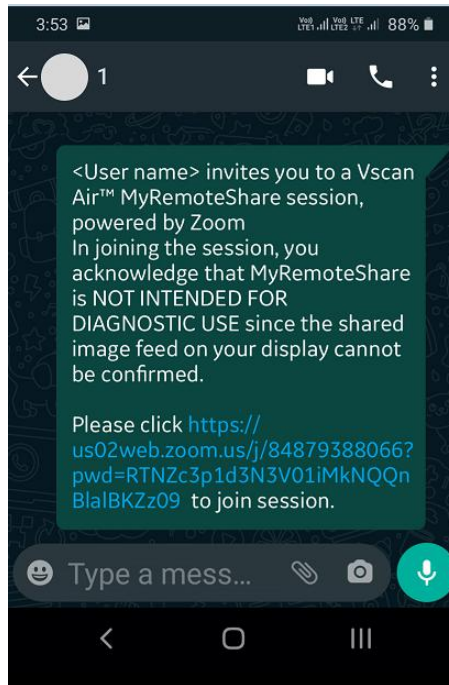
Figure 5-121.   Participant invite

6. The participant(s) must click on the URL in the invitation link to join the session.

7. MyRemoteShare session is initiated.

Usage of MyRemoteShare (continued)

8. On the participant side, there is a static banner throughout the screen share session which indicates that screen share is intended for non-diagnostic use.
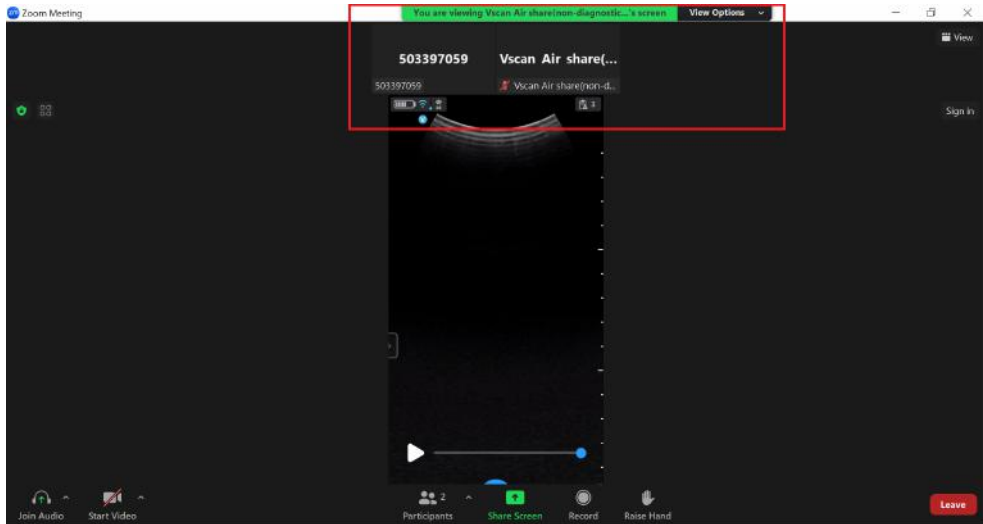
Figure 5-122.   Non-diagnostic banner on the participant side (not a Vscan Air screen)

NOTE: *The screen is a sample shot from participant side (this may vary depending on Zoom client version).*

Usage of MyRemoteShare (continued)

9. The host can enable/disable audio/video during the remote session.
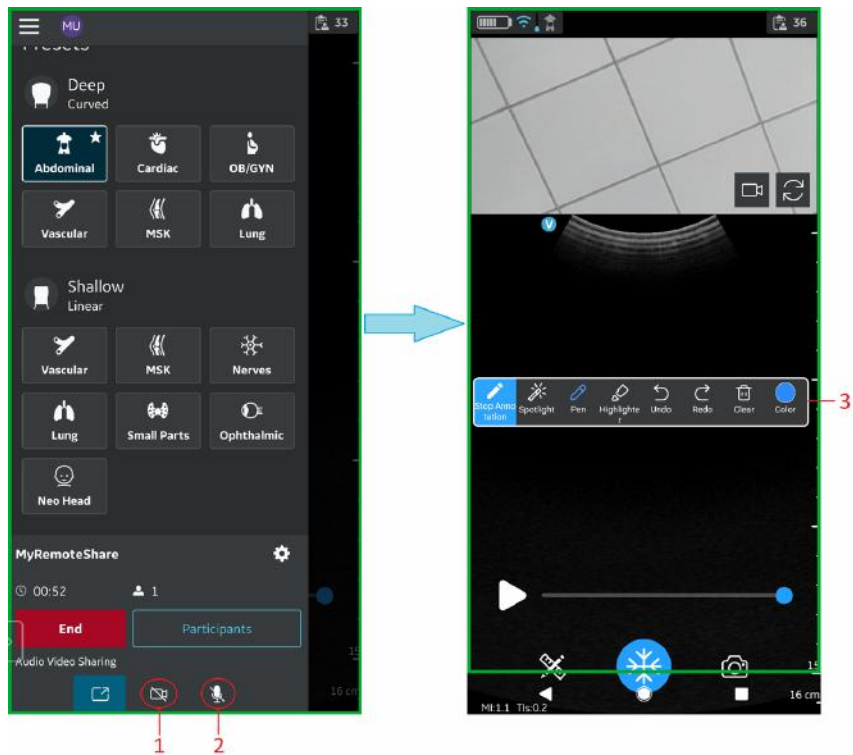
1. Enable/disable video
2. Enable/disable audio
3. Annotation bar

Figure 5-123.   MyRemoteShare session

10. The host can annotate on the scan screen during the remote session (Android only).

Usage of MyRemoteShare (continued)

11. The host can toggle between front and rear camera feed during the remote session.

Click on 📷 icon to open participant camera.

Click on 🔄 icon to rotate camera feed.
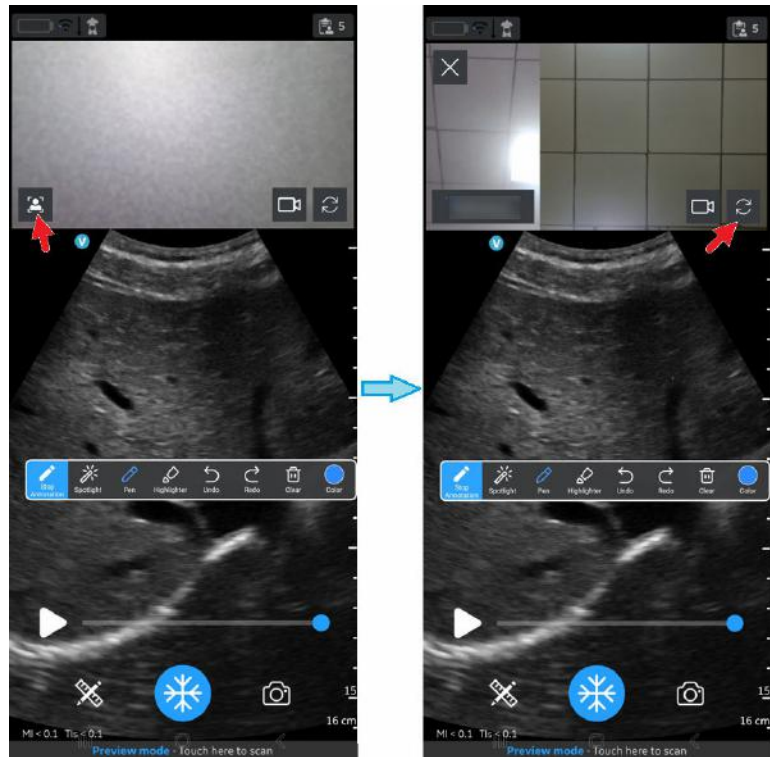
Figure 5-124.   Front and rear camera feed

Usage of MyRemoteShare (continued)

12. The host can add/remove participant(s) during the remote session via the menu accessed by swiping in the left panel.
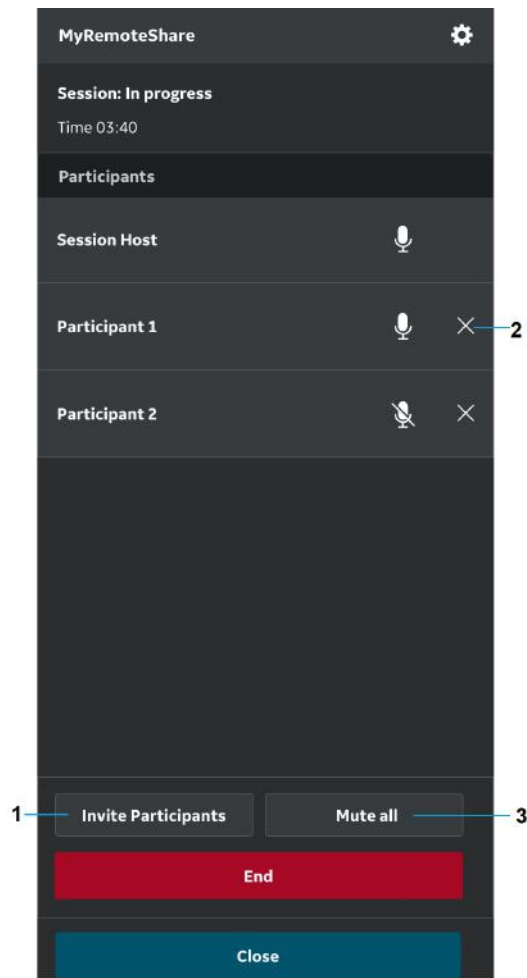
1. Add participant
2. Remove client (participant)
3. Mute all (other than Host)

Figure 5-125.   Add/Remove participants

Usage of MyRemoteShare (continued)

13. The host can end the remote session.
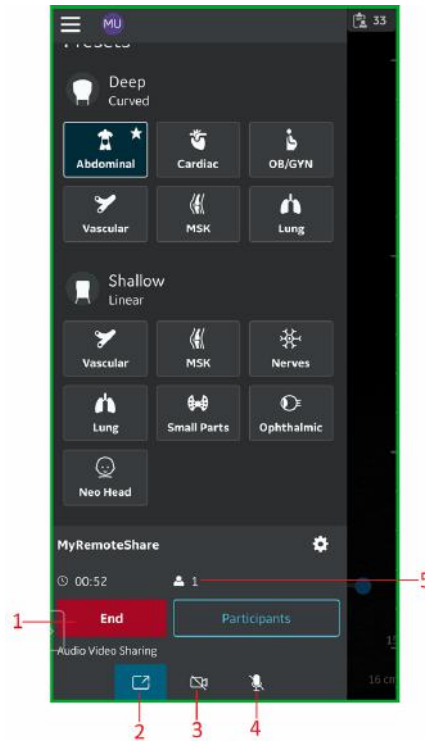
1. End call
2. Toggle screensharing on/off
3. Toggle Host camera on/off
4. Mute Host
5. Session duration and number of participants

Figure 5-126. End the session

Usage of MyRemoteShare (continued)

14. Settings and preferences for MyRemoteShare can be configured by clicking on the Settings button on the MyRemoteShare tab.

The available settings include a choice to allow participants to join automatically or approve each one, as well as choices for the camera and microphone to be on or off when starting a session. Note that screen sharing is enabled by default when starting a MyRemoteShare session.
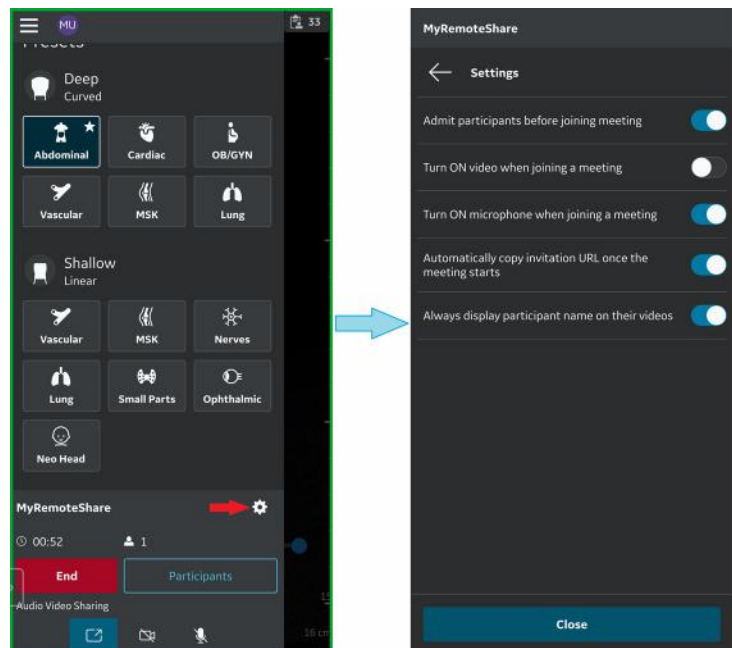
Figure 5-127.   MyRemoteShare Settings configuration

3. MyImageCloud Solution

GEHC offers a cloud-based exam management solution, MyImageCloud. Exams and images from Vscan Air can be exported to MyImageCloud if this solution is purchased. If available for use with your Vscan Air, the option will be visible as a pre-configured export destination on the Server Settings page accessed via Menu-> Configurations.
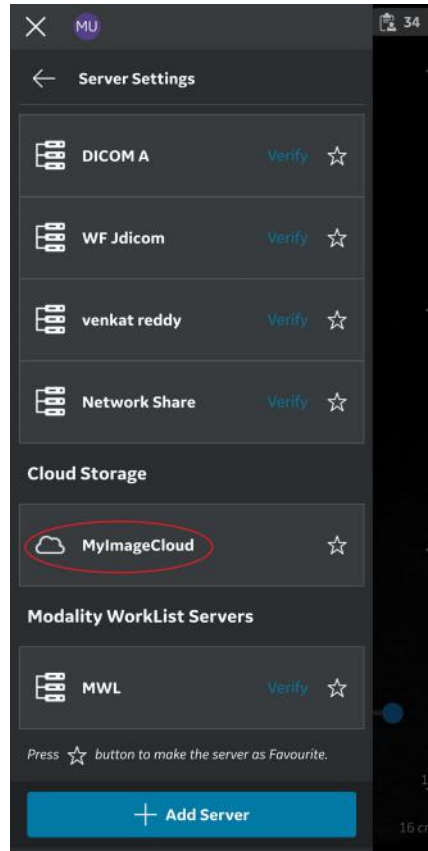
Figure 5-128. MyImageCloud option

Regional Instance Support

To comply with regional data privacy regulations such as HIPAA and GDPR, GEHC supports regional cloud servers (e.g. USA, EU) for the MyImageCloud solution. Prior to the first export of exams to MyImageCloud, go to the Server Settings page in the Menu and select the regional instance for MyImageCloud appropriate to your location. Until this selection is made, the MyImageCloud export option will not be enabled. Once selected, this setting will be remembered until it is changed.
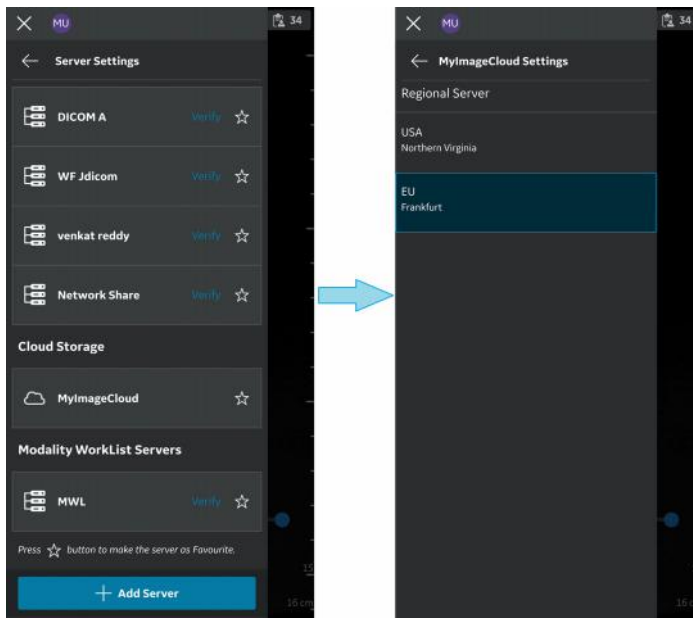
Figure 5-129.   Selecting relevant MyImageCloud region

Regional Instance Support (continued)

An error message pops up when the destination server is not selected.
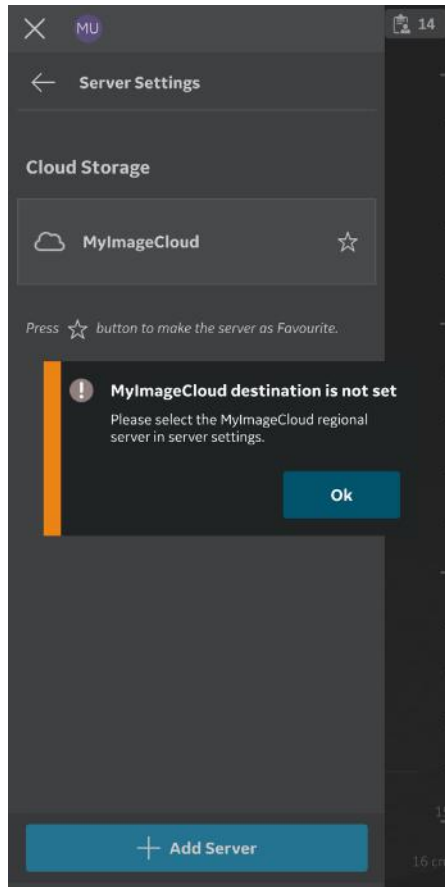
Figure 5-130.   Error message

3. MyImageCloud Solution (continued)

The exported exam/image data can be accessed by visiting myvscan.gehealthcare.com and signing in using the same account credentials used for the Vscan Air application.

An indication will be shown in the gallery against images or exams that have been exported to MyImageCloud.

NOTE: *An error message pops up, if an attempt is made to re-export images/exams that are already exported MyImageCloud.*
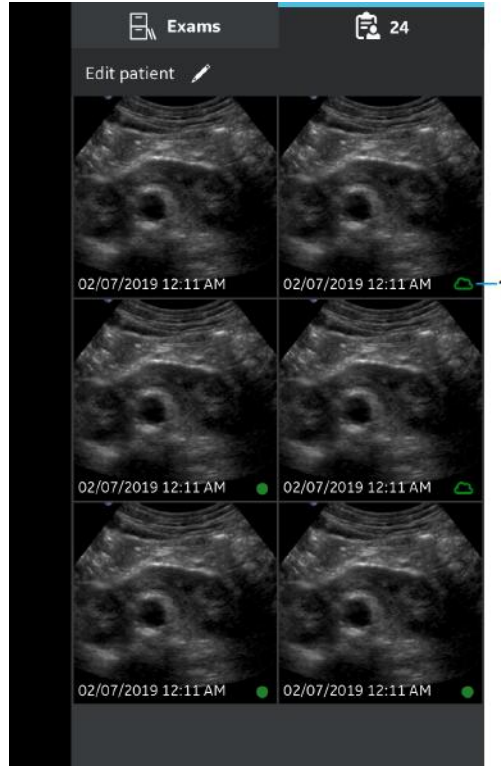
1.   MyImageCloud

Figure 5-131.   Exams exported to MyImageCloud

AI Tools

Vscan Air Artificial Intelligence (AI) tools are optional and enabled if purchased, but may not available or cleared for sale in all markets.

Cardiac Guidance

Cardiac guidance is a real-time AI software that enables the user to obtain different cardiac views through text and icon guidance, and reference images. Cardiac guidance also includes an automatic diagnostic-quality video recording. Cardiac guidance includes automatic saving of videos to the image gallery.

Cardiac interpretation is an automated ejection fraction software that provides an estimated ejection fraction stated as a percentage, along with an indication of the confidence regarding that estimate. The calculation of the estimated ejection fraction is automated based on the algorithm's processing of the echocardiography images.

Cardiac guidance is supported on tablets in landscape orientation only. Please check 'Vscan Air - Compatible Display Devices' on *page 3-28* or visit the Vscan Air support center to access the most recent list of validated display devices http://vscanair-support.gehealthcare.com/.

NOTE: *Cardiac guidance is only visible in the presets and tools menu if purchased and is supported by the Vscan Air SL only. Cardiac guidance is not available in Vscan Air Guest mode.*

For instructions, warnings, labeling and other support information about the cardiac guidance tool, refer to the Caption AI Operator's Manual.

Cardiac guidance and Interpretation by Caption AI includes Caption Guidance[TM] and Caption Interpretation AutoEF[TM] software developed and licensed by Caption Health, Inc.

Cardiac Guidance (continued)

Accessing the Cardiac guidance tool:

1. Open the presets menu.
2. Tap Cardiac guidance.
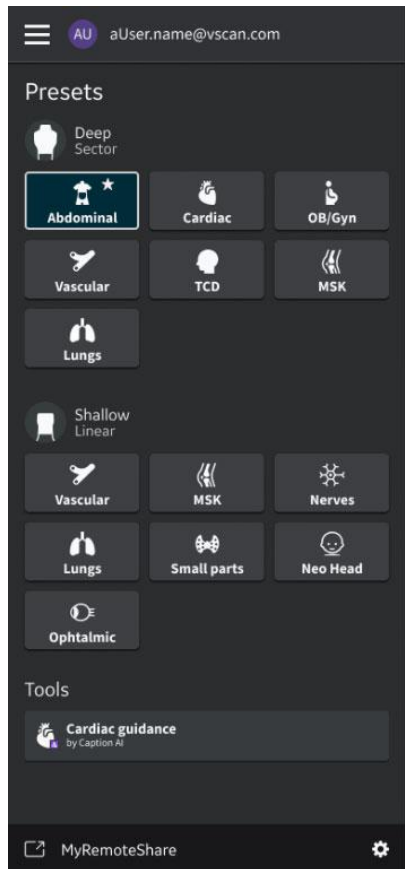
Figure 5-132.   Accessing Cardiac guidance

NOTE: *For instructions, warnings, labeling and other support information about the Cardiac guidance tool, refer the Caption AI Operator's Manual.*

Cardiac Guidance (continued)

To access the electronic Caption AI Operator's Manual in the Vscan Air app:

1. Tap the menu icon in the top left corner.

2. Tap Support -> User manual (Caption AI).
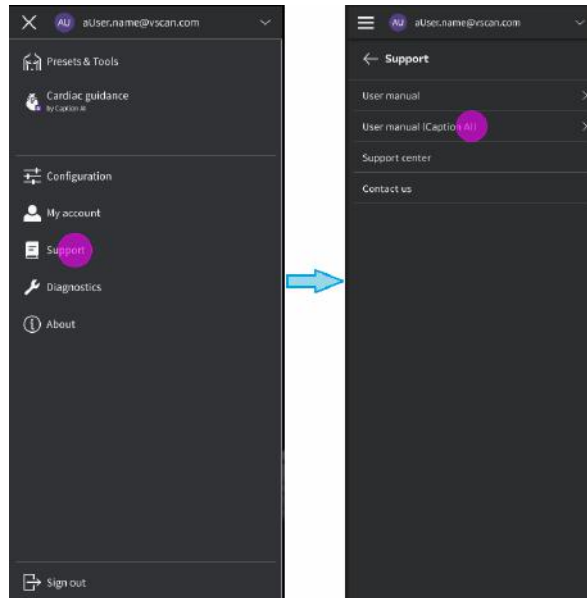
Figure 5-133.   Accessing Caption AI Operator's Manual

To access your stored images, swipe right to left or tap on Exam icon on the top right corner as described in the section 'Review and recall of stored data' on *page 5-100*.

Cardiac Guidance (continued)

The image gallery videos and AutoEF reports stored via selected views in Cardiac guidance will be labeled indicating the view captured.
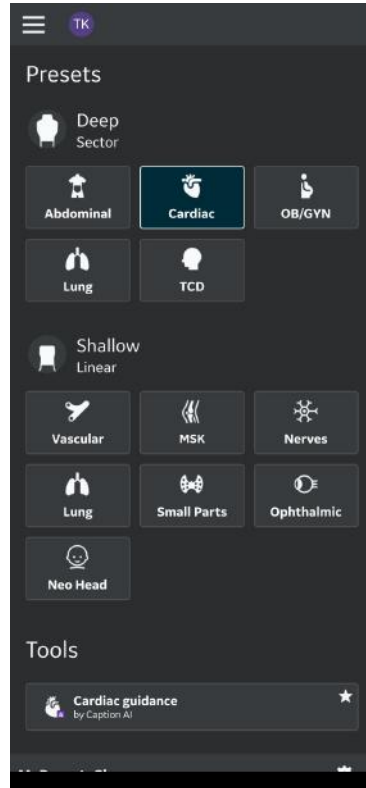
Figure 5-134.   Cardiac guidance selected as favorite

Cardiac Guidance (continued)
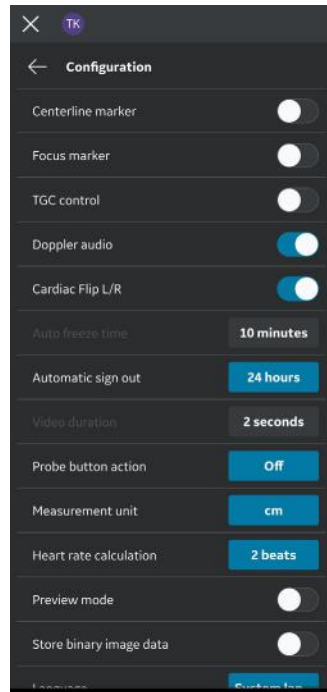
Figure 5-135.   Video duration and Auto freeze time disabled

NOTE: *The Video duration and Auto freeze time configuration is disabled when Cardiac guidance is selected. See the Caption AI Operator's Manual.*

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Chapter 6

Vscan Air Maintenance

Contents

System care and maintenance

Overview

 CAUTION Only trained persons should perform the safety inspections.

The Vscan Air probes requires regular care and maintenance to function safely and properly.

The expected service life of the Vscan Air probes is 5 years.

To ensure that the Vscan Air constantly operates at maximum efficiency, we recommend that the following procedures be observed as part of the customer's internal routine maintenance program.

NOTE: *The user must ensure that safety inspections are performed at least every 12 months according to the requirements of the patient safety standard EN/ES/IEC 60601-1 and its national deviations or according to the requirements of the IEC 62353 standard, medical electrical equipment – recurrent test and test after repair of medical electrical equipment.*

Special attention shall be paid to the following:

- Safety related marking / labels are legible and complete for the Vscan Air probe.
- The integrity of the probe e.g. is there any observed damage to the Vscan Air probe.
- Assess the accessories for damage (AC adapter, USB cable, wireless charger).
- Assess if the required documentation is available and reflects the current revision and/or configuration of the Vscan Air.

Physical Attributes that Indicate End of Service Life of Vscan Air probes

      a.   Probe body: cracks, abrasions, or evidence of impact.

      b.   Acoustic lens: cuts, tears, gouging, abrasion, swelling, bubbling, or delamination.

Inspection

Inspecting the Vscan Air

⚠ CAUTION	If any defects or damages are found on the Vscan Air probe, do not use it. Contact GEHC.

Examine the following on a monthly basis (or whenever there is a reason to assume that any issue may have occurred):

•   Equipment for cracks, loose or missing hardware.

⚠ WARNING	To avoid electrical shock hazard, do not remove covers from the Vscan Air CL or the Vscan Air SL probe.

Before each use

1.   Inspect the lens and the probe housing.
2.   Look for damage that might allow liquid into the probe.
3.   Test the functionality of the probe.

Quality assurance

A good Quality Assurance Evaluation program consists of periodic systematic actions that provide the user with adequate confidence that their diagnostic ultrasound system will produce consistently high-quality images and quantitative information. Therefore, it is in the best interests of every ultrasound user to routinely monitor equipment performance.

Typical Tests to Perform

Quality assurance measurements provide results relating to system performance. Typically. these are:

• Axial Measurement Accuracy

• Lateral Measurement Accuracy

• Axial and Lateral Resolution

• Penetration

• Functional and Contrast Resolution

• Gray Scale Photography.

With these tests, a performance baseline can be set at installation with the phantom in your department. Future test results can be compared to the baseline in order to maintain a record of system performance trends.

Leakage current and dielectric strength tests

The Vscan Air probes are completely sealed. All data communication to and from the probe, and all energy transfer to the probe is performed wirelessly. The probe does not have any connectors, metal-parts, or live parts accessible to the operator or the patient. The biocompatible probe handle plastic material is fully encapsulating the internal electronics, and also serves as dielectric protection against any live parts. The dielectric strength was tested during product approval as well as testing for IP67 compliance. Design in combination with the tightness test performed on all manufactured units guarantees the safety of the operator and/or patient. A hazardous electrical circuit could only be created if two live parts were exposed to the patient or the user in such a way that a closed electrical circuit could be created. For the operator or patient to gain access to one or two live parts, the plastic housing of the Vscan Air probe would need to be cracked open, first in one location, then in a second location. The two cracks would next need to be large enough for the operator or patient to insert one left hand finger and one right hand finger, both being live, to create a closed loop. The likelihood of this to occur is not reasonably foreseeable.

The Vscan Air probe is an internally powered ultrasound device and it does not have any electrical closed loop during intended patient or operator use, therefore no electrical hazard applies. It is not possible to conduct standard high-voltage tests, leakage current tests, dielectric strength tests without destroying the product due to the isolated/enclosed design of the Vscan Air probe. The Vscan Air risk assessment does not identify a necessity of leakage current and dielectric tests to be performed as routine tests.

Cleaning and disinfection

Reprocessing recommendation (Frequency)

After Each Use

1. Inspect the Vscan Air probe (See 'Inspecting the Vscan Air' on *page 6-3*).
2. Clean the Vscan Air probe.
3. If required, clean the display device.

NOTE: *The display device should be cleaned and/or disinfected according to the device manufacturer's recommendations. Example: https://support.apple.com/en-us/HT204172. Please be aware that medical grade display devices often support a wider range of cleaners and disinfectants compared to display devices for the consumer market.*

4. If required, disinfect the Vscan Air probe.

   Ensure that the Vscan Air probe is properly cleaned and disinfected after each use and before storage in the protective case.

CAUTION   If any defects or damages are found on the Vscan Air probe, do not use it. Contact GEHC service.

WARNING   Risk of Infection. ALWAYS clean and disinfect the probe between patients to the level appropriate for the type of examination.

Cleaning and disinfection

Adequate cleaning and disinfection between patient cases are necessary to prevent disease transmission. All probes must be thoroughly cleaned prior to disinfection. The level of disinfection required is based on patient contact. Use the following guidance to determine the appropriate level of disinfection based on system use.

Use	Method
Contact with non-intact skin	Cleaning followed by High-Level Disinfection
Contact with intact skin	Cleaning followed by Intermediate-Level Disinfection Cleaning followed by Low-Level Disinfection

Vscan Air is not intended for intra-operative use, it is also not intended for intra-cavitary use. It may be used during interventional procedures such as biopsy which based on proximity of the probe to the needle injection site it could get contaminated with blood or bodily fluids during use.

Chemicals Used for Efficacy Validation

The table below lists the products and intended use (cleaning, Intermediate-level disinfection, high-level disinfection) that were validated with the Vscan Air CL and Vscan Air SL probes.

Table 6-1:   Chemicals used for Efficacy Validation with Vscan Air CL and Vscan Air SL

Product Type	Trade Name	Manufacturer	Active Ingredients
Cleaning (Wipe)	Sani-Cloth Prime Germicidal Disposable Wipe	PDI	Isopropanol, Ethyl Alcohol (Ethanol), Didecyl dimethyl ammonium chloride
Intermediate-level Disinfection (wipe)	Sani-Cloth Prime Germicidal Disposable Wipe	PDI	Isopropanol, Ethyl Alcohol (Ethanol), Didecyl dimethyl ammonium chloride
High-Level Disinfection (Solution)	Cidex OPA Solution	Advanced Sterilization Products (J&J)	Ortho-Phthalaldehyde

Special Label Designations, Warnings and Precautions

Never use thinner, benzene, abrasive cleaners, or other strong solvents, as these may cause damage to the Vscan Air probe.

Special accessories

Special accessories are not applicable.

Probe Reprocessing

Vscan Air probe Pre-Treatment at the Point of Use (Required for all Vscan Air probes)

The pre-treatment step is for removal of gel and to minimize risk for cross contamination.

1. After each use,

   - remove the protective sheath from the Vscan Air probe if used.

   - gently remove all coupling gel from the Vscan Air probe by wiping with a soft, low lint cloth.

⚠️ CAUTION

Do not use abrasive paper products when cleaning or wiping a GEHC ultrasound probe. The use of abrasive wipes can damage the soft lens (acoustic window).

To extend the life of the Vscan Air probe lenses, pat dry only.

2. Wipe the Vscan Air probe with one of the wipes (listed in the website: https://gehealthcare.com/probecare or https://www.gehealthcare.com/products/ultrasound/ultrasound-transducers) from the lens of one transducer to the other. Dispose the cloth, wipe and gloves in the clinical trash.

3. After each use, inspect the lenses and housing of the Vscan Air probe. Look for any damage that would allow liquid to enter the Vscan Air probe.

⚠️ DANGER

If the Vscan Air probe is damaged, do not place it into any liquid (e.g. for disinfection) and do not use it until it has been inspected and repaired/replaced by a GEHC Service Representative.

⚠️ WARNING

Avoid processing procedures and chemicals that may damage the probe, such as: Do not steam autoclave or subject or the probe to Ethylene Oxide (ETO).

Manual cleaning Instructions

Manual cleaning is required to ensure the Vscan Air probes are cleaned to the extent necessary for further processing.

When cleaning select one of the cleaning methods described below, cleaning using wipes or cleaning using a cleaning solution.

Cleaning using Wipes

1. Dispense a cleaning wipe from the wipe canister.
2. Hold the Vscan Air probe with the large lens facing away from your body.
3. Gently wipe the Vscan Air probe with a cleaning wipe along the length of the Vscan Air probe. Gently wipe the Vscan Air probe large lens.
4. Rotate the Vscan Air probe and wipe the surface of the Vscan Air probe. As the wipe becomes visibly soiled, discard the wipe into clinical trash and dispense fresh wipes as needed.
5. Wrap a clean wipe around a soft nylon bristle brush to access crevasses on the surface of the Vscan Air probe. Do not use the brush on the Vscan Air probe lenses.
6. Turn the Vscan Air probe so that the small lens is facing away from your body.
7. Gently wipe the Vscan Air probe with the cleaning wipe along the length of the Vscan Air probe. Gently wipe the Vscan Air probe small lens.
8. Rotate the Vscan Air probe and continue wiping until the entire surface of the Vscan Air probe has been wiped.
9. Visually inspect the Vscan Air probe for any remaining soil and, if necessary, repeat steps 2 through 8 until the Vscan Air probe is visibly clean.

NOTE: *Pay special attention to lenses, edges and groves.*

Cleaning using a cleaning solution

1. Prepare a basin with enzymatic cleaner per the manufacturer's instructions.

2. Immerse probe in the cleaning solution and ensure no air bubbles are trapped.

3. Use a soft nylon bristle brush to clean the probe. Do Not use the brush on the probe lenses as this can damage the soft acoustic lens.

4. Ensure the probe remains in the cleaning solution for the minimum contact time listed on the enzymatic cleaner label. Make sure to follow manufacturers' recommendations.

5. Visually inspect the probe and probe components for soil. Repeat steps 4 - 6 until all visible soil has been removed from the surface of the probe.

6. Thoroughly rinse the probe to remove traces of the cleaner solution. Follow the cleaner manufacturers' instructions.

7. Visually inspect the device in a well-lit area to ensure all surfaces are free from residual cleaning solution. Repeat Step 6 if visible cleaning solution is observed.

8. Thoroughly pat dry the probe using a clean low-lint soft, dry disposable cloth or wipe. Do not use abrasive paper products.

Low-level/Intermediate level disinfection with wipes

1. Use a clean set of gloves.
2. Hold the Vscan Air probe with the large lens facing away from your body.
3. Wipe the Vscan Air probe from the large lens to the small lens, slightly rotating the Vscan Air probe after each wiping pass.
4. Turn the Vscan Air probe so that the small lens is facing away from your body.
5. Use a new wipe and apply to the small lens. Now, wipe the Vscan Air probe from the small lens to the large lens, slightly rotating the Vscan Air probe after each wiping pass.
6. Wrap a clean wipe around a soft nylon bristle brush to access crevasses on the surface of the Vscan Air probe. Do not use the brush on the Vscan Air probe lenses.
7. Once the Vscan Air probe has been completely wiped, use additional wipes and continue wiping the Vscan Air probe as needed to ensure all surfaces remain wet for the required exposure time listed on the disinfectant manufacturer's label.
8. Dry all surfaces of the Vscan Air probe using a sterile, lint-free, soft wipe or cloth. Blot or pat the lenses dry.
9. After each use, inspect the lenses, and housing of the Vscan Air probe. If the Vscan Air probe is damaged, do not place it into any liquid (e.g. for disinfection) and do not use it until it has been inspected and repaired/replaced by a GEHC Service Representative.

High-level disinfection – Soak

High-Level Disinfection is required for devices that contact non-intact skin.

In order for cleaner to be effective, all visible residues must be removed during the cleaning process. Follow the cleaning instructions as given in 'Manual cleaning Instructions' on *page 6-9* to clean the probe before performing disinfection.

Do not soak probes in cleaner for longer than stated by the chemical manufacturers instructions for use. Extended soaking may cause probe damage and early failure of the enclosure, resulting in possible electric shock hazard.

1. Prepare a basin with the high-level disinfectant per the manufacturer's instructions for use. Be sure to follow all precautions for storage, use and disposal. Observe specifically soak times and dilution rates.
2. Immerse cleaned and dried probe in the disinfectant for the time specified by the chemical manufacturer and ensure no air bubbles are trapped.
3. Thoroughly rinse the probe to remove traces of the disinfectant. Follow the disinfectant manufacturers instructions.
4. Thoroughly dry all surfaces of the device using a sterile, lint-free wipe or cloth, changing wipes/ cloths when necessary to ensure the device is completely dry.

NOTE: *High-level disinfectants may be available as powder products. Follow the manufacturer's instructions for use for preparing the disinfecting solution from the powder product.*

WARNING DO NOT soak probes in cleaner for longer than is stated by the chemical instructions for use. Extended soaking may cause probe damage and early failure of the enclosure, resulting in possible electric shock hazard.

Choosing a Disinfectant

When choosing a disinfectant, determine the required level of disinfection. If the possibility of cross-contamination or exposure to unhealthy or non-intact skin exists, then high level disinfection should be performed. Good hand hygiene practice is highly recommended to help further reduce the risk of cross-contamination.

NOTE: *For additional information about cleaning and disinfection, refer to the recommendations of the Association for Professionals in Infection Control (APIC), the U.S. Food and Drug Administration (FDA), and the U.S. Centers for Disease Control (CDC). For country-specific disinfection regulations, check with your local regulatory infection control authorities.*

NOTE: *A validated, high-level disinfection process, combined with the use of a sterile gel and a probe cover/sheath is an accepted method of infection control for Ultrasound probes. Adequate records or a logbook detailing the time, date, disinfection method, and verification of disinfectant effectiveness or test results is recommended. For more information about establishing an evidence-based disinfection protocol for your practice, refer to the FDA, CDC, HICPAC, APIC, or the Joint Commission websites.*

Covering the Vscan Air probe using a Sterile, Protective Sheath

CAUTION   Vscan Air probe sheaths should be used in any clinical situation where infection is a concern.

1. Place an appropriate amount of gel inside the protective sheath and/or on the transducer face.

NOTE: *Failure to use imaging gel may result in poor image quality.*

2. Insert Vscan Air probe into sheath, making sure to use proper sterile technique. Pull cover tightly over Vscan Air probe face to remove wrinkles and air bubbles, taking care to avoid puncturing the sheath.

1. Protective sheath
2. Vscan Air probe with the Protective sheath

Figure 6-1.   Applying the sheath

3. Secure the sheath in place.

NOTE: *If using a rubber band for securing the sheath make sure that it does not affect the probe power button.*

4. Inspect the sheath to ensure there are no holes or tears. If the sheath becomes compromised, stop the procedure and replace immediately.

Cleaning the protective case

The protective case is compatible with the set of cleaners and disinfectants listed for the Vscan Air probe. When cleaning the protective case pay special attention to its edges and grooves. Requirements for the protective case cleanliness will be defined by the way the protective case is implemented in the workflow for storing the Vscan Air probe. Cleaning of the protective case will be required if the Vscan Air probe was not properly cleaned of disinfected before it was storage in the protective case.

Figure 6-2.   Protective case

GEHC ultrasound transducers web site

The GEHC Ultrasound transducers web site contains a list of chemicals that have been tested for compatibility with GEHC ultrasound probes. Verify probe compatibility via the GEHC ultrasound transducers web site. The reprocessing instructions provided in this document have been validated with the chemicals specified in 'Chemicals used for Efficacy Validation with Vscan Air CL and Vscan Air SL' on *page 6-7*.

GEHC ultrasound transducers web site
https://gehealthcare.com/probecare OR https://www.gehealthcare.com/products/ultrasound/ultrasound-transducers

WARNING

Creutzfeldt-Jakob disease

This device is not indicated for neurological use. Neurological contact on patients with this disease MUST BE avoided. If the Vscan Air CL or the Vscan Air SL becomes contaminated, there is no adequate means to disinfect it. In this case, the contaminated device/probe MUST BE discarded in accordance with local biological waste hazard procedures.

Chemicals compatible with Vscan Air probe

The table below lists the chemicals that were tested for compatibility with the probes.

⚠️ **WARNING** Products listed below are compatible with Vscan Air probe materials, but GE has not validated their efficacy. Questions related to these products should be directed to the detergent/disinfectant manufacturer. Refer to Table 6-1 *on page 6-7* to identify products validated by GE. Products listed might not be available in all regions. Check with your local infection control authorities or product manufacturer. GE warranties and service contracts do not cover, and GE is not responsible for, damages caused by cleaning, disinfection or gel products that are not compatible with GE probes.

Table 6-2: Chemicals compatible with the Vscan Air CL and Vscan Air SL probes

Trade Name	Manufacturer
Cidezyme/ Enzol	Advanced Sterilization Products (J&J)
Alcohol 70% Ethanol on a wipe **	All manufacturer
Alcohol 70% Isopropanol on a wipe **	All manufacturer
Bacillol 30 Foam	BODE Chemie GmbH (HARTMANN)
Bacillol AF Tissues	BODE Chemie GmbH (HARTMANN)
CaviWipes 1	Metrex
Cleanisept Wipes forte	Dr.Schumacher GmbH
Sekusept Aktiv	Ecolab
Mikrobac forte	BODE Chemie GmbH
Surfa'Safe Premium	Laboratoires Anios
Matrix Wipes	Whiteley Medical
Mikrobac tissues	BODE Chemie GmbH (HARTMANN)
Sani-Cloth Active (Ecolab)	Ecolab
Sani-Cloth Active (PDI)	PDI
Sani-Cloth AF3 Germicidal Disposable Wipe	PDI
SONO Ultrasound Wipes	Advanced Ultrasound Solutions Inc
Super Sani-Cloth Germicidal Disposable Wipe	PDI
Tristel Pre-Clean Wipes	Tristel Solutions Limited

Table 6-2:   Chemicals compatible with the Vscan Air CL and Vscan Air SL probes

Trade Name	Manufacturer
Tristel Rinse Wipes	Tristel Solutions Limited
Tristel Trio Wipes System *	Tristel Solutions Limited
mikrozid sensitive or mikrozid alcohol free (liquid and wipes)	Schulke & Mayr GmbH
mikrozid universal liquid and mikrozid universal wipes	Schulke & Mayr GmbH
Protex ULTRA Disinfectant Wipes	Parker Laboratories Inc
Reynard Premier Detergent & Disinfectant Wipes	Reynard Health Supplies
Anioxyde 1000	Laboratoires Anios
Wip'Anios Excel	Laboratoires Anios

Disclaimer: ** Disinfection with Tristel Trio Wipes System may cause discoloration of the lightbar, the button and the soft plastic surrounding the battery door. Such color change does not impact the performance, safety or lifetime of the probe. If color change occurs due to disinfection with Tristel Trio Wipes System, Vscan Air probes will not be repaired or replaced under warranty or contract agreements.*

Compatibility with trophon devices

There are different methods of disinfecting the Vscan Air probe based on its clinical use. When High-Level Disinfection is required, utilizing trophon EPR or trophon2 devices is one disinfection method. A trophon Wireless Ultrasound Probe Holder is required to hold the Vscan Air probe in the trophon chamber. Refer to the manufacturer's instructions for use when using the trophon EPR or trophon2 devices.

GE offers this holder as an accessory to the Vscan Air. GE HealthCare has not validated the effectiveness of the disinfection process utilizing trophon devices. For questions relating to efficacy testing please visit Nanosonics at www.nanosonics.com

Table 6-3:   Products compatible with the Vscan Air CL and Vscan Air SL probes

Trade Name	Manufacturer
trophon2 *	Nanosonics
trophon EPR *	Nanosonics

***Disclaimer:** * High usage of trophon devices may cause discoloration of the lightbar, the button and the soft plastic surrounding the battery door. Such color change does not impact the performance, safety or lifetime of the probe. If color change occurs due to disinfection in trophon chamber, Vscan Air probes will not be repaired or replaced under warranty or contract agreements.*

Upgrades

Upgrade software

Vscan Air software updates will be made available for download either from Google Play store or Apple Store.

Users are encouraged to update their Vscan Air devices to get access to the latest product improvements and to install updates at a convenient times.

Download app software upgrades when available from either Google Play store or Apple Store.

Perform a monthly check for Vscan Air app updates if the display device is configured to NOT accept automatic app updates.

NOTE: *Software upgrades through the Apple app store or Google play may not be available in all markets.*

Perform a monthly check for display device OS updates if the display device is configured to NOT accept automatic OS updates. Be aware that it is recommended to upgrade your device to the latest OS version verified to be compatible with the device.

See 'Vscan Air - Compatible Display Devices' on *page 3-28* for more information.

Vscan Air probe software upgrade

After downloading an app software upgrade the Vscan Air CL or the Vscan Air SL probe software might need to be upgraded.

Follow the on-screen instructions when connecting the probe to the app to upgrade probe software.

If a probe software upgrade is needed please make sure to update all probes being used with the Vscan Air app at a convenient time.

NOTE: *The system reverts to the previous active installation, if a power cycle happens before the probe software upgrade is completed.*

NOTE: *For the probe software update to start the probe charge level needs to be 50% or higher.*

NOTE: *If an App update is installed then make sure to connect all the Vscan Air probes normally used with that display device to update these as required or to confirm that the relevant update is already installed. Make sure that all the display devices connecting to any of the updated probes, are also updated and that all display devices are using the same Vscan Air app software revision.*

Check that the Vscan Air app and its connected Vscan Air probes works as expected after upgrading either the display OS or the Vscan Air app. Check that the probe connects seamlessly to the app, that the wireless connection quality indicator is indicating good quality, that the image updates without lags or interruptions and that all imaging modes are free from noise issues.

Vscan Air probe software upgrade

1. Pair the Vscan Air probe to the app. If the probe software needs to be updated it prompts for an upgrade '**probe needs update**'. Click on '**start update'**.
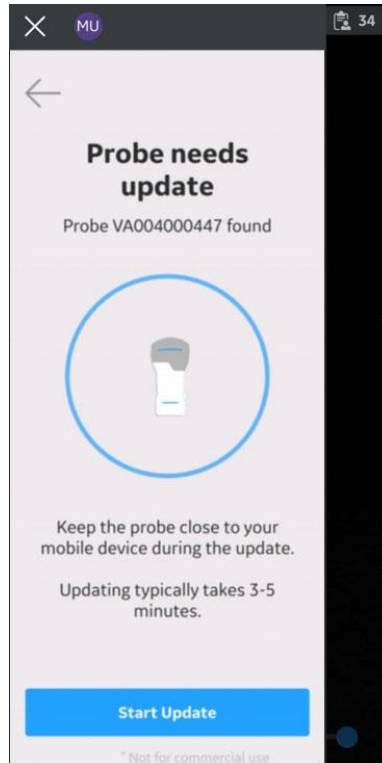
Figure 6-3.   Probe needs update

Vscan Air probe software upgrade (continued)

2. The probe update is in progress.
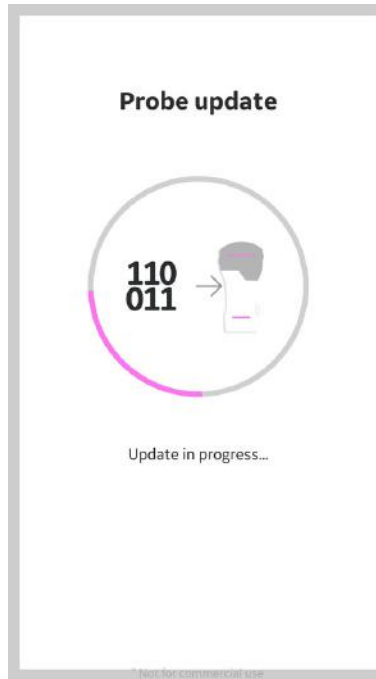
Figure 6-4.   Probe update in progress

Vscan Air probe software upgrade (continued)

3. The probe update process takes around 3 to 5 mins.
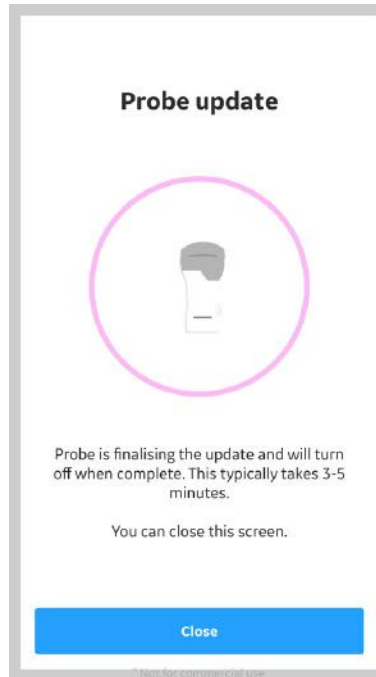
Figure 6-5.   Probe update in process

4. When the probe update is complete, the probe may need to power off to complete the update. The user will then need to manually restart the probe. Whenever probe-cycling is not required, the probe will start searching for and connect to any available nearby display device running the Vscan Air app.

Postpone update

In some cases software maintenance might be needed to stay compatible with new operating system (OS) releases or to correct important issues being reported. An example of an important correction would be addressing a problem preventing some users from logging into the app. To make sure that an installed Vscan Air app utilizes a software containing the latest product improvements a minimum software revision check will be performed upon starting the Vscan Air app.

The user will be notified via a "Software updated needed" message as shown in Figure 6-6 if a Vscan Air app software update is needed. The user can select to postpone updating the Vscan Air app for up to 7 days to fit the update at a convenient time. The user will be reminded upon starting the Vscan Air app as indicated in Figure 6-6 until the update will need to take place and update is required.
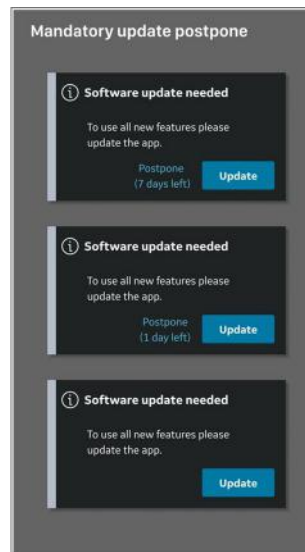
Figure 6-6.   Postpone update

Troubleshooting

No connection between the Vscan Air probe and the mobile device

To be able to connect the Vscan Air probe to the mobile device, the mobile device's Wi-Fi should be turned **ON**.

If the connection is broken, try these steps:

- Ensure the Wi-Fi is enabled in the mobile device.
- Ensure that the Vscan Air probe is turned **ON**.
- Ensure that '*Flight mode is* **OFF**.

Troubleshoot the Vscan Air probe

Table 6-4: Troubleshoot probe

Problem	Possible cause	Solution
1. Vscan Air probe - can not Power **ON**	Battery is discharged and the Vscan Air probe charge level is <8%.	Probe will need to charge above 8% to be powered on.
2. Vscan Air probe is not charging.	Defective battery or probe hardware issue	Contact GEHC Service (see 'Contact information' on *page 1-15*)
	Defective AC adapter.	Contact GEHC Service (see 'Contact information' on *page 1-15*)
	Defective wireless charger.	Contact GEHC Service (see 'Contact information' on *page 1-15*)
	Defective USB cable.	Contact GEHC Service (see 'Contact information' on *page 1-15*)
	Mains power is down.	Ensure that the charger is connected to a powered wall outlet.
	Temperature is outside the specified limits.	Ensure the ambient temperature is within the specified limits (see 'Contact information' on *page 1-15*)
	Incompatible AC adapter or cable connected to the Vscan Air wireless charger indicated by the charger LED flashing green.	Connect a compatible AC adapter and/or cable to the Vscan Air wireless charger.
3. Parts of the image is missing when scanning.	Channels are missing.	Contact GEHC Service (see 'Contact information' on *page 1-15*) Run the transducer element test as mention in 'Transducer Element test' on *page 6-48*.
4. The Vscan Air wireless charger LED is flashing or 'breathing' blue using 2 seconds per cycle.	A metal obstruction is detected.	Remove the metal obstruction from the Vscan Air wireless charger.
5. Low volume high pitch sound from probe while scanning.	Vibrations in probe electronics might in certain setting create a low volume high pitched noise. This sound is more likely to appear when activating the curved transducer than with the other transducers. It should be considered being natural and not an error with the actual probe.	A subset of users may be able to sense the sound/noise. It may cause discomfort, headache and/or hearing sensations. To reduce this, consider modifying settings if possible, moving the probe further away from the user, and consider also using hearing protection.

Troubleshoot probe pairing

Table 6-5:   Troubleshoot pairing

Issue/Symptom	Potential Causes	Recommended Actions
1. Probe is powered on and its LEDs indicate searching (waiting to pair) despite having launched the app on mobile device.	This is the first attempt to pair with this probe.	Press the button on the side of the probe to allow it to pair with a new mobile device.
	The probe and app mobile device are too far apart.	Move/orient the probe and app mobile device closer to one another. Watch for the probe LEDs to indicate display found (pairing has been initiated).
	The orientation of the probe and app mobile device is not optimal for Bluetooth beacon reception.	Orient the probe and app mobile device with respect to one another (e.g. front/back, left/right. Watch for the probe LEDs to indicate display found (pairing has been initiated).
	The app mobile device is not transmitting advertising beacons.	Close the app and launch again. If the problem persists, reboot the mobile device and relaunch the app.*
2. Not able to pair with probe	Probe may already be connected to a different instance of the app.	Make sure that the probe is turned off. Close the app fully on the device that has been paired previously. Apple devices: Open Settings, select Wi-Fi, and if the selected network is the SSID of the probe (VAXXXXXXXX), either select it to see its details and choose Forget This Network or just choose the SSID for a different network. Android devices: Open Settings and navigate to the Wi-Fi Direct panel. Depending on the manufacturer of the Android device the Wi-Fi direct panel is found in different places in Settings. You can use the search capability to find it if it is not obvious.

Table 6-5:   Troubleshoot pairing

Issue/Symptom	Potential Causes	Recommended Actions
		When you are on the Wi-Fi direct panel, you should see a list of Peer Devices, Available Devices, Remembered groups or something similar Select the device that matches your probe (VAXXXXXXXX) and make sure to disconnect. Turn ON the probe and press probe button to connect to the wanted display device. If issue persists, Contact GEHC Service (see 'Contact information' on *page 1-15*)
3. Probe LEDs indicate display found (pairing initiated), but connection fails and the probe shuts down.	The probe battery level is too low.	Place the probe on the charger and try again when sufficiently charged.
	The probe has experienced an internal failure.	If issue persists despite having charged the probe, Contact GEHC Service 'Contact information' on *page 1-15*.
4. When connecting to an iOS device, the probe LEDs indicate display found (pairing initiated), Join was selected when the Vscan Air Wants to Join Wi-Fi Network "VAXXXXXXXXX" dialogue was presented, but the connection fails. The probe LEDs may or may not return to indicate searching (waiting to pair) state. Unable to join the network "VAXXXXXXXXX" dialogue observed.	User failed to select Join in dialogue on iOS device to join the probe network before the probe's 30 second timer expires.†	Dismiss the Unable to join the network "VAXXXXXXXXX" dialogue. If the app does not retry on its own, present the Join dialogue, and finally connect, close the app and launch again. If the problem persists, reboot the iOS device and try again.*
	There is an issue with the networking on the iOS device.	Dismiss the dialogue. Reboot the iOS device and try again.*
	New from iOS 14 and later, the Vscan Air app has not been given Local Network access permission.	Close the app, open Settings, scroll down to the Vscan Air app and select it to see its access permissions. On the right side, ensure that under the list of "ALLOW VSCAN AIR TO ACCESS" the setting for Local Network is enabled. Also check that when under the Location setting that While Using the App is selected, and Precise Location is enabled. Launch the app and try again.

Table 6-5:   Troubleshoot pairing

Issue/Symptom	Potential Causes	Recommended Actions
5. When connecting to an iOS device, the probe LEDs indicate display found (pairing initiated), the Vscan Air Wants to Join Wi-Fi Network "VAXXXXXXXXX" dialogue was presented and a choice was selected, but after the dialogue goes away the connection is not completed.	User has selected Cancel instead of Join.	Press Click to retry in the Searching for probe screen.
	New from iOS 14 and later, the Vscan Air app has not been given Local Network access permission.	Close the app, open Settings, scroll down to the Vscan Air app and select it to see its access permissions. On the right side, ensure that under the list of "ALLOW VSCAN AIR TO ACCESS" the setting for Local Network is enabled. Also check that when under the Location setting that While Using the App is selected, and Precise Location is enabled. Launch the app and try again.
	A VPN (Virtual Private Network) service enabled on the user's device.	Close the app fully. Pause or disable the VPN service (In some cases, instead of pausing or disabling VPN, it is possible to use split tunneling and to designate Vscan Air as a trusted app or to allow local network discovery to permit access to devices on the local network. It may be necessary to turn Wi-Fi off and on again, depending on the VPN service.) Launch the app and try again.
6. When connecting to an Android device, the probe LEDs had indicated display found (pairing initiated), but connection fails and probe LEDs return to indicate searching (waiting to pair) state.	Failure to create network interface or problems with negotiating group formation when connecting to Android devices.	If the app does not retry on its own and successfully connect, close the app and launch again.
	There is an issue with networking on the Android device.	Close the app, open Settings and navigate to the Wi-Fi Direct panel. Depending on the manufacturer of the Android device the Wi-Fi direct panel is found in different places in Settings. You can use the search capability to find it if it is not obvious. When you are on the Wi-Fi direct panel, if you see a list of Remembered Groups and it contains your probe VAXXXXXXXXX, select it and answer OK when asked to Forget this group? Launch the app again.
		If the problem still persists, reboot the Android device and try again.*

Table 6-5: Troubleshoot pairing

Issue/Symptom	Potential Causes	Recommended Actions
7. When connecting to an Android device, the probe LEDs had indicated display found (pairing initiated), but connection is not completed.	Vscan Air app permissions for Location are set incorrectly.	Close the app, open Settings and navigate to the app permissions for the Vscan Air app. Ensure that location permission is enabled while using the app and that use of the precise location is enabled. Launch the app again.
	A VPN (Virtual Private Network) service enabled on the user's device.	Close the app fully. Pause or disable the VPN service (In some cases, instead of pausing or disabling VPN, it is possible to use split tunneling and to designate Vscan Air as a trusted app or to allow local network discovery to permit access to devices on the local network. It may be necessary to turn Wi-Fi off and on again, depending on the VPN service.) Launch the app and try again.
8. My probe or app mobile device is connecting to the wrong app mobile device or probe.	When a probe has been paired with multiple display devices, the timing of when an app was launched on a mobile device and a probe begins searching (waiting to pair) mode can result in the selection of the wrong device when multiple users are attempting to work in proximity.	Close the app on the mobile device and power off the probe. Then move 1.5 meters or more away from the other probes and display devices. Launch the app on the mobile device. After the app display shows Searching for probe, power on the probe and hold it near the mobile device (around 10 centimeters) to ensure it will detect the correct mobile device as being the closest.

Table 6-5:   Troubleshoot pairing

Issue/Symptom	Potential Causes	Recommended Actions
9. The app on my mobile devices is in the background or closed, but my probe has not shut off after 5 minutes of inactivity.	The network established between the probe and app mobile device is still active.	With an iOS device, open Settings, select Wi-Fi, and if the selected network is the SSID of the probe (VAXXXXXXXX), either select it to see its details and choose Forget This Network or just choose the SSID for a different network.
		With an Android device, open Settings and navigate to the Wi-Fi Direct panel. Depending on the manufacturer of the Android device the Wi-Fi direct panel is found in different places in settings. You can use the search capability to find it if it is not obvious. When you are on the Wi-Fi direct panel, you should see a list of Peer Devices or Available devices or something similar. Select the device that matches your probe (VAXXXXXXXXX) to disconnect.
10. When attempting to connect to an Android device, the connection fails repeatedly.	There is a pending software upgrade to the Android device.	Close the app, open Settings and navigate to the System update panel. Depending on the manufacturer of the Android device the System update panel is found in different places in Settings. If an update is available, follow the steps to download and install the update.
		After the upgrade finishes, you will likely be instructed to restart the device. After the device restarts and you are able to open the Vscan Air app, attempt to pair again.
11. When an Android display device is connected to a Vscan Air probe using a given network, actions like ping, image upload to PACS, print to network printer or any file transfer fails.	If the IP schema of the network is 192.168.20.x, the Android display device cannot ping or transfer data on the network when a Vscan Air probe is connected.	The IP address of the network where the display device is operating has to be changed to anything different from 192.168.20.x
* The need to reboot the device to solve this issue is rare. † This currently does not behave as expected and will be improved.		

Troubleshoot probe connection

Table 6-6:   Troubleshoot probe connection

Issue/Symptom	Potential Causes	Recommended Actions
1. The Wi-Fi Quality indicator indicates insufficient network bandwidth. It is likely the update of the image display will appear to stutter (pausing and resuming repeatedly).	The primary channel that was chosen by the probe to establish the network is the same as that of one or more networks in the area, and the existing network congestion is limiting the throughput of the Vscan Air network.	On an iOS device, disconnect from the probe by closing the Vscan Air app. When the probe returns to searching (waiting to pair), launch the app again. The probe randomly selects a primary channel for iOS devices, and choosing a different one may solve the throughput issue.
	An Android device connected to an existing network prior to pairing with the probe might negotiate with the probe to form the results in a situation where the Wi-Fi module on the Android device becomes inefficient at managing the throughput of both networks.	On the Android device, disconnect from the probe by closing the Vscan Air app. Navigate to the Wi-Fi section of Settings and either "Forget" the network the device was connected to prior to pairing or turn off "Auto-connect" (may also be called "Auto reconnect") and disconnect from the network. Launch the app again. The new network will be formed on a random selection of the supported channels the probe and Android device have in common. In the event there is still an indication of insufficient network bandwidth, close the app and launch again (a strategy like the one for iOS above).

Troubleshoot subscriptions

Table 6-7:   Troubleshoot subscriptions

Issue/Symptom	Potential Causes	Recommended Actions
Can not see the subscribed feature	The subscribed feature has expired	Check the 'Probe subscription details' on *page 4-65* and use 'Get latest' as described on page 4-59 to make sure that the connected probe does have an expired subscription. To continue to use the feature then renew the subscription to activate it again.
	Since a subscription is linked to a probe the connected probe might not have the subscription you are looking for	Check the 'Probe subscription details' on *page 4-65* and use 'Get latest' as described on page 4-59 to make sure that the connected probe actually is the one that has the subscribed features you are looking for

Steps to troubleshoot Network shared folder connectivity challenges

1. Lack of permission for network shared folder on windows PC.

   • Step 1: Right click on the folder and select Properties. Go to '**Sharing**' tab.
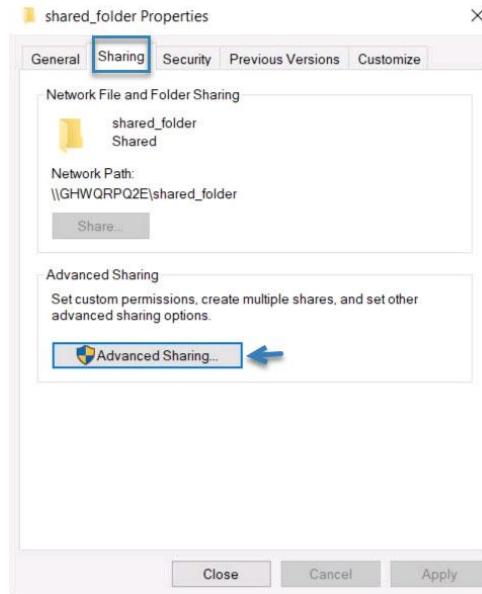
   • Step 2: Click on '**Advanced Sharing**'. Make sure '**Share this folder**' is selected.
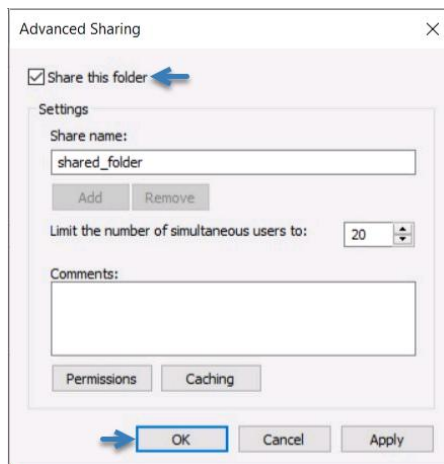
Steps to troubleshoot Network shared folder connectivity challenges (continued)

- Step 3: Click on '**Share Permissions**'.
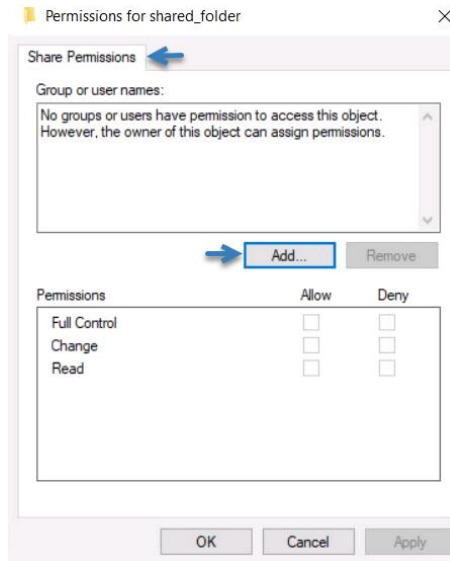
- Step 4: Click on '**Add**'.
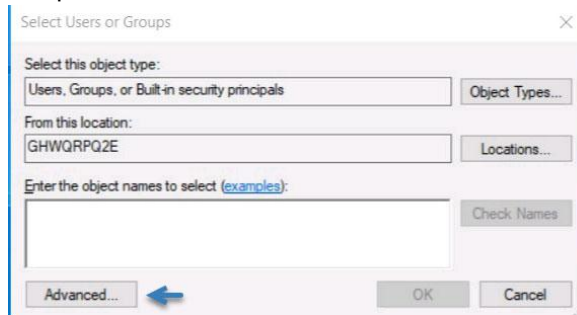
Steps to troubleshoot Network shared folder connectivity challenges (continued)

- Step 5: Click on '**Advanced**' and click '**Find now**'. Observe that list of user group shows up below in **Search results**.
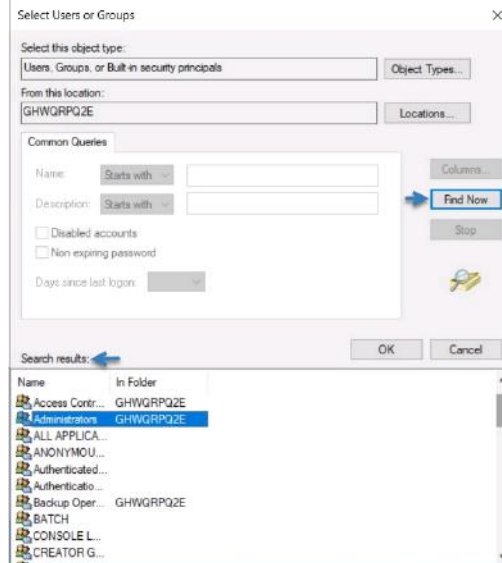
- Search for your user name and select. Also select Administrators and Authenticated users in the list to provide access to admin group and to all the authenticated users. Click '**OK**'. Under '*Share Permissions*' window, Select '**Full Control**' for all the user group added. Click '**Apply**' and Click '**OK**'..
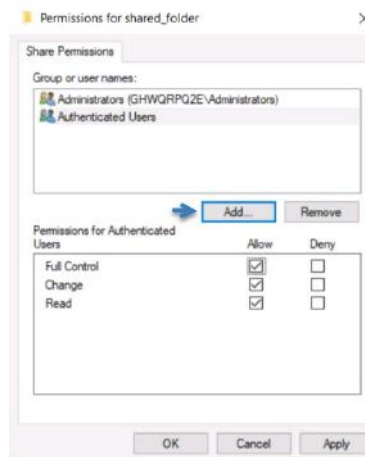
Steps to troubleshoot Network shared folder connectivity challenges (continued)

2. Check in User accounts of PC for the right user name.

   Open Control Panel -> User Accounts -> User Accounts ->Manage User Accounts. Make sure the User Name entered in the Network shared folder configuration in Vscan Air is same as the User Name displayed in User Accounts of PC.

Troubleshooting FAQs for Digital tools

Table 6-8:   Troubleshooting FAQs - Digital tools

Problem	Possible reason	Resolution
1. Not able to create user accounts	a. Display device not connected to a network that can access the user account creation server. b. The user authentication server is down. c. Password guidelines are not met. d. User has selected a region/country which is not yet cleared for Vscan Air. e. User is deactivated in the backend.	• (a, b) Retry the workflow when the internet connection is available. If issue persists, Contact GEHC Service (see 'Contact information' on *page 1-15*) • (c) For password refer 'Password Guidelines' on *page 6-39* • (d, e) Contact GEHC Service ('Contact information' on *page 1-15*}
2. User sign in fails	a. The user authentication server is down. b. No Internet connectivity. c. The username/password combination is incorrect. d. The user has forgotten the password. e. The user is not the accessible list for the enterprise probe. f. Difficult to type lengthy, complex usernames, passwords with one hand.	• Guest user option is available to the user. • Answer confirmation email to reset password. • User can ask admin to give access to specific probe. • Guidance text in user manual on the usage of predictive text, swipe keyboard settings on android/iOS devices for ease of usage. If issue persists, 'Contact information' on *page 1-15*)
3. MyRemoteShare failure	Tried on an iPad without SIM card	• For MyRemoteShare feature to work on iPad's, they need to have SIM card with data enabled.

Password Guidelines

- The password must have at least 8 characters.
- The password should include at least one number, one uppercase letter, one lowercase letter, and one of the following special characters: ! " # $ % & ' ( ) * + , - . / : ; < = > ? @ [\ ] ^ _ ` { | } ~

Additional messages

Table 6-9: DICOM messages

Problem	Possible causes	Solution
1. Verification failure of DICOM image server/ MWL Server / Network share folder.	The DICOM end point does not support the initiated service (Echo or Storage or MWL servicer).	Contact hospital IT staff to find the root cause and can resolve the issue by addressing root cause.
	Configuration details such as IP address, port, AE title can be incorrect for DICOM end points.	
	Firewall restriction in the hospital network.	
2. Exported image/loops are not transferred or failed in Image queue.	Network availability for device Wi-Fi to transfer.	- Contact hospital IT staff to find the root cause and can resolve the issue by addressing root cause. - Ensure configurations and certificates are loaded to device correctly. - Validate the certificate.
	Configurations on DICOM End points (Storage server/MWL) in case of secure communication over TLS.	
	Certificates expiry	
	Configuration on DICOM End points for Storage commit with Vscan Air IP address/AE title/listening port.	
	DICOM Encoding support	
	Permission for the shared folder to receive the transferred data from Vscan Air in case of Network share folder.	
3. Failed to get scheduled Exam list from MWL	Network availability for device Wi-Fi to transfer.	Contact hospital IT staff to find the root cause and can resolve the issue by addressing root cause.
	Incorrect configuration of MWL server on Vscan Air.	

Troubleshooting – Brazilian Portuguese (iPhone and iPad)

The following needs to be configured when using an iPhone or iPad and wanting the app to display texts in Brazilian Portuguese.

Option 1: Select "***Português (Brasil)***" in the Vscan Air app via Menu > Configuration > Language.
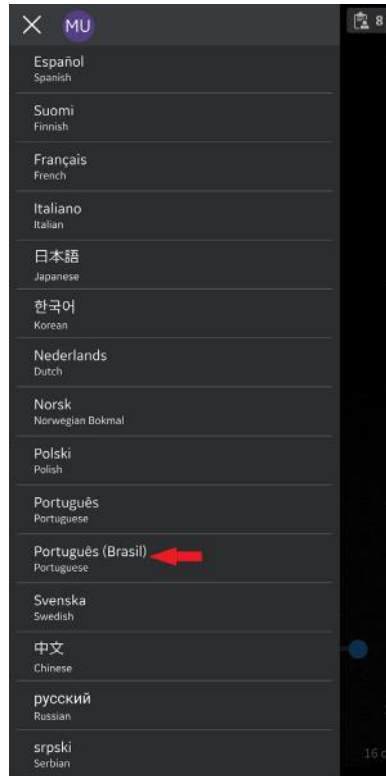
Figure 6-7.   Brazilian Portuguese

Troubleshooting – Brazilian Portuguese (iPhone and iPad) (continued)

Option 2: Select "*System language*" in the Vscan Air app via Menu > Configuration > Language.
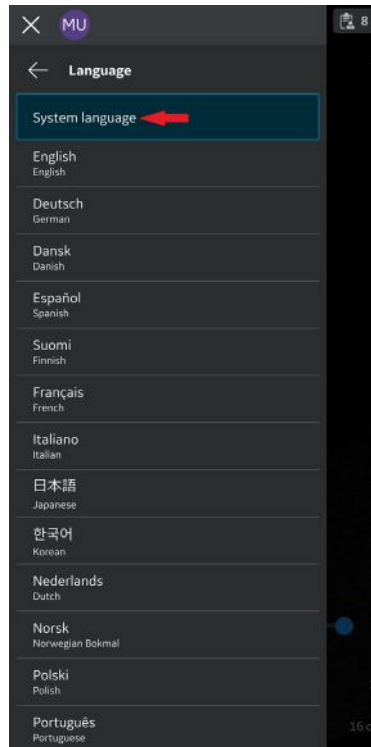
Figure 6-8.   System language

Troubleshooting – Brazilian Portuguese (iPhone and iPad) (continued)

• Via the iPhone or iPad Settings > General > Language and
Region, select "**Brazil**" via the device Region selection.
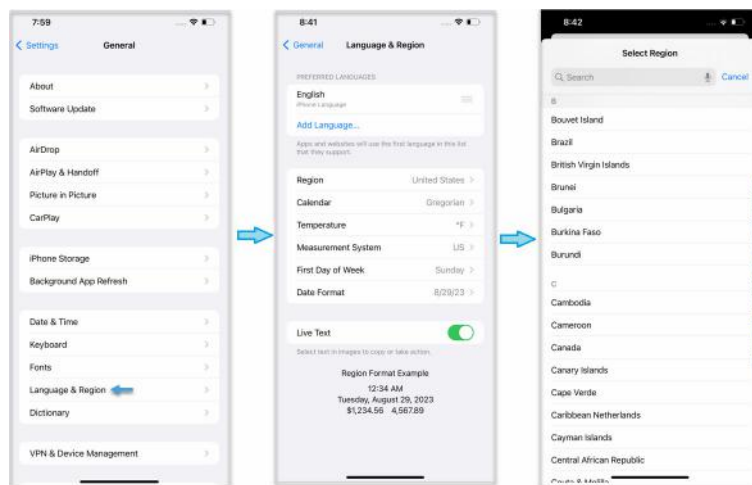
Figure 6-9.   Device region selection (iPhone 12 Pro Max, iOS
16.1.2)

• Via the iPhone or iPad Settings > General > Language and
Region, select "**Português (Brasil)**" via the device
language selection.
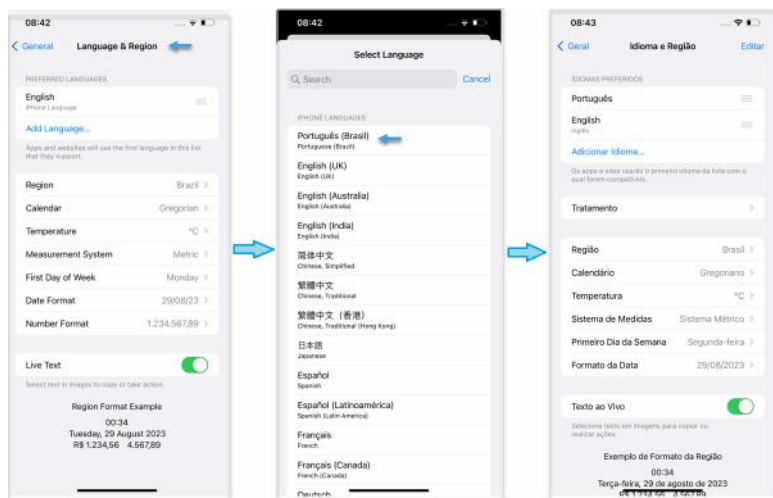
Figure 6-10.   Device language selection (iPhone 12 Pro Max,
iOS 16.1.2)

Diagnostics

Diagnostics Test

1. Slide the left panel.
2. Press **Diagnostics** from the Menu.
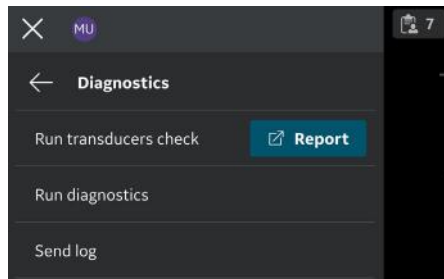
Figure 6-11.   Diagnostics menu

3. Press the **Run Diagnostic** button to start the test.

Diagnostics Test (continued)

4. Press the '**Start**' button to start the diagnostics test. The progress will be shown at the bottom of the screen.

NOTE: *The display device must be connected to a probe to be able to start the diagnostics.*

1. Diagnostic screen
2. Diagnostic progress bar

Figure 6-12.   Diagnostics in progress

Diagnostics Test (continued)
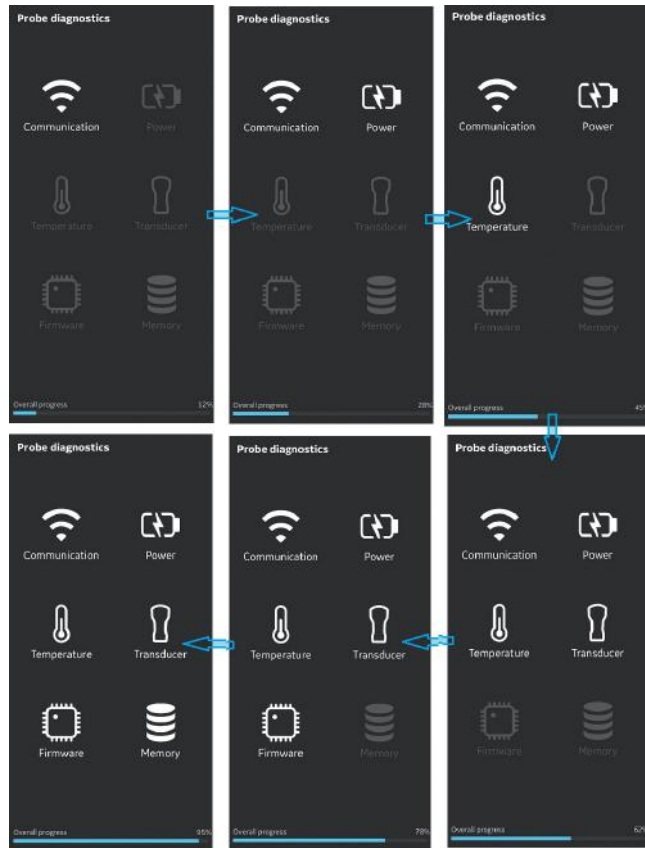
Figure 6-13.   Diagnostics process

Diagnostics Test (continued)

5. If the Diagnostics test passes the below screen displays:
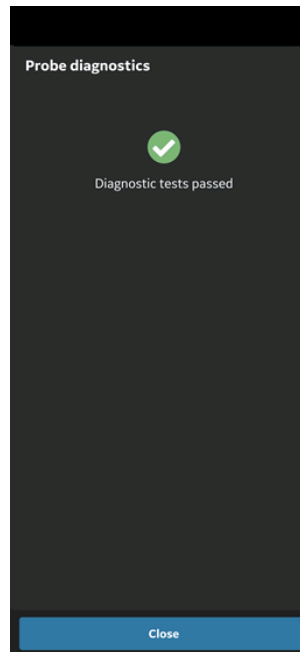
Figure 6-14.   Diagnostics passed

Diagnostics Test (continued)

OR

If the Diagnostics test fails, contact GEHC Service via the hotline number:

You can share device logs with GEHC if diagnostic test fails.
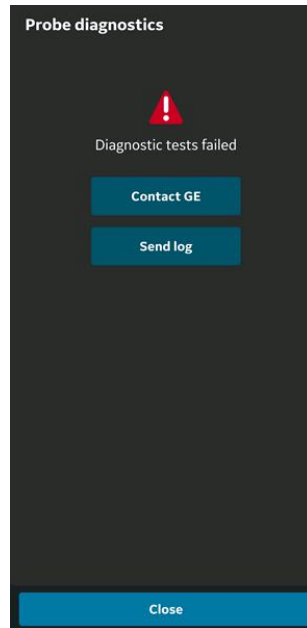
Figure 6-15.   Diagnostics failed

6. GEHC service guides the customer through the procedure to upload the system log file.

NOTE: *System logs exported from the device will be stored for GEHC service access 1 year before being deleted from the server.*

7. GEHC service runs checklist.

8. GEHC service places the order for the replacement Vscan Air probe and provides shipment details.

Transducer Element test

The transducer element test transmits/receives on each element to determine if the element is working as intended. If the Element test fails there is an option to export the test results to a local folder. The failing element(s) are listed in this transducer element test results file.

To manually start the transducer check go to Menu -> Diagnostics -> Run Transducers check

The transducers element test is also included as one of the tests being performed when running the diagnostic tests via Menu -> Diagnostics -> Run diagnostics.

NOTE: *Please make sure that the transducer surfaces are clean and that excessive gel has been removed before running the probe element test. The element test might incorrectly report failing elements if excessive gel are left on the probe front faces while running the probe element test.*

1. Transducers check is indicated while running.
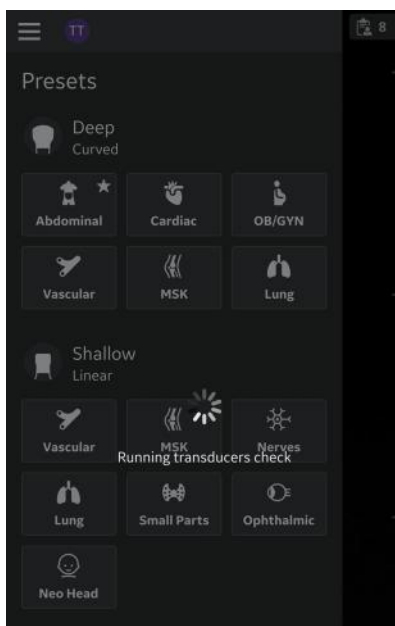
Figure 6-16.   Transducers check running

NOTE: *There is no indication given when the transducer element test is successful.*

Transducer Element test (continued)

2. Transducer element test failed for CL and SL probe:

NOTE: *If the transducer element test fails go to Menu-> Diagnostics and click the Report button for the Run transducers check. Inspect the transducer element test results file.*

NOTE: *If needing to contact service please select Menu-> Diagnostics -> Run diagnostics and select Menu-> Diagnostics -> Send log before contacting service. Service will then be able to help identify the failing transducer element(s) and guide on further actions needed.*
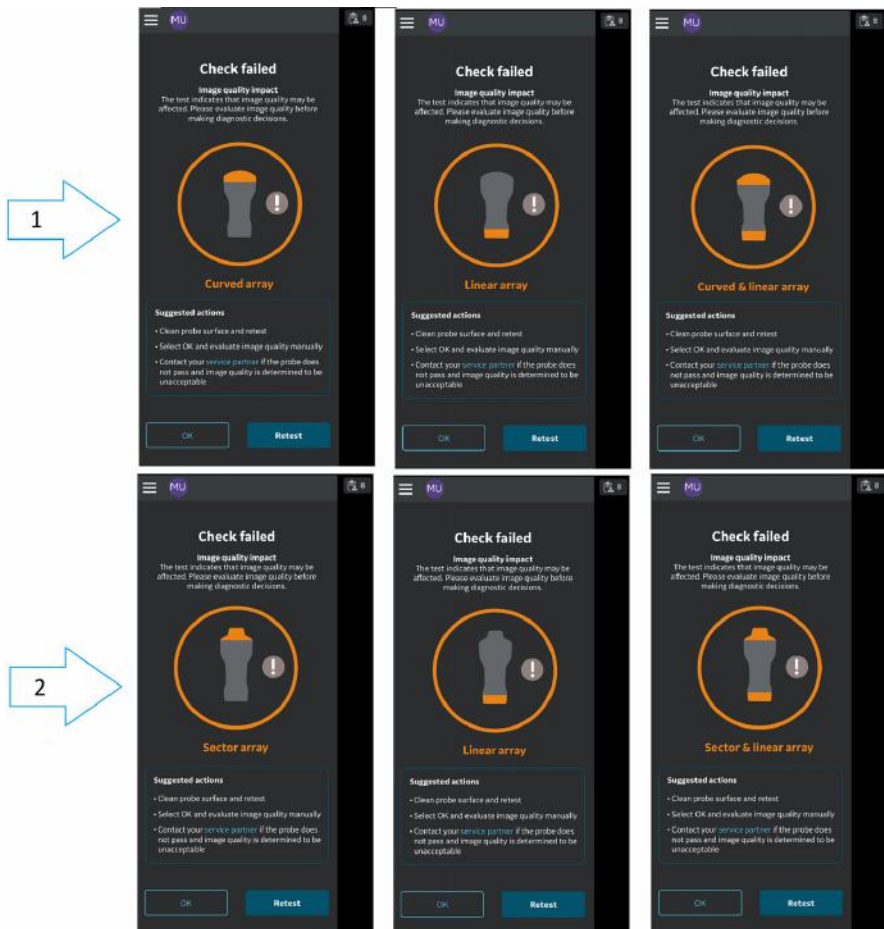
Figure 6-17.   Transducer element test failed for Vscan Air CL (1) and SL (2) probe

Transducer Element test (continued)

3. Configuration: Tap the **Menu** icon, press Diagnostics and tap the Run transducers check menu item to Run the transducers check test.
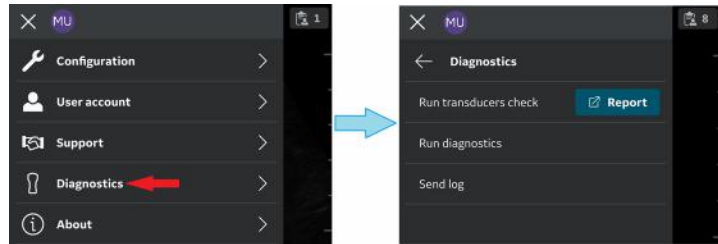
Figure 6-18.   Perform probe test

4. Once the transducer check is finished, click on the ⧉ Report icon for exporting the results.
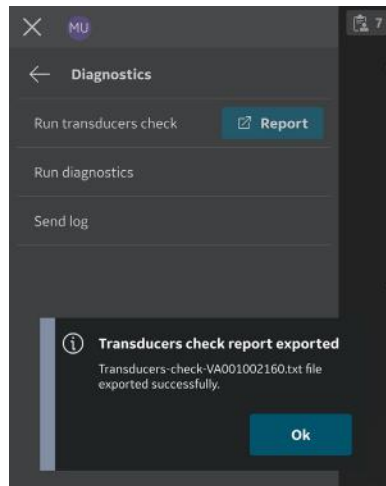
Figure 6-19.   Transducers check report exported

Transducer Element test (continued)

5. Android: Navigate to downloads folder in the device and open exported .txt file.
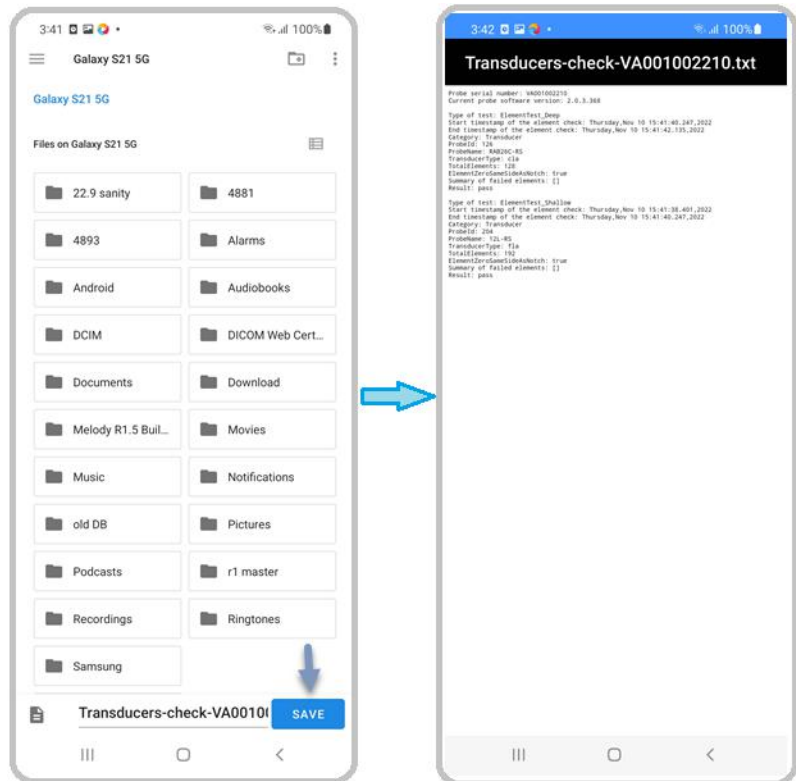
Figure 6-20.   Exported transducers check report - Android

Transducer Element test (continued)

6. iOS- example from iPhone: Navigate to the On My iPhone/ Vscan Air/Downloads folder in the device and open exported .txt file.
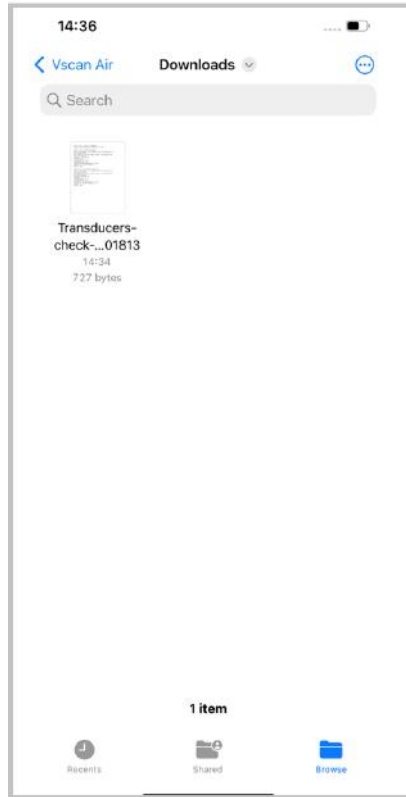
Figure 6-21.   Exported transducers check report - iOS

Probe warning messages

Probe errors

Probe overheats

⚠️ WARNING   Probe is overheating and the system will shut down. If the problem persists, contact GEHC.

Battery low

⚠️ WARNING   Battery critically low. Connect charger immediately.

Probe voltage critical

⚠️ WARNING   Probe voltage is at critical level and will shut down. If the problem persists, contact GEHC.

Connectivity error

⚠️ WARNING   Unable to connect. Check the internet connection and try again.

Handling a defective Vscan Air probe

If the Vscan Air probe is damaged and needs a replacement, make sure you clean and disinfect the Vscan Air probe, pack it in the packing box, before shipping or returning to GEHC.

If the battery does not charge, stop using the unit. Contact GEHC for battery replacement.

Automatic deactivation of the Vscan Air app

Deactivation soft limit

The Vscan Air app will on a daily basis try to contact the Vscan Air Product Registration server. If the Vscan Air app is inactive and/or not connected to internet for more than 70 days you will see the following message when you try to use the app.
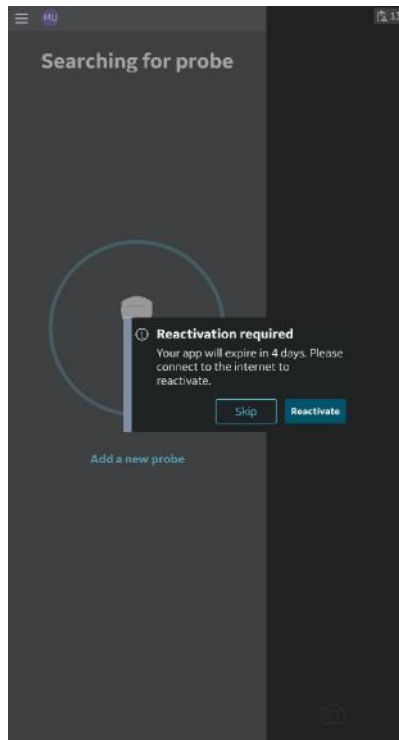
Figure 6-22.   Auto deactivated message

Deactivation hard limit

> The Vscan Air app will on a daily basis try to contact the Vscan Air Product Registration server. If the Vscan Air app is inactive and/or not connected to internet for more than 110 days the Vscan Air app is deactivated and you will see the following message when you try to use the app.
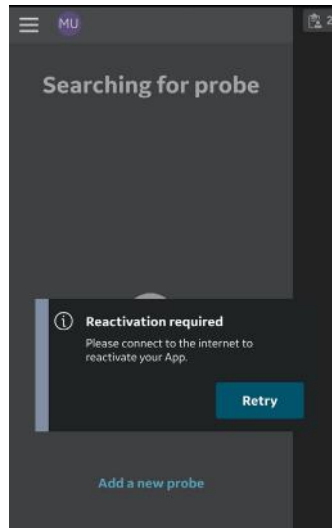
Figure 6-23.   Reactivate warning message

> *NOTE:*   *To avoid deactivation of the Vscan Air app, make sure you use the app while being connected to internet before reaching the deactivation hard limit.*

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Chapter 7

Appendix

Contents:

Specifications

Vscan Air probe Dimension and weight (maximum)

Table 7-1:   Dimension and Weight (maximum)

Parameters	Vscan Air CL	Vscan Air SL
Dimension (mm)	131 x 64 x 31 mm (length, width, height)	141 x 67 x 33 mm (length, width, height)
Weight (g)	205 +/- 3g	218 +/- 3g

Vscan Air CL and SL transducers

Parameters	Curved array transducer for deep scanning	Sector array transducer for deep scanning	Linear array transducer for shallow scanning
Broad-bandwidth curved array	from 2 - 5 MHz with center frequency of 3.3 MHz	from 1.6 – 3.7 MHz with center frequency of 2.65 MHz	from 3 - 12 MHz with center frequency of 7.7 MHz
Number of elements	128	64	192
Footprint	64 mm x 16 mm (lens)	22 mm x 17 mm (lens)	40 mm x 7 mm (lens)
Viewing angle	60°	90°	Not applicable
Depth	up to 24 cm	up to 24 cm	up to 8 cm

Acoustic output

The real-time display of acoustic output indices

The Vscan Air software have real-time display features according to IEC62359 Ed.2. A thermal (TI) and a mechanical (MI) index is displayed. These two indices are intended to estimate the potential for thermal and mechanical bioeffects induced by ultrasound. Both TI and MI are displayed with increments of 0.1. The displayed (estimated) TI and MI are nominal values.

Thermal Index

TI is defined as: $TI = W_o / W_{deg}$

where: W_0 is the time-averaged acoustic power and W_{deg} is the estimated power necessary to raise the target tissue 1°C.

The displayed TI is an estimate of temperature increase of soft tissue or bone, presented to make it easier for the operator to implement the ALARA (As Low As Reasonably Achievable) principle. There are three thermal index categories:

- TIS: Soft tissue thermal index. The main TI category. Used for applications that do not image bone.
- TIB: Bone thermal index (bone located in a focal region). Used for fetal application.
- TIC: Cranial bone thermal index (bone located close to the surface). Used for transcranial application.

The correct category is chosen based on display standard, mode of operation and chosen application, and the relevant TI category presented to the operator. It is therefore important that the operator chooses the right application.

Vscan Air will for each scan setup calculate and limit TI for the chosen index category to 3.0.

Thermal index display selection

The system provides the ability to select the display of any of the TI categories regardless of the current application while scanning. To switch in between the different thermal indices touch the MI/TI display in the lower left corner of the screen (see 'Black/white imaging mode (B-mode)' on *page 3-15*). Touching the indices display will circle through displaying the thermal index categories in the following order TIS – TIC – TIB, starting out from the factory selected TI category for the selected preset.

1. TIS
2. TIC
3. TIB

Figure 7-1.   Thermal Index display

NOTE: *Be aware that Figure 7-1 is illustrating the TI value display utilizing the Curved - Abdominal - Factory default setting. Displayed values can vary dependent on software version/ revision.*

Mechanical Index

MI is the estimated likelihood of tissue damage due to cavitation.

MI is defined as:

$$MI = \frac{p_{r,\alpha}(z_{MI})}{C_{MI}\sqrt{f_{awf}}}$$

equivalent to Track3 MI when the depth ZMI=Zsp.

The MI will not exceed a value of 1.9 according to Track 3 in the FDA 510(k) guidance of September 9, 2008.

The depth for $p_{r,\alpha}(z)$ is not limited by the breakpoint depth.

The MI according to IEC62359 Ed2 will not exceed 1.9.

Controls affecting acoustic output

The initial means by which the user can affect acoustic output are by 1) selecting a probe, 2) selecting an application (exam category) and then 3) selecting the imaging mode or imaging characteristics (depth, color ROI center position). This is achieved through an acoustic output control scheme in which all parameters that directly or indirectly affect acoustic output are fed to the control algorithm. The algorithm estimates all relevant parameters and compares them to the FDA limits.

Output levels remain below the limits with a 95% confidence margin. The absolute maximum allowable output for all applications is:

- ISPTA less than or equal to 720 mW/cm2
- MI less than or equal to 1.9
- TI less than or equal to 6

The Acoustic output control scheme		
Input Parameters	**Control Algorithm**	**Output Parameters**
Transmit frequency ---->		
Transmit apodization ---->		
Focal depth ---->		
Steering angle ---->	Output control never to exceed limit minus tolerances	
Sector size ---->		----> Transmit voltage control to Beamformer
Pulse repetition frequency ---->		
Pulse length ---->		
Mode combination ---->	I_{SPTA}	
Application ---->	TIS/TIB/TIC	----> Thermal/mechanical Indices to Output Display
Acoustic output control ---->	MI	
Probe sensitivity ---->		

FDA Limits @ 95% confidence tolerance

Probe surface temperature safety mechanisms

The system has an Probe Surface Temperature Control Algorithm to ensure that each probe is set up and run within temperature limits given by the harmonized safety standard IEC60601-2-37. The Control Algorithm is implemented in the software and calibrated by laboratory measurements of surface temperature on each probe type. A Control Algorithm Input Parameter check is performed during setup of each new scan, and any detected error in the input, and/or malfunction are protected by software error handling that aborts setup and prevents start of scanning. The system has monitoring of voltage and power used by the ultrasound transmits circuitry and probe. If transmit voltage or power exceeds expected values, the transmit voltage will be set to zero and scanning will stop. This mechanism will protect against illegal setup and/or probe defects.

These safety mechanisms are designed to ensure that the lens surface temperature of the two transducers, is kept within values listed in the table 'Maximum probe temperature' on *page 2-25* section in this user manual. The Vscan Air probe is equipped with internal temperature sensors and mechanisms to monitor and limit the probe temperature so that the lens surface temperature is kept <43°C.

No particular user actions are required for the proper functioning of the described safety mechanisms.

Acoustic Parameters as Measured in Water

Definitions, symbols and abbreviations

The following definitions, symbols and abbreviations are used in the acoustic output reporting tables in this chapter:

IEC	Meaning—IEC/EN62359 Ed.2
MI	Mechanical Index
TIS	Soft Tissue Thermal Index
TISas	Soft Tissue Index at-surface, scanning or non-scanning
TISbs	Soft Tissue Index below-surface, scanning or non-scanning
TIB	Bone Thermal Index
TIBas	Bone Thermal Index at surface, scanning or non-scanning
TIBbs	Bone Thermal Index below-surface, scanning or non-scanning
TIC	Cranial-bone Thermal Index
$p_{r,\alpha}$	Attenuated peak-rare-factional acoustic pressure
C_{MI}	Normalizing Coefficient 1MPa*MHz-1/2
P	Output power
P_{1x1}	Bounded square output power
z_s	Depth for TIS below surface
z_b	Depth for TIB below surface
z_{MI}	Depth for MI
$Z_{pii,\alpha}$	Depth for $I_{pa,'\alpha}$ and $I_{spta,'\alpha}$
fawf	Acoustic working frequency
prr	Pulse repetition rate
srr	Scan repetition rate
n_{pps}	Number of pulses per scan line
$I_{pa,'\alpha}$	Attenuated pulse average intensity
$I_{spta,'\alpha}$	Attenuated spatial-peak temporal-average intensity
I_{spta}	Spatial-peak temporal-average intensity

IEC	Meaning—IEC/EN62359 Ed.2
pr	Peak-rare-factional acoustic pressure

Operating Conditions

All table entries are with the operating conditions specified at the end of the table.

Acoustic Output Reporting Tables for Track 3/EN/IEC 60601-2-37

> NOTE: These acoustic output reporting tables are produced according to IEC 62359 Ed.2.

> NOTE: The Acoustic Output tables are in English only.

Transducer Model: Curved array transducer - Vscan Air CL probe

Operating Mode: black and white (including harmonic)

	Index Label		MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
	Maximum: Index Value		1,68	0,20		0,16		#
	Index component value			0,20	0,20	0,16	0,16	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2,60					
	P	(mW)		73,9		57,4		-
	P_{1x1}	(mW)		17,9		14,2		
	z_s	(cm)			2,7			
	z_b	(cm)					5,2	
	z_{MI}	(cm)	5,6					
	$z_{pii,\alpha}$	(cm)	5,6					
	f_{awf}	(MHz)	2,39	2,40		2,35		-
Other Information	prr	(Hz)	1140					
	srr	(Hz)	12					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	187,1					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm²)	5,8					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm²)	14,7					
	p_r at z_{pii}	(MPa)	4,08					
Operating Conditions	Depth (cm)		13,4	13,4		12,4		-
	Width (°)		60	60		60		-
	Application		Abdominal	Abdominal		Ob		-

Figure 7-2. Curved array transducer - black/white (including harmonic)

> NOTE: The Curved array transducer does not have a preset optimized for Transcranial/Neonatal cephalic use.

Transducer Model: Curved array transducer - Vscan Air CL probe (continued)

Operating Mode: black and white (including harmonic) and color

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			1,70	0,75		0,51		#
Index component value				0,75	0,75	0,51	0,51	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2,60					
	P	(mW)		189		129		-
	P_{1x1}	(mW)		69,6		47,2		
	z_s	(cm)			2,7-2,9			
	z_b	(cm)					5,0-5,7	
	z_{MI}	(cm)	5,1					
	$z_{pii,\alpha}$	(cm)	5,1					
	f_{awf}	(MHz)	2,34	2,26-2,40		2,26-2,35		-
Other Information	prr	(Hz)	626					
	srr	(Hz)	8,6					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	139,6					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	3,8					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm^2)	8,5					
	p_r at z_{pii}	(MPa)	3,87					
Operating Conditions	Depth (cm)		13,4	13,4		12,4		-
	Width(°) black and white		60	60		60		-
	ROI center(cm)		6	6		6		-
	ROI span(cm)		5	5		5		-
	Width(°) color		20	20		20		-
	Application		Abdominal	Abdominal		Ob		-

Figure 7-3.   Curved array transducer - black/white (including harmonic) and color

NOTE: *The Curved array transducer does not have a preset optimized for Transcranial/Neonatal cephalic use.*

Transducer Model: Curved array transducer - Vscan Air CL probe (continued)

Operating Mode: M

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			1,52	0,20		0,69		#
Index component value				0,20	0,20	0,69	0,69	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2,36					
	P	(mW)		28,6		27,4		-
	P_{1x1}	(mW)		28,6		10,7		
	z_s	(cm)		2,7-2,9				
	z_b	(cm)				5,6-5,7		
	z_{MI}	(cm)	5,9					
	$z_{pii,\alpha}$	(cm)	5,9					
	f_{awf}	(MHz)	2,39	2,40		2,36		-
Other Information	prr	(Hz)	500					
	srr	(Hz)	-					
	n_{pps}		-					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	149,6					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	60,2					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm^2)	165,1					
	p_r at z_{pii}	(MPa)	3,74					
Operating Conditions	Depth (cm)		14,4	14,4		14,4		-
	Application		Abdominal	Abdominal		Ob		-
			-	-		-		-

Figure 7-4. Curved array transducer - M-mode

NOTE: *The Curved array transducer does not have a preset optimized for Transcranial/Neonatal cephalic use.*

Transducer Model: Curved array transducer - Vscan Air CL probe (continued)

Operating Mode: PW

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			1,06	0,68		2,75		#
Index component value				0,44	0,68	0,53	2,75	
Acoustic Parameters	$p_{r.\alpha}$ at z_{MI}	(MPa)	1,59					
	P	(mW)		96,9		133,4		-
	P_{1x1}	(mW)		40,2		49,0		
	z_s	(cm)			2,8			
	z_b	(cm)					6,4	
	z_{MI}	(cm)	4,8					
	$z_{pii.\alpha}$	(cm)	4,8					
	f_{awf}	(MHz)	2,26	2,40		2,27		-
Other Information	prr	(Hz)	1153					
	srr	(Hz)	-					
	n_{pps}		-					
	$I_{pa.\alpha}$ at $z_{pii.\alpha}$	(W/cm²)	171,8					
	$I_{spta.\alpha}$ at $z_{pii.\alpha}$ or $z_{sii.\alpha}$	(mW/cm²)	325,1					
	I_{spta} at z_{pii} or $z_{sii.\alpha}$	(mW/cm²)	700,9					
	p_r at z_{pii}	(MPa)	2,24					
Operating Conditions	Depth (cm)		9,4	9,4		9,4		-
	ROIc (cm)		4,0	6,0		7,4		-
	Application		Abdominal	Abdominal		Ob		-

Figure 7-5. Curved array transducer - PW-mode

NOTE: *The Curved array transducer does not have a preset optimized for Transcranial/Neonatal cephalic use.*

Transducer Model: Linear array transducer - Vscan Air CL probe

Operating mode: black and white (including harmonic)

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			1,16	0,09		#		0,29
Index component value				0,09	0,09	-	-	
Acoustic Parameters	$p_{r.\alpha}$ at z_{MI}	(MPa)	2,56					
	P	(mW)		9,38		-		8,33
	P_{1x1}	(mW)		4,01		-		
	z_s	(cm)			0,9			
	z_b	(cm)					-	
	z_{MI}	(cm)	1,2					
	$z_{pii.\alpha}$	(cm)	1,2					
	f_{awf}	(MHz)	4,88	4,83-4,96		-		6,77
Other Information	prr	(Hz)	1944					
	srr	(Hz)	18					
	n_{pps}		1					
	$I_{pa.\alpha}$ at $z_{pii.\alpha}$	(W/cm^2)	319,8					
	$I_{spta.\alpha}$ at $z_{pii.\alpha}$ or $z_{sii.\alpha}$	(mW/cm^2)	6,9					
	I_{spta} at z_{pii} or $z_{sii.\alpha}$	(mW/cm^2)	10,3					
	p_r at z_{pii}	(MPa)	3,01					
Operating Conditions	Depth (cm)		5,1	5,1		-		8,1
	Width (-)		2,2	2,2		-		2,2
	Application		Nerves	Small Parts		-		Neo Head

Figure 7-6. Linear array transducer - black/white (including harmonic)

NOTE: The Linear array transducer does not have a preset optimized for Obstetric/Fetal use.

Transducer Model: Linear array transducer - Vscan Air CL probe (continued)

Operating Mode: black and white (including harmonic) and color

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			1,35	0,45		#		1,07
Index component value				0,45	0,45	-	-	
Acoustic Parameters	$pr_{.\alpha}$ at z_{MI}	(MPa)	2,91					
	P	(mW)		23,2		-		21,2
	P_{1x1}	(mW)		23,2		-		
	Z_s	(cm)			0,8			
	Z_b	(cm)					-	
	Z_{MI}	(cm)	1,0					
	$Z_{pii,\alpha}$	(cm)	1,0					
	f_{awf}	(MHz)	4,63	4,58-5,04		-		4,6-6,7
Other Information	prr	(Hz)	3317					
	srr	(Hz)	158					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	542,1					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm²)	60					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm²)	82,5					
	p_r at z_{pii}	(MPa)	3,22					
Operating Conditions	Depth (cm)		5,5	3,4		-		4,5
	Width(-) black and white		2,2	2,2		-		2,3
	ROI center(cm)		1,3	1,6		-		1,3
	ROI span(cm)		1,0	1,0		-		1,0
	Width(-) color		0,9	0,9		-		0,9
	Application		Nerves	Small Parts		-		Neo Head

Figure 7-7.   Linear array transducer - black/white (including harmonic) and color

NOTE: The Linear array transducer does not have a preset optimized for Obstetric/Fetal use.

Transducer Model: Linear array transducer - Vscan Air CL probe (continued)

Operating Mode: black and white, Ophthalmic

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			0,19	0,0009		#		#
Index component value				0,0009	0,0009	-	-	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	0,58					
	P	(mW)		0,05		-		-
	P_{1x1}	(mW)		0,02		-		
	z_s	(cm)			0,9			
	z_b	(cm)					-	
	z_{MI}	(cm)	1,6					
	$z_{pii,\alpha}$	(cm)	1,6					
	f_{awf}	(MHz)	9,09	8,93		-		-
Other Information	prr	(Hz)	1440					
	srr	(Hz)	15					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	12,1					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm²)	0,1					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm²)	0,2					
	p_r at z_{pii}	(MPa)	0,95					
Operating Conditions	Depth (cm)		4,1	4,5		-		-
	Width (-)		2	2		-		-
	Application		Ophthalmic	Ophthalmic		-		-

Figure 7-8.   Linear array transducer - black/white, Ophthalmic

NOTE: *The Linear array transducer Ophthalmic preset is neither optimized for Obstetric/Fetal nor Transcranial/Neonatal cephalic use.*

Transducer Model: Linear array transducer - Vscan Air CL probe (continued)

Operating Mode: black and white and color, Ophthalmic

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			0,19	0,0103		#		#
Index component value				0,0103	0,0103	-	-	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	0,42					
	P	(mW)		0,59		-		-
	$P_{1\times1}$	(mW)		0,41		-		
	z_s	(cm)			0,8-0,9			
	z_b	(cm)					-	
	z_{MI}	(cm)	1,7					
	$z_{pii,\alpha}$	(cm)	1,7					
	f_{awf}	(MHz)	5,15	5,15-9,07		-		-
Other Information	prr	(Hz)	5011					
	srr	(Hz)	162					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	6,4					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm²)	1,2					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm²)	2,0					
	p_r at z_{pii}	(MPa)	0,58					
Operating Conditions	Depth (cm)		4,1	4,1		-		-
	Width (-) black and white		2,2	2,2		-		-
	ROI center (cm)		2,2	2,2		-		-
	ROI span(cm)		1	1		-		-
	Width (-) color		1,3	1		-		-
	Application		Ophthalmic	Ophthalmic		-		-

Figure 7-9.   Linear array transducer - black/white and color, Ophthalmic

NOTE: The Linear array transducer Ophthalmic preset is neither optimized for Obstetric/Fetal nor Transcranial/Neonatal cephalic use.

Transducer Model: Linear array transducer - Vscan Air CL probe (continued)

Operating Mode: M

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			1,06	0,05		#		0,04
Index component value				0,05	0,05	-	-	
Acoustic Parameters	$p_{r.\alpha}$ at z_{MI}	(MPa)	2,34					
	P	(mW)		2,33		-		1,2
	P_{1x1}	(mW)		2,29		-		
	z_s	(cm)			1,1			
	z_b	(cm)					-	
	z_{MI}	(cm)	1,1					
	$z_{pii.\alpha}$	(cm)	1,1					
	f_{awf}	(MHz)	4,9	4,72-4,93		-		6,43
Other Information	prr	(Hz)	500					
	srr	(Hz)	-					
	n_{pps}		-					
	$I_{pa.\alpha}$ at $z_{pii.\alpha}$	(W/cm²)	264,7					
	$I_{spta.\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm²)	35,8					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm²)	52,7					
	p_r at z_{pii}	(MPa)	2,69					
Operating Conditions	Depth (cm)		4,5	8,1		-		8,1
			-	-		-		-
	Application		Nerves	MSK		-		Neo Head

Figure 7-10. Linear array transducer - M-mode

NOTE: *The Linear array transducer does not have a preset optimized for Obstetric/Fetal use.*

Transducer Model: Linear array transducer - Vscan Air CL probe (continued)

Operating Mode: PW

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			0,65	0,18		#		0,25
Index component value				0,18	0,18	-	-	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1,39					
	P	(mW)		8,42		-		5,84
	P_{1x1}	(mW)		8,42		-		
	z_s	(cm)			0,9			
	z_b	(cm)					-	
	z_{MI}	(cm)	1,7					
	$z_{pii,\alpha}$	(cm)	1,7					
	f_{awf}	(MHz)	4,58	4,58		-		4,57
Other Information	prr	(Hz)	1184					
	srr	(Hz)	-					
	n_{pps}		-					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	96,1					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm²)	140,5					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm²)	241,7					
	p_r at z_{pii}	(MPa)	1,77					
Operating Conditions	Depth (cm)		4,1	2,5		-		3,1
			-	-		-		-
	Application		Nerves	Vascular		-		Neo Head

Figure 7-11. Linear array transducer - PW-mode

NOTE: *The Linear array transducer does not have a preset optimized for Obstetric/Fetal use.*

Transducer Model: Linear array transducer - Vscan Air CL probe (continued)

Operating Mode: M, Ophthalmic

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			0,18	0,001		#		#
Index component value				0,001	0,001	-	-	
Acoustic Parameters	$p_{r.\alpha}$ at z_{MI}	(MPa)	0,53					
	P	(mW)		0,01		-		-
	P_{1x1}	(mW)		0,01		-		
	z_s	(cm)			0,8			
	z_b	(cm)					-	
	z_{MI}	(cm)	1,6					
	$z_{pii.\alpha}$	(cm)	1,6					
	f_{awf}	(MHz)	9,0	9,0		-		-
Other Information	prr	(Hz)	500					
	srr	(Hz)	-					
	n_{pps}		-					
	$I_{pa.\alpha}$ at $z_{pii.\alpha}$	(W/cm²)	10,1					
	$I_{spta.\alpha}$ at $z_{pii.\alpha}$ or $z_{sii.\alpha}$	(mW/cm²)	0,8					
	I_{spta} at z_{pii} or $z_{sii.\alpha}$	(mW/cm²)	2,15					
	p_r at z_{pii}	(MPa)	0,86					
Operating Conditions	Depth (cm)		4,1	4,1		-		-
			-	-		-		-
	Application		Ophthalmic	Ophthalmic		-		-

Figure 7-12. Linear array transducer - M-mode, Ophthalmic

NOTE: *The Linear array transducer Ophthalmic preset is neither optimized for Obstetric/Fetal nor Transcranial/Neonatal cephalic use.*

Transducer Model: Linear array transducer - Vscan Air CL probe (continued)

Operating Mode: PW, Ophthalmic

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			0,16	0,006		#		#
Index component value				0,006	0,006	-	-	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	0,33					
	P	(mW)		0,254		-	-	
	P_{1x1}	(mW)		0,254		-		
	z_s	(cm)			0,9			
	z_b	(cm)					-	
	z_{MI}	(cm)	1,8					
	$z_{pii,\alpha}$	(cm)	1,8					
	f_{awf}	(MHz)	4,57	4,57		-	-	
Other Information	prr	(Hz)	1184					
	srr	(Hz)	-					
	n_{pps}		-					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	3,6					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm²)	5,5					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm²)	9,75					
	p_r at z_{pii}	(MPa)	0,44					
Operating Conditions	Depth (cm)		4,1	4,1		-		-
	ROI center		2,0	2,0		-		-
	Application		Ophthalmic	Ophthalmic		-		-

Figure 7-13. Linear array transducer - PW-mode, Ophthalmic

NOTE: *The Linear array transducer Ophthalmic preset is neither optimized for Obstetric/Fetal nor Transcranial/Neonatal cephalic use.*

Transducer Model: Sector array transducer - Vscan Air SL probe

Operating Mode: black and white (including harmonic)

	Index Label		MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			1,63	0,67		0,65		0,84
Index component value				0,67	0,67	0,65	0,65	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2,11					
	P	(mW)		164,6		81,2		52,9
	P_{1x1}	(mW)		84,4		62,5		
	z_s	(cm)			2,9			
	z_b	(cm)					1,8	
	z_{MI}	(cm)	1,4					
	$z_{pii,\alpha}$	(cm)	1,7					
	f_{awf}	(MHz)	1,69	1,68		2,11		2,55
Other Information	prr	(Hz)	2340					
	srr	(Hz)	30					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	129,7					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	43,5					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm^2)	53,4					
	p_r at z_{pii}	(MPa)	2,14					
Operating Conditions	Depth (cm)		5,4	22,4		5,4		22,4
	Width (°)		70	70		90		70
	Application		Cardiac	Cardiac		Ob		Cranial

Figure 7-14.   Sector array transducer - black and white (including harmonic)

Transducer Model: Sector array transducer - Vscan Air SL probe (continued)

Operating Mode: black and white (including harmonic) and color

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			1,57	1,04		0,38		1,17
Index component value				1,04	1,04	0,38	0,38	
Acoustic Parameters	$p_{r.\alpha}$ at z_{MI}	(MPa)	2,04					
	P	(mW)		226		82,8		62,9
	P_{1x1}	(mW)		105,4		35,9		
	z_s	(cm)			3,7-4,1			
	z_b	(cm)					4,6-6,5	
	z_{MI}	(cm)	3,9					
	$z_{pii,\alpha}$	(cm)	3,9					
	f_{awf}	(MHz)	1,69	1,69-2,23		2,26-2,27		2,28
Other Information	prr	(Hz)	1320					
	srr	(Hz)	18,1					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	174,3					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm²)	19,8					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm²)	31,1					
	p_r at z_{pii}	(MPa)	2,49					
Operating Conditions	Depth (cm)		9,4	9,4		10,4		8,4
	Width(°) black and white		70	70		76,5		70
	ROI center(cm)		7	7		8		7
	ROI span(cm)		6	6		6		6
	Width(°) color		20	20		20		20
	Application		Cardiac	Cardiac		Ob		Cranial

Figure 7-15.   Sector array transducer - black and white (including harmonic) and color

Transducer Model: Sector array transducer - Vscan Air SL probe (continued)

Operating Mode: M

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			1,36	0,14		0,56		0,35
Index component value				0,10	0,14	0,14	0,56	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2,18					
	P	(mW)		23,9		17,1		21,8
	P_{1x1}	(mW)		12,3		13,2		
	z_s	(cm)			2,8			
	z_b	(cm)					1,9	
	z_{MI}	(cm)	5,8					
	$z_{pii,\alpha}$	(cm)	5,8					
	f_{awf}	(MHz)	2,58	1,68		2,05-2,19		2,58
Other Information	prr	(Hz)	500					
	srr	(Hz)	-					
	n_{pps}		-					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	133					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	34,9					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm^2)	102,2					
	p_r at z_{pii}	(MPa)	3,49					
Operating Conditions	Depth (cm)		22,4	22,4		5,4		22,4
	Application		Cranial	Cardiac		Ob		Cranial
			-	-		-		-

Figure 7-16.   Sector array transducer - M-mode

Transducer Model: Sector array transducer - Vscan Air SL probe (continued)

Operating Mode: PW

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			0,54	0,52		1,85		1,27
Index component value				0,52	0,51	0,49	1,85	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	0,81					
	P	(mW)		62,4		114,0		60,5
	P_{1x1}	(mW)		48,0		45,7		
	z_s	(cm)			1,8			
	z_b	(cm)					3,9	
	z_{MI}	(cm)	4,5					
	$z_{pii,\alpha}$	(cm)	4,5					
	f_{awf}	(MHz)	2,28	2,27		2,27		2,27
Other Information	prr	(Hz)	2317					
	srr	(Hz)	-					
	n_{pps}		-					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	30,7					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm²)	236,1					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm²)	494,8					
	p_r at z_{pii}	(MPa)	1,09					
Operating Conditions	Depth (cm)		6,4	7,4		10,4		6,4
	ROIc(cm)		3,0	2,0		9,0		2,0
	Application		Ob	Abdominal		Ob		Cranial

Figure 7-17. Sector array transducer - PW-mode

Transducer Model: Linear array transducer - Vscan Air SL probe

Operating Mode: black and white (including harmonic)

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			1,25	0,08		#		0,27
Index component value				0,08	0,08	-	-	
Acoustic Parameters	$p_{r.\alpha}$ at z_{MI}	(MPa)	3,23					
	P	(mW)		7,59		-		7,83
	P_{1x1}	(mW)		3,24		-		
	Z_s	(cm)			0,9			
	Z_b	(cm)					-	
	Z_{MI}	(cm)	1,5					
	$Z_{pii.\alpha}$	(cm)	1,5					
	f_{awf}	(MHz)	6,64	4,81-5,0		-		6,80
Other Information	prr	(Hz)	2340					
	srr	(Hz)	20					
	n_{pps}		1					
	$I_{pa.\alpha}$ at $Z_{pii.\alpha}$	(W/cm²)	382,8					
	$I_{spta.\alpha}$ at $Z_{pii.\alpha}$ or $Z_{sii.\alpha}$	(mW/cm²)	8,0					
	I_{spta} at Z_{pii} or $Z_{sii.\alpha}$	(mW/cm²)	15,8					
	p_r at Z_{pii}	(MPa)	4,42					
Operating Conditions	Depth (cm)		4,5	5,1		-		8,1
	Width (-)		2,2	2,2		-		2,2
	Application		Neo Head	Small Parts		-		Neo Head

Figure 7-18.   Linear array transducer - black and white (including harmonic)

NOTE: *The Linear array transducer does not have a preset optimized for Obstetric/Fetal use.*

Transducer Model: Linear array transducer - Vscan Air SL probe (continued)

Operating Mode: black and white (including harmonic) and color

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			1,35	0,42		#		0,98
Index component value				0,42	0,42	-	-	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2,91					
	P	(mW)		21,7		-		19,3
	P_{1x1}	(mW)		19,3		-		
	z_s	(cm)			0,8			
	z_b	(cm)					-	
	z_{MI}	(cm)	1,1					
	$z_{pii,\alpha}$	(cm)	1,1					
	f_{awf}	(MHz)	4,63	4,89-5,04		-		4,6-6,8
Other Information	prr	(Hz)	3317					
	srr	(Hz)	158					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	524,6					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm²)	56,6					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm²)	80,4					
	p_r at z_{pii}	(MPa)	3,27					
Operating Conditions	Depth (cm)		5,5	3,4		-		4,5
	Width(-) black and white		2,0	2,2		-		2,3
	ROI center(cm)		1,3	1,6		-		1,3
	ROI span(cm)		1,0	1,0		-		1,0
	Width(-) color		0,9	0,9		-		0,9
	Application		Nerves	Small Parts		-		Neo Head

Figure 7-19.   Linear array transducer - black and white (including harmonic) and color

NOTE: *The Linear array transducer does not have a preset optimized for Obstetric/Fetal use.*

Transducer Model: Linear array transducer - Vscan Air SL probe (continued)

Operating Mode: black and white, Ophthalmic

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			0,18	0,001		#		#
Index component value				0,001	0,001	-	-	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	0,53					
	P	(mW)		0,03		-		-
	P_{1x1}	(mW)		0,01		-		
	z_s	(cm)			0,8			
	z_b	(cm)					-	
	z_{MI}	(cm)	1,6					
	$z_{pii,\alpha}$	(cm)	1,6					
	f_{awf}	(MHz)	9,04	9,07		-		-
Other Information	prr	(Hz)	1440					
	srr	(Hz)	15					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	10,4					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm²)	0,1					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm²)	0,1					
	p_r at z_{pii}	(MPa)	0,87					
Operating Conditions	Depth (cm)		4,1	4,1		-		-
	Width (-)		2,2	2,2		-		-
	Application		Ophthalmic	Ophthalmic		-		-

Figure 7-20. Linear array transducer - black and white, Ophthalmic

NOTE: *The Linear array transducer Ophthalmic preset is neither optimized for Obstetric/Fetal nor Transcranial/Neonatal cephalic use.*

Transducer Model: Linear array transducer - Vscan Air SL probe (continued)

Operating Mode: black and white and color, Ophthalmic

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			0,18	0,009		#		#
Index component value				0,009	0,009	-	-	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	0,40					
	P	(mW)		0,51		-	-	
	P_{1x1}	(mW)		0,35		-		
	z_s	(cm)			0,8-0,9			
	z_b	(cm)					-	
	z_{MI}	(cm)	1,7					
	$z_{pii,\alpha}$	(cm)	1,7					
	f_{awf}	(MHz)	5,15	5,15-9,04		-		-
Other Information	prr	(Hz)	5096					
	srr	(Hz)	164,4					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	5,7					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm²)	1,0					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm²)	1,9					
	p_r at z_{pii}	(MPa)	0,55					
Operating Conditions	Depth (cm)		4,1	4,1		-		-
	Width (-) black and white		2,2	2,2		-		-
	ROI center (cm)		2,0	2,0		-		-
	ROI span(cm)		1	1		-		-
	Width (-) color		1,3	1,3		-		-
	Application		Ophthalmic	Ophthalmic		-		-

Figure 7-21.   Linear array transducer - black and white and color, Ophthalmic

NOTE: *The Linear array transducer Ophthalmic preset is neither optimized for Obstetric/Fetal nor Transcranial/Neonatal cephalic use.*

Transducer Model: Linear array transducer - Vscan Air SL probe (continued)

Operating Mode: M

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			1,03	0,035		#		0,04
Index component value				0,035	0,035	-	-	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2,27					
	P	(mW)		1,52		-		1,08
	P_{1x1}	(mW)		1,52		-		
	z_s	(cm)			0,9			
	z_b	(cm)					-	
	z_{MI}	(cm)	1,1					
	$z_{pii,\alpha}$	(cm)	1,1					
	f_{awf}	(MHz)	4,87	4,80-4,94		-		6,60
Other Information	prr	(Hz)	500					
	srr	(Hz)	-					
	n_{pps}		-					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	253,9					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm²)	34,6					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm²)	50,9					
	p_r at z_{pii}	(MPa)	2,58					
Operating Conditions	Depth (cm)		4,5	5,1		-		8,1
			-	-		-		-
	Application		Nerves	Small Parts		-		Neo Head

Figure 7-22. Linear array transducer - M-mode

NOTE: *The Linear array transducer does not have a preset optimized for Obstetric/Fetal use.*

Transducer Model: Linear array transducer - Vscan Air SL probe (continued)

Operating Mode: PW

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			0,67	0,16		#		0,23
Index component value				0,16	0,16	-	-	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1,42					
	P	(mW)		7,56		-		5,44
	P_{1x1}	(mW)		7,56		-		
	z_s	(cm)			0,9			
	z_b	(cm)					-	
	z_{MI}	(cm)	1,7					
	$z_{pii,\alpha}$	(cm)	1,7					
	f_{awf}	(MHz)	4,58	4,58		-		4,58
Other Information	prr	(Hz)	1184					
	srr	(Hz)	-					
	n_{pps}		-					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	94,7					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm²)	137,6					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm²)	236,3					
	p_r at z_{pii}	(MPa)	1,82					
Operating Conditions	Depth (cm)		4,1	2,1		-		3,1
	ROI center		2,0	2,0		-		2,0
	Application		Nerves	Vascular		-		Neo Head

Figure 7-23. Linear array transducer - PW-mode

NOTE: *The Linear array transducer does not have a preset optimized for Obstetric/Fetal use.*

Transducer Model: Linear array transducer - Vscan Air SL probe (continued)

Operating Mode: M, Ophthalmic

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			0,18	0,001		#		#
Index component value				0,001	0,001	-	-	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	0,54					
	P	(mW)		0,012		-		-
	P_{1x1}	(mW)		0,012		-		
	z_s	(cm)			0,8			
	z_b	(cm)					-	
	z_{MI}	(cm)	1,6					
	$z_{pii,\alpha}$	(cm)	1,6					
	f_{awf}	(MHz)	9,04	9,04		-		-
Other Information	prr	(Hz)	500					
	srr	(Hz)	-					
	n_{pps}		-					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	10,5					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm²)	0,8					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm²)	2,21					
	p_r at z_{pii}	(MPa)	0,88					
Operating Conditions	Depth (cm)		4,1	4,1		-		-
			-	-		-		-
	Application		Ophthalmic	Ophthalmic		-		–

Figure 7-24. Linear array transducer - M-mode, Ophthalmic

NOTE: *The Linear array transducer Ophthalmic preset is neither optimized for Obstetric/Fetal nor Transcranial/Neonatal cephalic use.*

Transducer Model: Linear array transducer - Vscan Air SL probe (continued)

Operating Mode: PW, Ophthalmic

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			0,15	0,005		#		#
Index component value				0,005	0,005	-	-	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	0,32					
	P	(mW)		0,238		-		-
	P_{1x1}	(mW)		0,238		-		
	z_s	(cm)			0,9			
	z_b	(cm)					-	
	z_{MI}	(cm)	1,7					
	$z_{pii,\alpha}$	(cm)	1,7					
	f_{awf}	(MHz)	4,58	4,58		-		-
Other Information	prr	(Hz)	1184					
	srr	(Hz)	-					
	n_{pps}		-					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	3,5					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm²)	5,5					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm²)	8,83					
	p_r at z_{pii}	(MPa)	0,41					
Operating Conditions	Depth (cm)		4,1	4,1		-		-
	ROI center		2,0	2,0		-		-
	Application		Ophthalmic	Ophthalmic		-		-

Figure 7-25. Linear array transducer - PW-mode, Ophthalmic

> *NOTE:* *The Linear array transducer Ophthalmic preset is neither optimized for Obstetric/Fetal nor Transcranial/Neonatal cephalic use.*

Appendices

Statements on the safety of ultrasound

October 1982, revised March 1983 and October 1983.

Diagnostic ultrasound has been in use for over 35 years. Given its known benefits and recognized efficacy for medical diagnosis, including use during human pregnancy, the American Institute of Ultrasound In medicine herein addresses the clinical safety of such use.

No confirmed biological effects on patients or instrument operators caused by exposure at intensities typical of present diagnostic ultrasound instruments have ever been reported. Although the possibility exists that such biological effects may be identified in the future, current data indicate that the benefits to patients of the prudent use of diagnostic ultrasound outweigh the risks, if any, that may be present.

Measurement accuracy

Measurement accuracy

The following information is intended to provide guidance to the user in determining the amount of variation or measurement error that should be considered when performing clinical measurements with this equipment. Error can be contributed by equipment limitations and improper user technique. Be sure to follow all measurement instructions and develop uniform measurement techniques among all users to minimize the potential operator error. Also, in order to detect possible equipment malfunctions that could affect measurement accuracy, a quality assurance (QA) plan should be established for the equipment that includes routine accuracy checks with tissue mimicking phantoms.

General

When using measurements, it is important to keep in mind the different aspects that affect the accuracy of the measurements. These include acoustical properties, patient echogenicity, measurement tools and algorithms, system setup (especially Field-of-view or Range settings), probe type used, and operator inputs.

Sources of error

Image Quality

The accuracy of each measurement is highly dependent on image quality. Image quality is highly dependent on system design, operator variability, and patient echogenicity. The operator variability and patient echogenicity are independent of the ultrasound system.

Operator variability

One of the largest potential sources of error is operator variability. A skilled operator can reduce this by optimizing the image quality for each type of measurement. Clear identification of structures, good probe alignment and correct cursor placement is important. Because of pixel resolution, the accuracy of a measurement decreases with decreasing distance on screen. Therefore it is important when scaling the object on the screen to avoid measuring objects that are too small.

NOTE: *See also 'Optimizing Measurement Accuracy' on page 8-186 for recommended techniques.*

Image measurement

The accuracy in lateral direction is limited by the beam width and the beam positioning. The radial accuracy is mainly limited by the acoustic pulse length.

Doppler alignment

Errors in velocity measurements increase with the cosine of the angle between the measured flow and the ultrasound beam. For under-estimation of the velocities, while an error of 40 degrees will cause the under-estimation to be 24%. It is highly recommended to optimize transducer position to align the ultrasound beam with the flow direction.

NOTE: *If alignment is not possible, you may use the Angle Correction control to compensate if the flow direction is known.*

Screen pixel resolution

The display screen is composed of an array of square picture elements (pixels). The smallest resolvable unit is +/- 1pixel. This pixel error is only significant when measuring short distances on the screen. By observing good scanning practices, the settings of the field of view should be such that the measured distance is significant with respect to the full size of the screen. When such scaling is impossible, the pixel error may come into play.

Speed of Sound in Tissue

The average speed of sound value of 1540 meters / second is used for all calculations. Depending on the tissue structures, this generalization may give errors from 2% (typical) to 5% (much fatty tissue layers present).

Optimizing Measurement Accuracy

Probe selection

Select a transducer appropriate for the application. Higher imaging frequencies provide better resolution, but less penetration than lower frequencies. Lower Doppler frequencies can measure higher max velocities, and at greater depths, but with less velocity resolution than higher Doppler frequencies.

Field of View

All display modes should be adjusted so that the area of interest covers as large portion of the display as possible. Use Depth, Zoom, Horizontal Sweep and Velocity controls to optimize the different modes.

Cursor Placement

All measurements are dependent on the accuracy of their "input" data. Consistency and precision in placing cursors correctly on the images are important.

NOTE: *Avoid placement of the cursor near the top of the image, close to the transducer, when using convex or linear probes.*

Measurement Uncertainties

The accuracy percentages reported below are based on data taken with optimum control settings, using calibrated phantoms and test equipment. The calibration was done for the basic measurable parameters: Distance, Time and Velocity. Independent sources of uncertainty contribute to a total uncertainty by a RMS (Root Mean Square) combination of the sources. Refer to the discussions above regarding measurement accuracy and sources of error when reading the table below.

Table 7-2: Measurement accuracy

Measurement	Unit	Useful range	Accuracy
Calipers - Curved array (deep scanning) transducer			
Vertical distance (2D, M-mode)	cm or mm	2mm-200mm	+/-1mm or +/-3% whichever is greater
Horizontal distance	cm or mm	4mm-100mm	+/-2mm or +/-5% whichever is greater
Circumference (ellipse)	cm or mm	10mm-300mm	+/-5% or +/-2mm whichever is greater
Time (M-mode, PW)	Sec	50-4000 ms	10ms or 5.0% whichever is greater
Velocity (PW)	m/s or cm/s	0.1-1.5 m/s	10%
Calipers - Linear array (shallow scanning) transducer			
Vertical distance (2D, M-mode)	cm or mm	1mm-60mm	+/-0.5mm or +/-3% whichever is greater
Lateral	cm or mm	2mm-40mm	+/-1mm or +/-5% whichever is greater
Circumference (ellipse)	cm or mm	5mm-150mm	+/-5% or +/-1mm whichever is greater
Time (M-mode, PW)	Sec	50-4000 ms	10ms or 5.0% whichever is greater
Velocity (PW)	m/s or cm/s	0.1-1.5 m/s	10%
Calipers - Sector array (deep scanning) transducer			
Vertical distance (2D, M-mode)	cm or mm	2mm-200mm	+/-1mm or +/-3% whichever is greater
Horizontal distance	cm or mm	4mm-100mm	+/-2mm or +/-5% whichever is greater

Table 7-2:   Measurement accuracy

Measurement	Unit	Useful range	Accuracy
Circumference (ellipse)	cm or mm	10mm-300mm	+/-5% or +/-2mm whichever is greater
Time (M-mode, PW)	Sec	50-4000 ms	10ms or 5.0% whichever is greater
Velocity (PW)	m/s or cm/s	0.1-1.5 m/s	10%

The ellipse circumference is calculated via the below formula from §16 in Ramanujan, Srinivasa (1914), "Modular Equations and Approximations to π". Quart. J. Pure App. Math. 45: 350–372. ISBN 9780821820766.

$$\pi \left[3(a+b) - \sqrt{(3a+b)(a+3b)} \right]$$
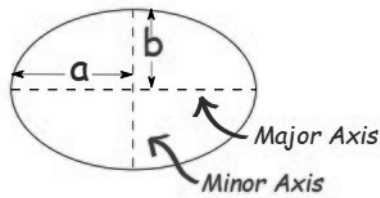
OB Tables

Abdominal Circumference (AC) HADLOCK 84

Reference: Hadlock,F.P., Deter,R.L., Harrist,R.B., Park,S.K.," Estimating fetal age: computer-assisted analysis of multiple fetal growth parameters", Radiology Vol. 152 No. 2, 1984, pages 497-501

$$GA = 8.14 + 0.753 \times AC + 0.0036 \times AC^2$$

Input Unit:	cm
Output Unit:	w (weeks)
Min Range	5.0 cm
Max Range:	38.0 cm

Table 7-3:   AC: Hadlock, Radiology 1984, Vol. 152:497 (Fetal Age)

Unit: AC (mm); Age (Week); 2SD (Week)											
AC	Age	2SD	AC	Age	2SD	AC	Age	2SD	AC	Age	2SD
<50	n/a	——	135	19.0	2.06	225	26.9	2.18	315	35.4	2.96
50	12.0	1.66	140	19.4	2.06	230	27.4	2.18	320	35.9	2.96
55	12.4	1.66	145	19.8	2.06	235	27.8	2.18	321	36.0	3.04
60	12.8	1.66	150	20.2	2.06	240	28.3	2.18	325	36.4	3.04
65	13.2	1.66	155	20.7	2.06	245	28.7	2.18	330	36.9	3.04
70	13.6	1.66	160	21.1	2.06	250	29.2	2.18	335	37.4	3.04
75	14.0	1.66	165	21.5	2.06	255	29.7	2.18	340	37.9	3.04
80	14.4	1.66	170	22.0	2.06	258	30.0	2.96	345	38.4	3.04
85	14.8	1.66	175	22.4	2.06	259	30.1	2.96	350	38.9	3.04
90	15.2	1.66	180	22.9	2.06	260	30.2	2.96	355	39.4	3.04
95	15.6	1.66	185	23.3	2.06	265	30.6	2.96	360	39.9	3.04
100	16.0	1.66	190	23.7	2.06	270	31.1	2.96	365	40.4	3.04
105	16.4	1.66	192	23.9	2.06	275	31.6	2.96	370	40.9	3.04
110	16.9	1.66	193	24.0	2.18	280	32.0	2.96	375	41.4	3.04
115	17.3	1.66	195	24.2	2.18	285	32.5	2.96	380	42.0	3.04
120	17.7	1.66	200	24.6	2.18	290	33.0	2.96	>380	n/a	——
123	17.9	1.66	205	25.1	2.18	295	33.5	2.96			
124	18.0	2.06	210	25.5	2.18	300	34.0	2.96			
125	18.1	2.06	215	26.0	2.18	305	34.5	2.96			
130	18.5	2.06	220	26.4	2.18	310	34.9	2.96			

Biparietal Diameter (BPD) HADLOCK 84

Reference: Hadlock,F.P., Deter,R.L., Harrist,R.B., Park,S.K.," Estimating
fetal age: computer-assisted analysis of multiple fetal growth
parameters", Radiology Vol. 152 No. 2, 1984, pages 497-501.

$$GA = 9.54 + 1.482 \times BPD + 0.1676 \times BPD^2$$

Input Unit:	cm	
Output Unit:	w (weeks)	
Min Range	1.40 cm	
Max Range:	10.2 cm	

Table 7-4:   BPD Hadlock, Radiology 1984, Vol. 152:497 (Fetal Age) [a]

Unit: BPD (mm); Age (Week); 2SD (Week)											
BPD	Age	2SD	BPD	Age	2SD	BPD	Age	2SD	BPD	Age	2SD
<14	n/a	——	36	17.0	1.19	59	24.1	2.18	82	33.0	3.08
14	11.9	1.19	37	17.3	1.19	60	24.5	2.18	83	33.4	3.08
15	12.1	1.19	38	17.6	1.19	61	24.8	2.18	84	33.8	3.08
16	12.3	1.19	39	17.9	1.19	62	25.2	2.18	85	34.2	3.08
17	12.5	1.19	40	18.1	1.73	63	25.5	2.18	86	34.7	3.08
18	12.8	1.19	41	18.4	1.73	64	25.9	2.18	87	35.1	3.08
19	13.0	1.19	42	18.7	1.73	65	26.3	2.18	88	35.6	3.08
20	13.2	1.19	43	19.0	1.73	66	26.6	2.18	89	36.0	3.20
21	13.4	1.19	44	19.3	1.73	67	27.0	2.18	90	36.5	3.20
22	13.6	1.19	45	19.6	1.73	68	27.4	2.18	91	36.9	3.20
23	13.8	1.19	46	19.9	1.73	69	27.7	2.18	92	37.4	3.20
24	14.1	1.19	47	20.2	1.73	70	28.1	2.18	93	37.8	3.20
25	14.3	1.19	48	20.5	1.73	71	28.5	2.18	94	38.3	3.20
26	14.5	1.19	49	20.8	1.73	72	28.9	2.18	95	38.7	3.20
27	14.8	1.19	50	21.1	1.73	73	29.3	2.18	96	39.2	3.20
28	15.0	1.19	51	21.5	1.73	74	29.7	2.18	97	39.7	3.20
29	15.2	1.19	52	21.8	1.73	75	30.1	3.08	98	40.2	3.20
30	15.5	1.19	53	22.1	1.73	76	30.5	3.08	99	40.6	3.20
31	15.7	1.19	54	22.4	1.73	77	30.9	3.08	100	41.1	3.20
32	16.0	1.19	55	22.8	1.73	78	31.3	3.08	101	41.6	3.20
33	16.3	1.19	56	23.1	1.73	79	31.7	3.08	102	42.1	3.20
34	16.5	1.19	57	23.4	1.73	80	32.1	3.08	>102	n/a	——
35	16.8	1.19	58	23.8	1.73	81	32.5	3.08			

Crown Rump Length (CRL) HADLOCK

Reference: Hadlock F., Shah Y.P, Kanon D.J., Math B., Lindsey J.V., "Fetal Crown-Rump Length: Reevaluation of Relation to Menstrual Age (5-18 weeks) with High-Resolution Real-Time Ultrasound." Radiology, 182:501-505, 1992.

$$GA = e^{1.684969 + 0.315646 \times CRL - 0.049306 \times CRL^2 + 0.004057 \times CRL^3 - 0.000120456 \times CRL^4}$$

Table 7-5: CRL Hadlock - Part 1

CRL (cm)	GA (weeks)			CRL (cm)	GA (weeks)		
	5%	50%	95%		5%	50%	95%
0.20	5,24	5,70	6,16	3.20	9,29	10,10	10,91
0.30	5,43	5,90	6,37	3.30	9,38	10,20	11,02
0.40	5,61	6,10	6,59	3.40	9,48	10,30	11,12
0.50	5,70	6,20	6,70	3.50	9,57	10,40	11,23
0.60	5,89	6,40	6,91	3.60	9,66	10,50	11,34
0.70	6,07	6,60	7,13	3.70	9,75	10,60	11,45
0.80	6,16	6,70	7,24	3.80	9,84	10,70	11,56
0.90	6,35	6,90	7,45	3.90	9,94	10,80	11,66
1.00	6,53	7,10	7,67	4.00	10,03	10,90	11,77
1.10	6,62	7,20	7,78	4.10	10,12	11,00	11,88
1.20	6,81	7,40	7,99	4.20	10,21	11,10	11,99
1.30	6,90	7,50	8,10	4.30	10,30	11,20	12,10
1.40	7,08	7,70	8,32	4.40	10,30	11,20	12,10
1.50	7,27	7,90	8,53	4.50	10,40	11,30	12,20
1.60	7,36	8,00	8,64	4.60	10,49	11,40	12,31
1.70	7,45	8,10	8,75	4.70	10,58	11,50	12,42
1.80	7,64	8,30	8,96	4.80	10,67	11,60	12,53
1.90	7,73	8,40	9,07	4.90	10,76	11,70	12,64
2.00	7,91	8,60	9,29	5.00	10,76	11,70	12,64
2.10	8,00	8,70	9,40	5.10	10,86	11,80	12,74
2.20	8,19	8,90	9,61	5.20	10,95	11,90	12,85
2.30	8,28	9,00	9,72	5.30	11,04	12,00	12,96
2.40	8,37	9,10	9,83	5.40	11,04	12,00	12,96
2.50	8,46	9,20	9,94	5.50	11,13	12,10	13,07
2.60	8,65	9,40	10,15	5.60	11,22	12,20	13,18
2.70	8,74	9,50	10,26	5.70	11,32	12,30	13,28
2.80	8,83	9,60	10,37	5.80	11,32	12,30	13,28
2.90	8,92	9,70	10,48	5.90	11,41	12,40	13,39
3.00	9,11	9,90	10,69	6.00	11,50	12,50	13,50
3.10	9,20	10,00	10,80	6.10	11,59	12,60	13,61

Crown Rump Length (CRL) HADLOCK (continued)

Table 7-6:   CRL Hadlock - Part 2

CRL	GA (weeks)			CRL	GA (weeks)		
(cm)	5%	50%	95%	(cm)	5%	50%	95%
6.20	11,59	12,60	13,61	9.20	13,89	15,10	16,31
6.30	11,68	12,70	13,72	9.30	13,98	15,20	16,42
6.40	11,78	12,80	13,82	9.40	14,08	15,30	16,52
6.50	11,78	12,80	13,82	9.50	14,08	15,30	16,52
6.60	11,87	12,90	13,93	9.60	14,17	15,40	16,63
6.70	11,96	13,00	14,04	9.70	14,26	15,50	16,74
6.80	12,05	13,10	14,15	9.80	14,35	15,60	16,85
6,90	12,05	13,10	14,15	9.90	14,44	15,70	16,96
7.00	12,14	13,20	14,26	10.00	14,63	15,90	17,17
7.10	12,24	13,30	14,36	10.10	14,72	16,00	17,28
7.20	12,33	13,40	14,47	10.20	14,81	16,10	17,39
7.30	12,33	13,40	14,47	10.30	14,90	16,20	17,50
7.40	12,42	13,50	14,58	10.40	15,00	16,30	17,60
7.50	12,51	13,60	14,69	10.50	15,09	16,40	17,71
7.60	12,60	13,70	14,80	10.60	15,18	16,50	17,82
7.70	12,70	13,80	14,90	10.70	15,27	16,60	17,93
7.80	12,70	13,80	14,90	10.80	15,36	16,70	18,04
7.90	12,79	13,90	15,01	10.90	15,46	16,80	18,14
8.00	12,88	14,00	15,12	11.00	15,55	16,90	18,25
8.10	12,97	14,10	15,23	11.10	15,64	17,00	18,36
8.20	13,06	14,20	15,34	11.20	15,73	17,10	18,47
8.30	13,06	14,20	15,34	11.30	15,82	17,20	18,58
8.40	13,16	14,30	15,44	11.40	15,92	17,30	18,68
8.50	13,25	14,40	15,55	11.50	16,01	17,40	18,79
8.60	13,34	14,50	15,66	11.60	16,10	17,50	18,90
8.70	13,43	14,60	15,77	11.70	16,19	17,60	19,01
8.80	13,52	14,70	15,88	11.80	16,28	17,70	19,12
8.90	13,62	14,80	15,98	11.90	16,38	17,80	19,22
9.00	13,71	14,90	16,09	12.00	16,47	17,90	19,33
9.10	13,80	15,00	16,20	12.10	16,56	18,00	19,44

Femur Length (FL) HADLOCK 84

Reference:
Hadlock,F.P., Deter,R.L., Harrist,R.B., Park,S.K.," Estimating fetal age: computer-assisted analysis of multiple fetal growth parameters", Radiology Vol. 152 No. 2, 1984, pages 497-501.

$$GA = 10.35 + 2.46 \times FL + 0.17 \times FL^2$$

Input Unit:		cm
Output Unit:		w (weeks)
Min Range		0.6 cm
Max Range:		8.2 cm

Table 7-7: FL: Hadlock, Radiology 1984, Vol. 152:497 (Fetal Age)

Unit: FL (mm); Age (Week); 2SD (Week)											
FL	**Age**	**2SD**	**FL**	**Age**	**2SD**	**FL**	**Age**	**2SD**	**FL**	**Age**	**2SD**
<6	n/a	——	25	17.6	1.38	45	24.9	2.08	65	33.5	2.96
6	11.9	1.38	26	17.9	1.38	46	25.3	2.08	66	34.0	2.96
7	12.2	1.38	27	18.2	1.80	47	25.7	2.08	67	34.5	2.96
8	12.4	1.38	28	18.6	1.80	48	26.1	2.08	68	34.9	2.96
9	12.7	1.38	29	18.9	1.80	49	26.5	2.08	69	35.4	2.96
10	13.0	1.38	30	19.3	1.80	50	26.9	2.08	70	35.9	2.96
11	13.3	1.38	31	19.6	1.80	51	27.3	2.08	71	36.4	3.12
12	13.5	1.38	32	20.0	1.80	52	27.7	2.08	72	36.9	3.12
13	13.8	1.38	33	20.3	1.80	53	28.2	2.08	73	37.4	3.12
14	14.1	1.38	34	20.7	1.80	54	28.6	2.08	74	37.9	3.12
15	14.4	1.38	35	21.0	1.80	55	29.0	2.08	75	38.4	3.12
16	14.7	1.38	36	21.4	1.80	56	29.5	2.08	76	38.9	3.12
17	15.0	1.38	37	21.8	1.80	57	29.9	2.08	77	39.4	3.12
18	15.3	1.38	38	22.2	1.80	58	30.3	2.96	78	39.9	3.12
19	15.6	1.38	39	22.5	1.80	59	30.8	2.96	79	40.4	3.12
20	16.0	1.38	40	22.9	1.80	60	31.2	2.96	80	40.9	3.12
21	16.3	1.38	41	23.3	1.80	61	31.7	2.96	81	41.4	3.12
22	16.6	1.38	42	23.7	1.80	62	32.1	2.96	82	42.0	3.12
23	16.9	1.38	43	24.1	2.08	63	32.6	2.96	>82	n/a	——
24	17.2	1.38	44	24.5	2.08	64	33.1	2.96			

Head Circumference (HC) HADLOCK 84

Reference:	Hadlock,F.P., Deter,R.L., Harrist,R.B., Park,S.K.," Estimating fetal age: computer-assisted analysis of multiple fetal growth parameters", Radiology Vol. 152 No. 2, 1984, pages 497-501.

$$GA = 8.96 + 0.54 \times HC + 0.0003 \times HC^3$$

Input Unit:	cm
Output Unit:	w (weeks)
Min Range:	5.5 cm
Max Range:	35.8 cm

Table 7-8:   Head Circumference Hadlock 84 (Part 1)

HC (mm)	Age (weeks) mean	+/- 2SD	HC (mm)	Age (weeks) mean	+/- 2SD	HC (mm)	Age (weeks) mean	+/- 2SD	HC (mm)	Age (weeks) mean	+/- 2SD
<55	n/a	——	135	17.0	+/- 1.2	215	23.6	+/- 1.5	290	31.9	+/- 3.0
55	12.0	+/- 1.2	140	17.3	+/- 1.2	219	23.9	+/- 1.5	295	32.6	+/- 3.0
60	12.3	+/- 1.2	145	17.7	+/- 1.2	220	24.0	+/- 2.1	300	33.3	+/- 3.0
65	12.6	+/- 1.2	149	18.0	+/- 1.2	225	24.5	+/- 2.1	305	33.9	+/- 3.0
70	12.8	+/- 1.2	150	18.1	+/- 1.5	230	25.0	+/- 2.1	310	34.6	+/- 3.0
75	13.1	+/- 1.2	155	18.4	+/- 1.5	235	25.5	+/- 2.1	315	35.3	+/- 3.0
80	13.4	+/- 1.2	160	18.8	+/- 1.5	240	26.1	+/- 2.1	319	35.9	+/- 3.0
85	13.7	+/- 1.2	165	19.2	+/- 1.5	245	26.6	+/- 2.1	320	36.1	+/- 2.7
90	14.0	+/- 1.2	170	19.6	+/- 1.5	250	27.1	+/- 2.1	325	36.8	+/- 2.7
95	14.3	+/- 1.2	175	20.0	+/- 1.5	255	27.7	+/- 2.1	330	37.6	+/- 2.7
100	14.7	+/- 1.2	180	20.4	+/- 1.5	260	28.3	+/- 2.1	335	38.3	+/- 2.7
105	15.0	+/- 1.2	185	20.8	+/- 1.5	265	28.9	+/- 2.1	340	39.1	+/- 2.7
110	15.3	+/- 1.2	190	21.3	+/- 1.5	270	29.4	+/- 2.1	345	39.9	+/- 2.7
115	15.6	+/- 1.2	195	21.7	+/- 1.5	274	29.9	+/- 2.1	350	40.7	+/- 2.7
120	16.0	+/- 1.2	200	22.2	+/- 1.5	275	30.0	+/- 3.0	355	41.6	+/- 2.7
125	16.3	+/- 1.2	205	22.6	+/- 1.5	280	30.7	+/- 3.0	>358	n/a	——
130	16.6	+/- 1.2	>210	23.1	+/- 1.5	285	31.3	+/- 3.0			

EFW Hadlock 1 (AC, FL)

$$FW = 10^{1.304 + 0.05281 \times AC + 0.1938 \times FL - 0.004 \times AC \times FL}$$

Inputs:	AC, FL in (cm)
Output:	FW in (g)

Reference: Hadlock FP, et al, "Estimation of fetal weight with the use of head, body and femur measurements: A prospective study" Am. J. Obstet. Gynecol. 1985; 151: 333-337

EFW Hadlock 2 (BPD, AC, FL)

$$FW = 10^{1.335 - 0.0034 \times AC \times FL + 0.0316 \times BPD + 0.0457 \times AC + 0.1623 \times FL}$$

Inputs:	BPD, AC, FL in (cm)
Output:	FW in (g)

Reference: Hadlock FP, et al, "Estimation of fetal weight with the use of head, body and femur measurements: A prospective study" Am. J. Obstet. Gynecol. 1985; 151: 333-337

EFW Hadlock 3 (HC, AC, FL)

$$FW = 10^{1.326 - 0.00326 \times AC \times FL + 0.0107 \times HC + 0.0438 \times AC + 0.158 \times FL}$$

Inputs: HC, AC, FL in (cm)

Output: FW in (g)

Reference: Hadlock FP, et al, "Estimation of fetal weight with the use of head, body and femur measurements: A prospective study" Am. J. Obstet. Gynecol. 1985; 151: 333-337

EFW Hadlock 4 (BPD, HC, AC, FL)

$$FW = 10^{1.3596 - 0.00386 \times AC \times FL + 0.0064 \times HC + 0.00061 \times BPD \times AC + 0.0424 \times AC + 0.174 \times FL}$$

Inputs: BPD, HC, AC, FL in (cm)

Output: FW in (g)

Reference: Hadlock FP, et al, "Estimation of fetal weight with the use of head, body and femur measurements: A prospective study" Am. J. Obstet. Gynecol. 1985; 151: 333-337

Vscan Air CL and SL Indications reference guide

Disclaimer

The information in this section is meant to be reference for examples of anatomies and examinations that can be evaluated by this product. The list may not be all inclusive.

Curved Array (Deep scanning) Transducer

The curved array transducer on Vscan Air CL supports Black/ white (B-mode), Color (Color doppler), Harmonic, M-mode and PW doppler modes. Vscan Air is indicated for ultrasound imaging, measurement, and analysis of the human body in clinical applications that include:

Table 7-9:   Curved Array Transducer

Clinical Application	Anatomy	Evaluation
Abdominal (Adult/ Pediatrics)	• Gall bladder, biliary tree, common bile duct • Liver • Pancreas • Spleen • Bowel including Appendix, small bowel loops • Abdominal aorta • Kidneys • Inferior vena cava (IVC) • Iliac	• Gall stones • Gall bladder inflammation ((wall thickening, surrounding fluid) • Biliary obstruction (duct dilatation) • Hepatomegaly • Fatty liver • Splenomegaly • Intestinal obstruction • Appendicitis • Peritoneal fluid • Cyst/mass/abscess • Abdominal aortic aneurysm • Kidney stones
Urology (Adult/ Pediatrics)	• Kidneys • Ureter • Urinary Bladder • Uretero-vesicular junction • Prostate	• Kidney, ureteral, bladder stones • Kidney length • Hydronephrosis • Bladder dysfunction • Pre-post Bladder volume • Bladder inflammation (wall and mucosal changes, calcifications) • Ureteral jets with color • Prostate size and volume • Cyst/Mass

Table 7-9: Curved Array Transducer

Clinical Application	Anatomy	Evaluation
OB-GYN	• Uterus and endometrium • Ovaries • Cervix • Pouch of Douglas (POD) • Gestational Sac (GS) • Placenta • Amniotic fluid • Fetus(es)	• GS location (Intra-uterine/ extra-uterine) • Fetal viability/ heart motion • Placenta position- (including low-lying and previa) • Fetal position and presentation • Amniotic fluid assessment • Cervical length measurement/ cervical insufficiency • Fetal well-being assessment: Biophysical profile (breathing, movements, tone, amniotic fluid) • Confirmation of fetal death • Intrauterine device position • Endometrial thickness measurement • Uterine/ adnexal mass/ cyst (fibroids, cysts) • Free fluid in Pouch of Douglas (POD)

Lung/Thoracic (Adult/ Pediatrics)	• A-lines, B-lines, E-lines
	• Pleura
	• Lung tissue
	• Lung sliding
	• Lung point
		• Pneumothorax and hemothorax
		• Pleural Effusion
		• Lung consolidation
		  • Pneumonia/ pneumonitis
		  • Pulmonary fibrosis
		• Pulmonary interstitial and inflammatory disorders (Ex. ILD, COPD)
		• Acute respiratory distress syndrome

Cardiac and hemodynamic assessment (Adult/ Pediatrics*)
 	
Pediatric population for Cardiac application defined as minimum body weight 40 Kg and above.
	• Heart (atria, ventricles, valves) including pericardium
	  • Subcostal view
	• Inter-atrial and interventricular septum
	• Pulmonary arteries/ veins
	• Inferior vena cava (IVC)
		• Pericardial fluid
		• LV and RV size and function
		• Valvular regurgitations/ stenosis
		• Volume status and responsiveness
		  • IVC size
		  • Respiratory variation

Musculoskeletal (Conventional) (Adult/ Pediatrics)	• Hip/knee/ Shoulder joints • Femur • Humerus/elbow • Tibia/fibula • Radius/ulna • Muscles • Ligaments • Tendons • Nerves	• Fluid • Cyst/ Mass • Long bone fractures • Ligament and joint integrity • Tendon injuries (tendonitis, rupture/ tear) • Muscle tears • Peripheral nerve blocks

Table 7-9: Curved Array Transducer

Clinical Application	Anatomy	Evaluation
Procedure guidance (Adult/ Pediatrics)	• Heart • Lung • Uterus • Abdomen • Thorax • Bladder • Nerve plexus • Hip/Knee/ Shoulder joints	• Fluid detection: Pericardial, Pleural, Peritoneal, Amniotic, Joints • Procedures: Thoracentesis, Paracentesis, Pericardiocentesis, Amniocentesis, Arthrocentesis • Foreign body visualization/localization • Bladder catheterization • Nerve blocks • Biopsy • Placement and monitor position of tubes and catheters
Protocols	• Heart • Inferior vena cava (IVC) • Lungs • Abdomen	• FAST • eFAST • BLUE • FASH • FASE

Linear Array (Shallow scanning) Transducer

The linear array transducer on Vscan Air CL and the Vscan Air SL supports Black/white (B-mode), Color (Color doppler), Harmonic, M-mode and PW doppler modes. Vscan Air is indicated for ultrasound imaging, measurement, and analysis of the human body in clinical applications that include:

Table 7-10: Linear Array Transducer

Clinical Application	Anatomy	Evaluation
Peripheral Vascular (Adult and Pediatrics)	• Arteries including Carotid, vertebral, subclavian, axillary, brachial, iliac, saphenous, popliteal, femoral • Veins including Jugular, subclavian, cephalic, basilic, saphenous, femoral, popliteal, tibial	• Deep vein thrombosis • Atherosclerosis- Intima media thickness, plaques, vessel occlusion/ stenosis • Subclavian Steal syndrome

Lung/ Thoracic (Adult / Pediatric)	• A-lines, B-lines, E-lines
	• Pleura
	• Lung tissue
	• Lung sliding
	• Lung point
		• Pneumothorax and hemothorax
		• Pleural effusion
		• Lung consolidation
		   • Pneumonia/ pneumonitis
		   • Pulmonary fibrosis
		• Pulmonary interstitial and inflammatory disorders (Ex. ILD, COPD)
		• Acute respiratory distress syndrome

Table 7-10:   Linear Array Transducer

Clinical Application	Anatomy	Evaluation
Small organs (Adult/ Pediatric)	• Testes • Scrotum • Thyroid • Breast • Bowel • Abdominal wall • Skin • Subcutaneous tissue • Fascia • Lymph nodes	• Testicular torsion (size, echo-texture and vascularity) • Epididymo-orchitis • Fluid collection in scrotal sac • Hematomas, hernias • Breast nodules, cyst/mass • Abdominal wall masses, hernias • Thyroid nodules/cyst/mass/ diffuse enlargement • Bowel pathology (ex. appendicitis, diverticulitis, intestinal obstruction) • Pyloric stenosis/ Intussusception for pediatric patients • Soft tissue infection (cellulitis, abscess, bed sore) • Foreign body visualization/ localization • Cutaneous mass
Musculoskeletal – (Superficial and conventional) (Adult/ Pediatrics)	• Tendons • Muscles • Ligaments • Nerves • Long bones (ex. Humerus, Radius, Ulna, Femur, Tibia, Fibula) • Joints (Ankle, Shoulder, Knee, Elbow, Wrist) • Joint space/ bursa	• Tendon injuries (tendonitis, rupture/ tear) • Muscle tears • Long bone fractures • Carpal Tunnel syndrome • Fluid collection in joint space, muscles, bursae • Joint and ligaments integrity • Cyst/ Mass • Hip joint evaluation for neonates and infants
Nerves (Adult/ Pediatrics)	• Peripheral nerves (including interscalene, supraclavicular, infraclavicular, axillary plexus, median N, radial N, ulnar, femoral, popliteal, tibial, peroneal, saphenous N)	• Peripheral nerve blocks
Neck and airway (Adult/Pediatric)	• Cervical Lymph nodes • Trachea • Epiglottis, cricoid cartilage, cricothyroid membrane • Esophagus • Vocal folds	• Neck masses • Airway assessment • Vocal cord dysfunction

Table 7-10:   Linear Array Transducer

Clinical Application	Anatomy	Evaluation
Procedural guidance (Adult/ Pediatrics)	• Thorax • Veins (including Jugular/ Subclavian/ Axillary/ Femoral / Brachial/ Basilic/ Cephalic) • Arteries (including femoral, radial, brachial, axillary, dorsalis pedis) • Peripheral nerves • Joints • Vertebral spaces • Skin and subcutaneous tissue • Trachea and surrounding structures	• Fluid detection and removal support: thoracentesis • Peripheral venous access • Central venous catheterization • Arterial access • Assessment and support of dialysis access • Nerve blocks • Joint aspiration and injections • Cyst aspiration • Biopsy • Abscess drainage • Foreign body visualization/ localization • Lumbar Puncture • Endotracheal tubes placement and confirmation • Support placement and monitor position of tubes and catheters
Ophthalmic*	• Optic nerve sheath • Retina • Globe • Lens	• Retinal detachment • Vitreous hemorrhage • Intra-ocular foreign body visualization • Globe rupture • Optic Nerve sheath diameter • Lens dislocation
Cephalic (Neonatal)	• Fontanelle • Superficial and mid-superficial cranial structures	• Gyral-sulcal anatomy • Superior sagittal sinus thrombosis • Cerebral edema • Extra-axial fluid collections
Protocols	• Lungs	• eFAST • BLUE

Sector Array (deep scanning) transducer

The sector array transducer on Vscan Air SL supports Black/ white (B-mode), Color (Color doppler), Harmonic, M-mode and PW doppler modes. Vscan Air is indicated for ultrasound imaging, measurement, and analysis of the human body in clinical applications that include:

Table 7-11:   Sector Array Transducer

Clinical Application	Anatomy	Evaluation
Abdominal (Adult/ Pediatrics)	• Gall bladder, biliary tree, common bile duct • Liver • Pancreas • Spleen • Bowel including Appendix, small bowel loops • Abdominal aorta • Kidneys • Inferior vena cava (IVC)	• Gall stones • Gall bladder inflammation ((wall thickening, surrounding fluid) • Biliary obstruction (duct dilatation) • Hepatomegaly • Fatty liver • Splenomegaly • Intestinal obstruction • Appendicitis • Peritoneal fluid • Cyst/mass/abscess • Abdominal aortic aneurysm • Kidney stones
Urology (Adult/ Pediatrics)	• Kidneys • Ureter • Urinary Bladder • Uretero-vesicular junction • Prostate	• Kidney, ureteral, bladder stones • Kidney length • Hydronephrosis • Bladder dysfunction • Pre-post Bladder volume • Bladder inflammation (wall and mucosal changes, calcifications) • Prostate size and volume • Mass/ cyst • Ureteral jets with color
OB-GYN	• Uterus and endometrium • Ovaries • Cervix • Pouch of Douglas (POD) • Gestational Sac (GS) • Placenta • Amniotic fluid • Fetus(es)	• GS location (Intra-uterine/ extra-uterine) • Fetal viability/ heart motion • Placenta position- (including low-lying and previa) • Fetal position and presentation • Amniotic fluid assessment • Cervical length measurement/ cervical insufficiency • Fetal well-being assessment: Biophysical profile (breathing, movements, tone, amniotic fluid) • Confirmation of fetal death • Intrauterine device position • Endometrial thickness measurement • Uterine/ adnexal mass/cyst (fibroids, cysts) • Free fluid in Pouch of Douglas (POD)

Table 7-11: Sector Array Transducer

Clinical Application	Anatomy	Evaluation

Lung/Thoracic (Adult/ Pediatrics)	• A-lines, B-lines, E-lines
	• Pleura
	• Lung tissue
	• Lung sliding
	• Lung point
		• Pneumothorax and hemothorax
		• Pleural Effusion
		• Lung consolidation
		  • Pneumonia/ pneumonitis
		  • Pulmonary fibrosis
		• Pulmonary interstitial and inflammatory disorders (Ex. ILD, COPD)
		• Acute respiratory distress syndrome

Cardiac and hemodynamic assessment (Adult/ Pediatrics*)
 	
Pediatric population for Cardiac application defined as minimum body weight 40 Kg and above.
	• Heart (atria, ventricles, valves) including pericardium
	  • Subcostal view
	  • Apical 2-Chamber , Apical 3-Chamber, Apical 4-chamber, Apical 5-Chamber, parasternal view (long axis and short axis)
	  • LVOT
	• Inter-atrial and interventricular septum
	• Pulmonary arteries/ veins
	• Inferior vena cava (IVC)
		• Pericardial fluid
		• LV and RV size and function
		• Systolic and Diastolic function
		• Valvular regurgitations/ stenosis
		• Volume status and responsiveness
		  • IVC size
		  • Respiratory variation

Adult cephalic/ Transcranial doppler	• Circle of Willis • Vertebrobasilar system/artery • Middle cerebral artery (MCA)	• Stenosis • Cerebral vasculopathy • Vasospasms • Collateral pathways • Right to left shunts • Aneurysms • Positional vertigo • Cerebral microemboli • Ischemic stroke
Procedure guidance (Adult/ Pediatrics)	• Heart • Lung • Uterus • Abdomen • Thorax • Bladder • Nerve plexus • Hip/Knee/ Shoulder joints	• Fluid detection: Pericardial, Pleural, Peritoneal, Amniotic, Joints • Procedures: Thoracentesis, Paracentesis, Pericardiocentesis, Amniocentesis, Arthrocentesis • Bladder catheterization • Nerve blocks • Biopsy • Placement and monitor position of tubes and catheters
Protocols	• Heart • IVC • Lungs • Abdomen	• FAST • eFAST • BLUE • FASH • FASE

Disclaimer: *Ophthalmic is not available in Japan and China.*

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