Technical Publications

Vscan Air

CE 0123

User Manual

H45621AA
GP092019-1EN - English

Rev 02

General User Documentation

Regulatory requirement

Vscan Air™

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

CE 0123

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 for Android and all 2.X software versions of Vscan Air for iOS.

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

Revision History

Reason for Change

REV	DATE DD Month YYYY	REASON FOR CHANGE
Rev 1 to 2	09 Feb 2023	Internal release

Please verify that you are using the latest revision of this document. Information pertaining to this document is maintained on ePDM (GE electronic Product Data Management). If you need to know the latest revision, contact your distributor, local GE Sales Representative or in the USA call the GE Ultrasound Clinical Answer Center at 1 800 682 5327 or 1 262 524 5698.

This page intentionally left blank.

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
Europe-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 adapter is Class II.

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

• Turkey

NOTE: Importer information for Turkey does not have the font and font size normally used in the manual.
GE Medical Systems Türkiye Ltd. Şti.
Esentepe Mah. Harman Sok. No: 8
34394 Şişli İstanbul Türkiye

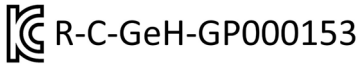
• Asia

Thailand

GE Medical Systems (Thailand) Ltd.
32nd Floor, Thanapoom Tower
1550 New Petchburi Road
Makkasan, Ratthewi, Bangkok 10400, Thailand
Tel: (+66) 2 624 8488

Telecom Certification Information for Vscan Air CL

- **Korea**



- **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**.

Telecom Certification Information for Vscan Air SL

- **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**.

Table of Contents

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

Documentation (continued)

- 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 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.

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.

Documentation (continued)

This manual covers the following configurations of the Vscan Air:

1. Vscan Air software application (app):
   - Vscan Air for iOS
   - Vscan Air 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 app for iOS devices.
- Vscan Air for Android – Vscan Air 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 40MHz.

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 andUNII-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: 0.540 W/kg (SAR Limit = 1.6 W/kg - over 1g) 0.295 W/kg (SAR Limit = 4.0 W/kg - over 10g) Vscan Air SL: 0.33 W/kg (SAR Limit = 1.6 W/kg - over 1g) 1.55 W/kg (SAR Limit = 4.0 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.

Indications for use (continued)

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).

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, vascular/peripheral vascular, musculoskeletal (conventional), pediatrics, adult cephalic, interventional guidance (includes free hand needle/catheter placement, fluid drainage, nerve block and biopsy).

Table 1-3: Supported imaging modes

Mode	Vscan Air		
	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 Ophthalmic preset when performing an eye exam.
- The system will not exceed the lower acoustic energy limits for ophthalmic use only if the Ophthalmic preset is selected.
- Be sure to use the linear array transducer for eye scanning.

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 in Japan 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 in China.

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 limited 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).

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 web portal for reference materials.

Prescription Device

For USA only:

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 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.

- 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)

- 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 3-6*) and to read and understand information given in the Vscan Air Battery section (refer ‘Vscan Air battery’ on *page 3-17*).

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

For service in the United States, 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	GE Healthcare Argentina Nicolas de Vedia 3616 piso 5 Buenos Aires - 1307	TEL: 0800-222-4342
BRAZIL	GE Healthcare do Brasil Comércio e Serviços para Equipamentos Médicos - Hospitalares Ltda. Av. Magalhães de Castro, 4800, Andar 11 Conj. 111 e 112, Andar 12 Conj. 121 e 122, Torre 3 - Cidade Jardim - CEP: 05676-120 - São Paulo/SP - Brasil CNPJ : 00.029.372/0001-40 Responsável Técnico: Renata Bellentani Brandão - CRF/SP nº 36.198 Capitais e Regiões metropolitanas Demais localidades	TEL: 3067-8010 FAX: (011) 3067-8280 TEL: 3004-2525 (Capitals and Metropolitan Regions) TEL: 08000 165 799 (Other Locations)
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

Table 1-5: Americas (Continued)

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	GE Sistemas Medicos de Mexico S.A. de C.V. Rio Lerma #302, 1º y 2º Pisos Colonia Cuauhtemoc 06500-Mexico, D.F.	TEL: 8002000111
COLOMBIA	#417 for Movistar, Claro & Tigo telecom operators	TEL: 01 8000 181350
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	32 Phillip Street Parramatta 2150 Sydney, NSW, 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

Table 1-6: Asia (Continued)

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 Koutervelds traat 20 1831 DIEGEM	TEL: (+32) 2 719 7204 FAX: (+32) 2 719 7205
CZECH REPUBLIC	GE Medical Systems Ceská Republika, s.r.o. Bucharova 2641/14 158 00 Praha 5 Česká republika Bratislava servis.gehc@ge.com	TEL: (+420) 224 446 162 FAX: (+420) 224 446 161 TEL: 800120180 FAX: (+420) 220 190 691
SLOVAKIA	Bratislava servis.gehc@ge.com	TEL: 02 44460030 FAX: 00421244460032
ROMANIA	Bucharest callcenterro@ge.com; ana-maria.gindea@ge.com	TEL: 0040311305293/ VIP: 0040 311 305 099/ Affidea: 0040 311 305 294 FAX: (+40) 372074699
BULGARIA	Sofia Iva.Ilieva@ge.com , Nikoleta.Lulcheva@ge.com	TEL: 00359 2 971 2040 - Office 00359 080018170 - Call Center FAX- +359 2 8704002
SERBIA	Belgrade marina.jankovic@ge.com	00381 112200791
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 Solingen ServiceCenterDeutschland@ge.com	TEL: (+49) 0800 4373 784 FAX: (+49) 212-38327-590
GREECE	GE Healthcare 8-10 Sorou Str. Marousi Athens 15125 Hellas @HEALTH Greece Service Center	TEL: (+30) 210 89 30 660 0030 210 8930660
HUNGARY	GE Hungary Zft. Bence utca 3 Budapest BU 1138 HU juhasz.magdolna@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

LUXEMBORG	See Belgium.	
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 SerwisPolska@ge.com	TEL: (+48) 22 330 83 30 or 00800 803 803 0048 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

TURKEY	GE Healthcare Türkiye Istanbul Office Levent Ofis Esentepe Mah. Harman Sok. No:8 Sisli-Istanbul	TEL: +90 212 398 07 00 FAX: +90 212 284 67 00
EGYPT		19434
SAUDI		8001243002
NIGERIA		0023414642220
GHANA		00233501555066
KENYA		0800721761
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

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:

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.

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, test, align, calibrate, troubleshoot, repair or modify the system. The owner should make certain that only properly trained, fully qualified service personnel undertake maintenance of the equipment. 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.

Overview (continued)

The owner of Vscan Air must be aware of the data protection policies GEHC is not responsible for data sharing.

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.

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.

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.

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.


CAUTION

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

Personnel and equipment safety

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

Explosion hazard

Never operate the equipment in the presence of flammable or explosive liquids, vapors or gases. Malfunction in the Vscan Air probe or in the personal mobile device, can electrically ignite these 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 the device.
- If flammable substances are detected after the device has been turned on, do not attempt to turn off the Vscan Air probe, or to unplug it.
- If flammable substances are detected, evacuate and ventilate the area before turning off Vscan Air probe.

Electrical hazard

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

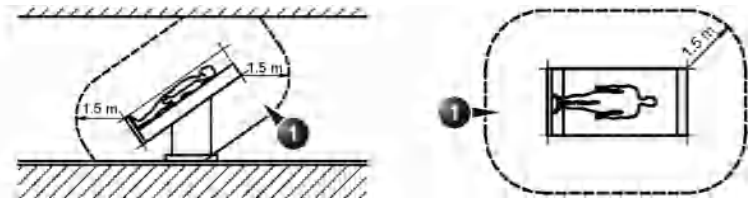
Device classifications

The Vscan Air CL and the Vscan Air SL probes are internally powered devices, type BF. The AC adapter is Class II.

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 does 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)

AII 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 2-9*).

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

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.

The ultrasound unit is intended for use in the electromagnetic environment specified in the tables below ‘Electromagnetic emissions’ on *page 2-16*.

Electromagnetic Compatibility (EMC) (continued)

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

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.

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.

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.

This device complies with Industry Canada RSSs applicable to devices license-exempt radio. Operation is permitted under the following two conditions: (1) the device may not cause interference, and (2) the user of the device must agree to undergo any radio frequency interference, even if the interference is likely to compromise the device operation. The 5150-5250 MHz band is reserved only for indoor use to reduce the risk of harmful interference to mobile satellite systems using the same channels.

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 or hospital 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 or hospital 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 or hospital environment. If the user of the ultrasound unit requires continued operation during power mains interruptions, it is recommended that the Vscan Air probes are powered from an uninterruptible power supply or a battery.
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 or hospital environment.
NOTE: U_T is the a. c. mains voltage prior to application of the test level.			

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/IEC62359: 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 3-13*.

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,Mar?s ´ al 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 5-18*, ‘Color flow (Color Doppler)’ on *page 5-26*, ‘Pulsed wave (PW) spectral doppler’ on *page 5-33* and ‘M-mode (Motion mode)’ on *page 5-47*

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	47.8
Vscan Air CL – Linear array transducer (for shallow scanning)	41.8	44.8
Vscan Air SL – Sector array transducer (for deep scanning)	41.1	42.8
Vscan Air SL – Linear array transducer (for shallow scanning)	40.8	47.4

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

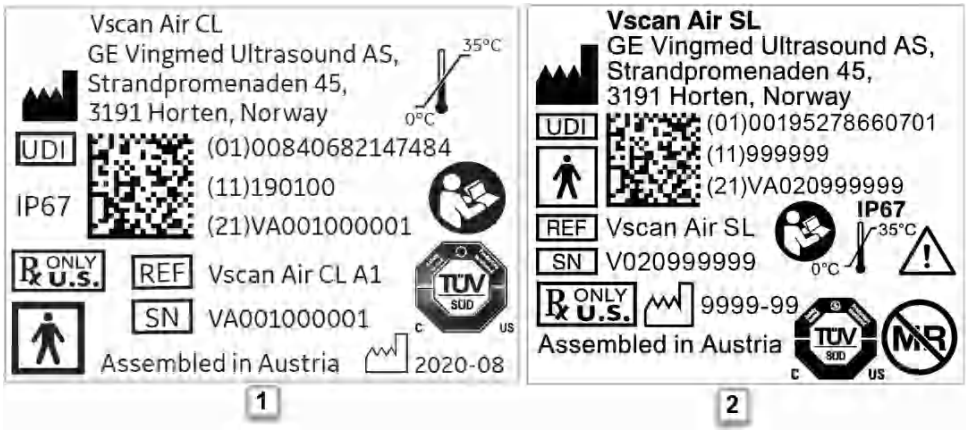
NOTE: The probe will stop scanning, if exceeding an applied part surface temperature of 43°C

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 30 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 samples. 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
	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
	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
	TUV SUD NRTL Certification Mark	Vscan Air probe	N/A - by certification body
	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
	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
	Type BF Applied Part symbol (see ‘Classifications’ on *page i-6*)	Vscan Air probe	IEC 60417-5333

Table 2-8: Label Icons

Label	Purpose	Location	Standard
	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
	Brand and model identifier.	- Vscan Air probe - Vscan Air app	ISO 7000-2493
	Serial number	Vscan Air probe	ISO 7000-2498
	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
	This symbol indicates the item is a medical device	- Vscan Air probe - Vscan Air app	ISO15223-1
	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 2-9: 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
	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 susbtances 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 orparts 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.

Chapter 3

Preparing Vscan Air for Use

Contents:

Package contents

Vscan Air shipment box contents

Vscan Air product box contents

1. Vscan Air Quick Start Guide
2. Vscan Air Charger
3. Protective case
4. Vscan Air CL probe
5. Vscan Air SL probe
6. SL probe with Protective Case

Figure 3-1. Vscan Air 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. Starting a charging cycle is the FIRST STEP that needs to be performed before trying to turn the Vscan Air on. The Vscan Air probe will not start unless an initial charging cycle has been initiated.
2. Plug one end of the USB cable into the wireless charger and the other into the AC adapter.

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

How to charge the Vscan Air probes (continued)

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

6. 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 3-20*).

How to charge the Vscan Air probes (continued)

NOTE: *The Vscan Air probe will stay connected to the app and start charging if placed on the wireless charger while being powered on. The app battery icon will indicate that the battery is charging and the battery charging level will be indicated via the Vscan Air battery status indicator as illustrated in 'Battery level indicator' on page 3-19".*

NOTE: *If the Vscan Air probe is powered off when the probe is placed onto the wireless charger it will start charging.*

NOTE: *Both LEDs will be blinking 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	Nonoperational	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, 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, 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 3-6 for more information.*
- The Vscan Air probes are not certified for being charged inside a road- or air ambulance.
- The AC Adapter 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-3*. 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-3*. Additional regulations might apply.

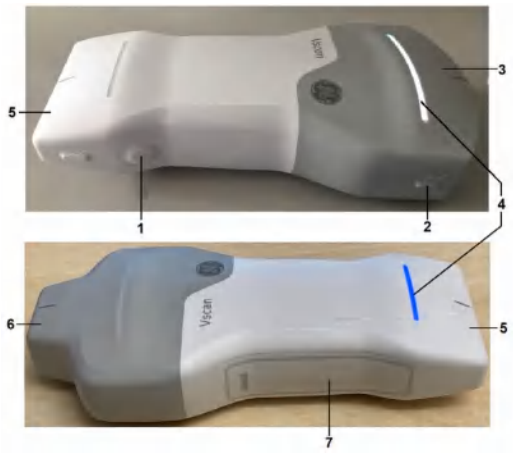
System description

System overview

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.

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 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 installed 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.



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

Figure 3-2. Vscan Air probe

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

Display screens

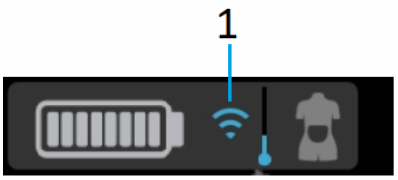
Connection and probe battery status

- NOT CONNECTED TO PROBE - No outline of the battery and no battery charge indicator

- CONNECTED TO PROBE - White outline of the battery and battery charge indicator

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

Wireless connection quality indicator



1. Wireless connection quality indicator

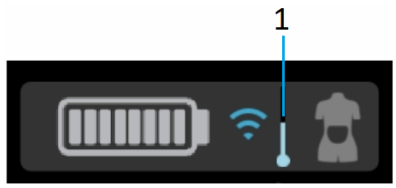
A wireless probe has a limited inherent risk of a disrupted connection due to various factors that could lead to loss of real time imaging.

Wireless connection quality indicator (continued)

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:

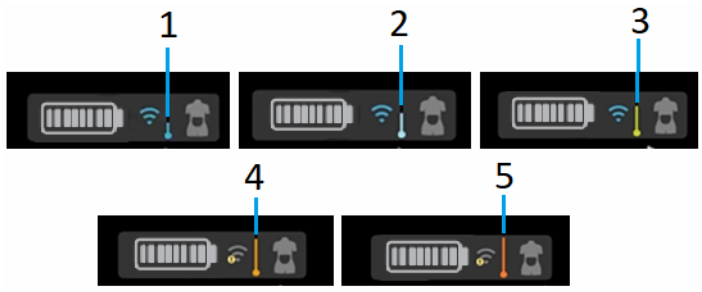
- Transducer: Curved array transducer gets warm more quickly than linear array due to higher power consumption.
- Preset: Certain presets like Abdominal and cardiac have higher power requirements depending on the image settings causing the probe to warm up faster than other presets.
- Mode: Operating in Color flow mode warms up probe faster than 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.

Probe temperature indicator and thermal management (continued)

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.

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 3-3 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 3-12*).

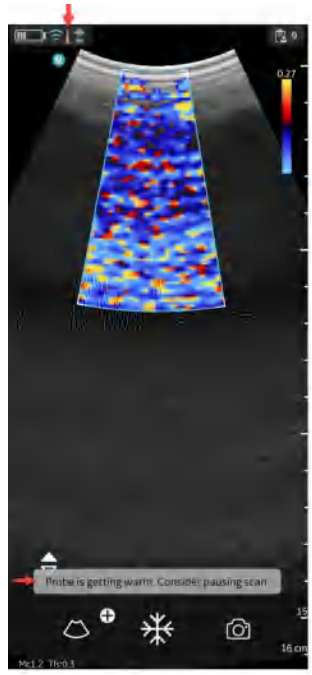
NOTE: Probe temperature and related user notifications are independent of the probe battery status.



1. Level 0
2. Level 1
3. Level 2
4. Level 3
5. Level 4

Figure 3-3. Thermal indicator levels

Probe temperature indicator and thermal management (continued)



1. Level 3
2. Level 4

Figure 3-4. Thermal indicator toast message

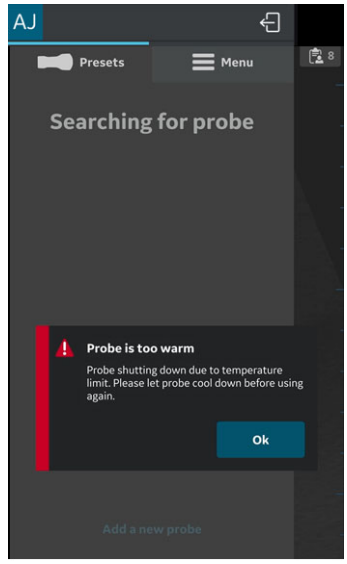


Figure 3-5. Thermal warning message

Black/white imaging mode (B-mode)

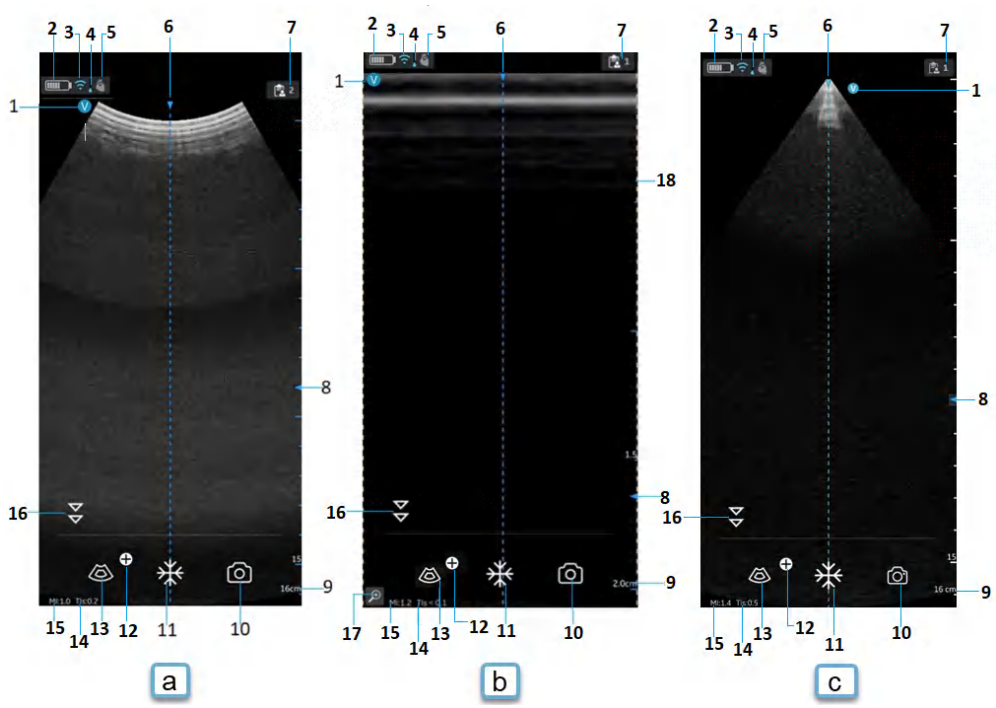


Figure 3-6. Black/white imaging mode (B-mode)

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

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

Accessories

Optional accessories

Power plugs

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

Figure 3-7. International AC Adapter

1. Type C - Europe, Turkey, 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

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	
Vscan Rollstand	

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 probe as described in the section ‘How to charge the Vscan Air probes’ on *page 3-3*

The battery specification is shown in the below table.

Battery specification

Table 3-3: Basic Battery specification

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

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

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

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.

Table 3-4: Battery specification

Item	Specification
Charging time starting at 10%, charging to 90% capacity using a new battery at room temperature 20 to 25 deg C	75 minutes
Capacity	50 minutes continuous scan (see Note)
Lifetime	At least 500 charges

In order to get maximum charging capacity with 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.

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 3-3*

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

Figure 3-8. 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.

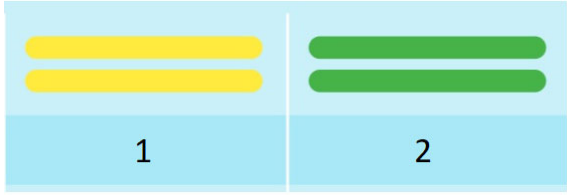
- A **steady purple light** on both LEDs indicates the Vscan Air probe is ON, is occupied and shall not be interrupted. E.g. when running test or upgrading software.

- 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.

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 3-9. LED states when Vscan Air probe is OFF

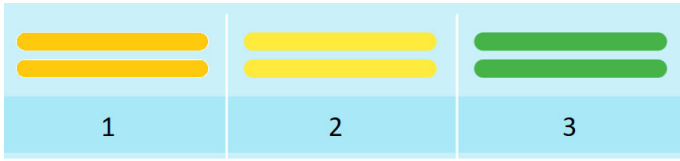
- **No light** indicates a Vscan Air probe charge level in the range <8% and probe will need to charge above 8% to be powered on.

- 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 3-3*‘.



1. Battery level <8%
2. Battery level 8-90%
3. Fully charged

Figure 3-10. 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 memory when starting.

Supported Mobile Platforms

- Operating system options

  - Android phones and tablets with OS version 11, 12 or 13, 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 14, 15 or 16
- Screen requirements

  - Size: from 5 to 20 inches

  - 960 x 640 (or 640 x 960) pixel or more
- Internal memory requirement: 8GB 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 14 Pro Max	iOS 16.0
iPhone 14 Pro	iOS 16.0
iPhone 14 Plus	iOS 16.0
iPhone 14	iOS 16.0
iPhone 13 Pro Max	iOS 15.4
iPhone 13 Pro	iOS 15.0
iPhone 13	iOS 15.0
iPhone 13 mini	iOS 15.0
iPhone 12 Pro Max	iOS 14.2 iOS 15.4
iPhone 12 Pro	iOS 15.0 iOS 14.4
iPhone 12	iOS 15.3 iOS 14.1
iPhone 12 Mini	iOS 15.0 iOS 14.2
iPhone SE 2nd Gen	iOS 14.2
iPhone 11 Pro Max	iOS 14.4
iPhone 11 Pro	iOS 15.0 iOS 14.1
iPhone 11	iOS 14.2
iPhone XR	iOS 14.4

Vscan Air - Compatible Display Devices (continued)

Apple iPads	Operating system
iPad Pro 5th Gen	iPadOS 15 iPadOS 14
iPad Pro 4th Gen	iPadOS 14.4
iPad Mini 6th Gen	iPadOS 15.1
iPad Mini 5th Gen	iPadOS 15.0
iPad 9th Gen	iPadOS 15.1
iPad 8th Gen	iPadOS 15.4 iPadOS 14.6
iPad 7th Gen	iPadOS 14.3
iPad Air 4th Gen	iPadOS 15.4 iPadOS 14.2

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

Samsung Mobiles	Operating system
Samsung Galaxy S22 Ultra	Android 12
Samsung Galaxy S22+	Android 12
Samsung Galaxy S22	Android 12
Samsung Galaxy S21 Ultra (Intl.)	Android 11
Samsung Galaxy S21+ (Intl.)	Android 11
Samsung Galaxy S21 (Intl.)	Android 11
Samsung Galaxy S20 FE 5G (Intl.)	Android 11
Samsung Galaxy S20 (Intl.)	Android 11
Samsung Galaxy S10+ (Intl.)	Android 11
Samsung Galaxy S10 (Intl.)	Android 11
Samsung Galaxy A51 (Intl.)	Android 11
Samsung Galaxy A32	Android 11

Vscan Air - Compatible Display Devices (continued)

Samsung Tablets	Operating system
Samsung Galaxy Tab S8 Ultra 5G	Android 12
Samsung Galaxy Tab S8+ 5G	Android 12
Samsung Galaxy Tab S8 5G	Android 12
Samsung Galaxy Tab S6	Android 11
Samsung Galaxy Tab S7	Android 11
Samsung Galaxy Tab Active 3	Android 11

Google Mobiles	Operating system
Google Pixel 6	Android 12
Google Pixel 5	Android 12
Google Pixel 3	Android 12

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 not recommended to upgrade your device OS to a major release not listed for your device.

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

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 grey are discernible.

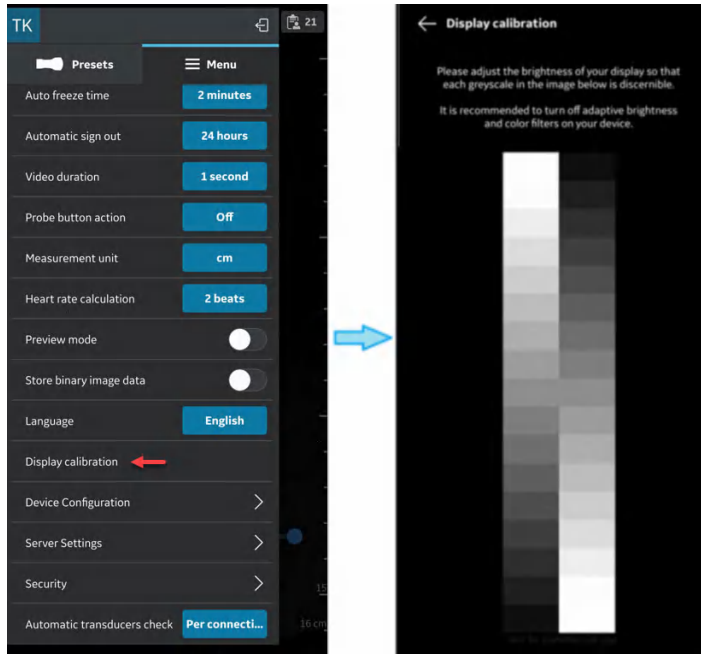


Figure 3-11. Display calibration

NOTE: There are example reference images available in the '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.

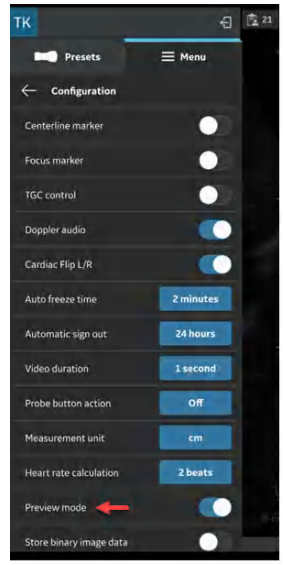


Figure 3-12. Screen with preview mode

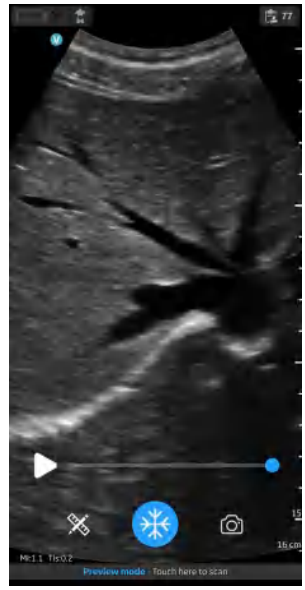


Figure 3-13. Abdominal preset with curved

Display device image quality verification (continued)

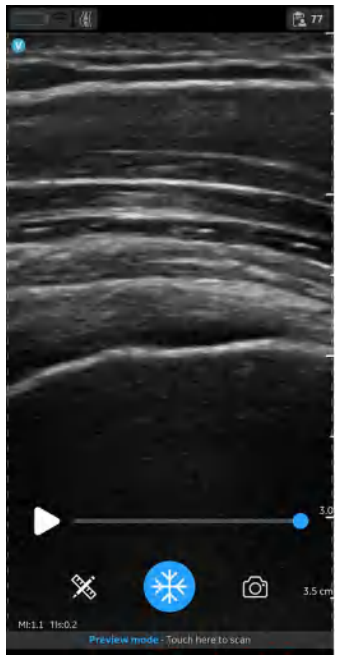


Figure 3-14. MSK preset with linear

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

Power ON/OFF

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 3-3*

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.

Vscan Air App Version

App Version/Revision	
Version	2.0
Revision	2.0.5.19114

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.

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. Press **Register** to start registration

Figure 3-15. Start registration

Create a Vscan Air account (continued)

NOTE: The Vscan Air app can be explored by selecting "Preview". In this mode, scanning is disabled.

3. Select "**Create new account**".

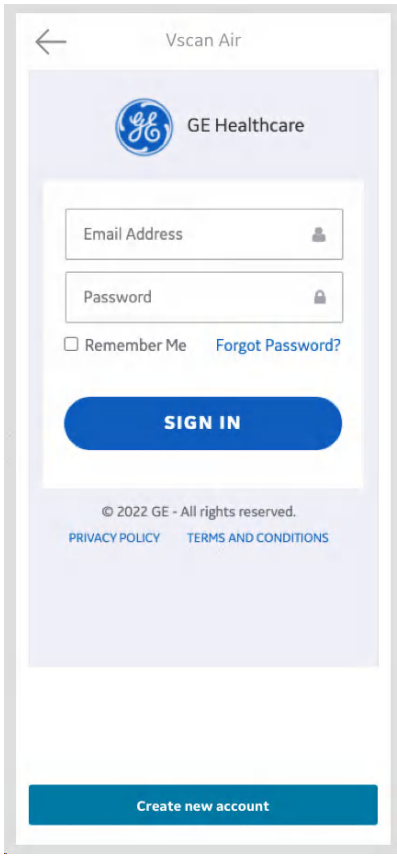


Figure 3-16. Register the Vscan Air app

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.

NOTE: Before the app is registered, an option for SSO based sign in for GE Healthcare employees will be visible. Once a customer has registered the app on their mobile device, this option will no longer be available.

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.

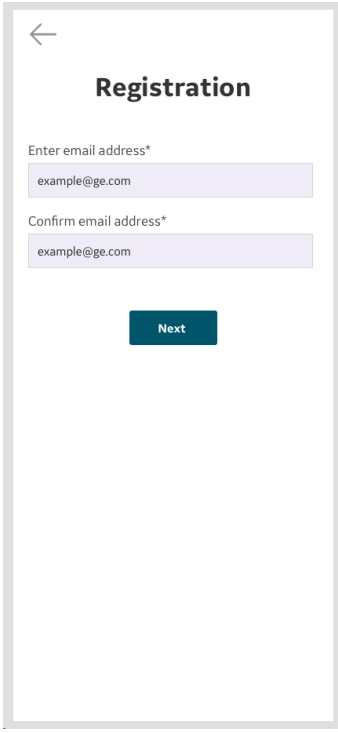


Figure 3-17. Confirm email address

Create a Vscan Air account (continued)

4. **Turn on** Vscan Air probe.

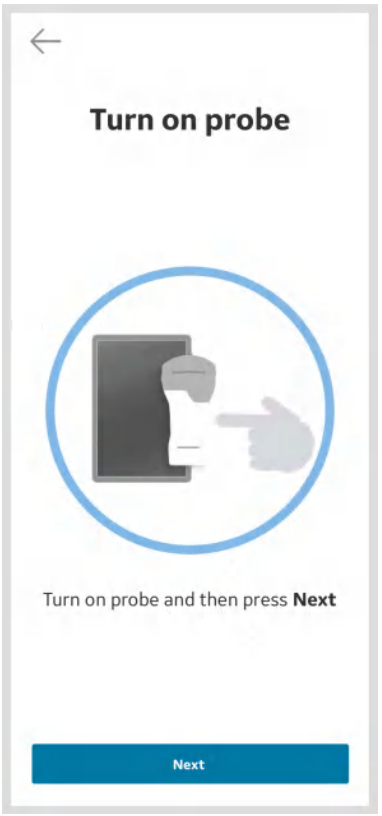


Figure 3-18. Search for Vscan Air probe

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)

5. Wait for initialization of Vscan Air probe.

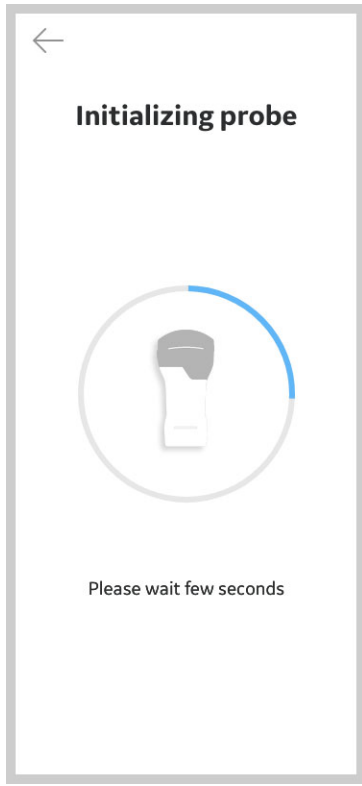


Figure 3-19. Initialization of Vscan Air probe

Create a Vscan Air account (continued)

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

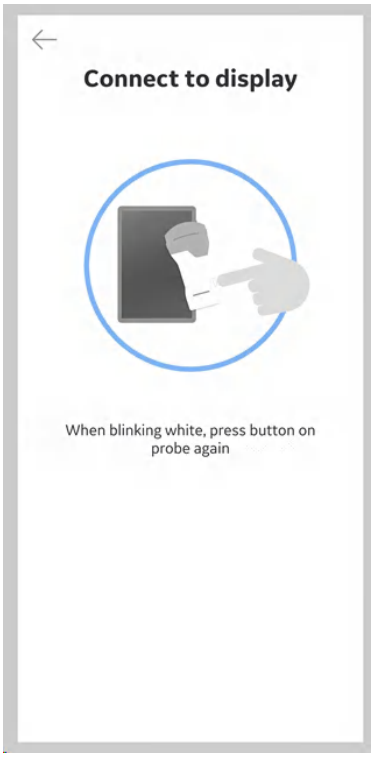


Figure 3-20. Connect to display

Create a Vscan Air account (continued)

7. Once Vscan Air probe is found, select “**Continue registration**”.

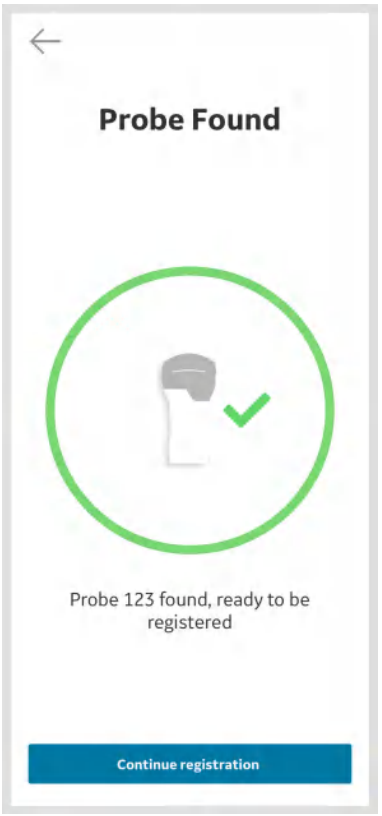


Figure 3-21. Vscan Air probe detected

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

Create a Vscan Air account (continued)

10. 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.
11. Press **Submit**.

Figure 3-22. Registration submission

*NOTE: The password must be at 8-30 characters long and should contain at least one letter, one number and one special character. The supported special characters are: ! " # $ % & ' ( ) * + , - . / : ; < = > ? @ [\ ] ^ _ ` { | } ~.*

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

Create a Vscan Air account (continued)

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

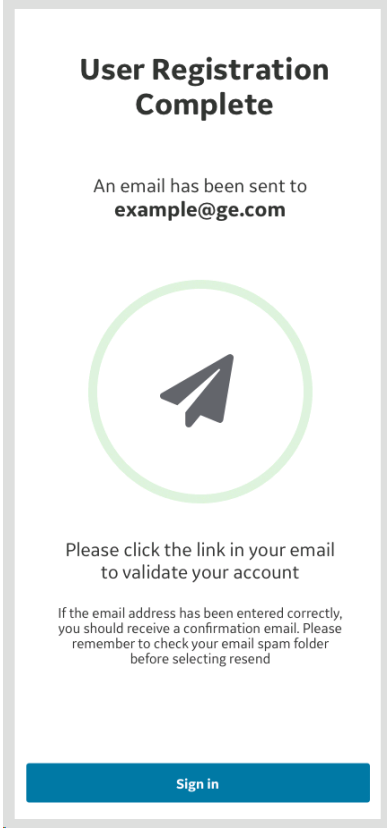


Figure 3-23. Confirm email

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

Create a Vscan Air account (continued)

13. The following activation email will be sent to the registered email.

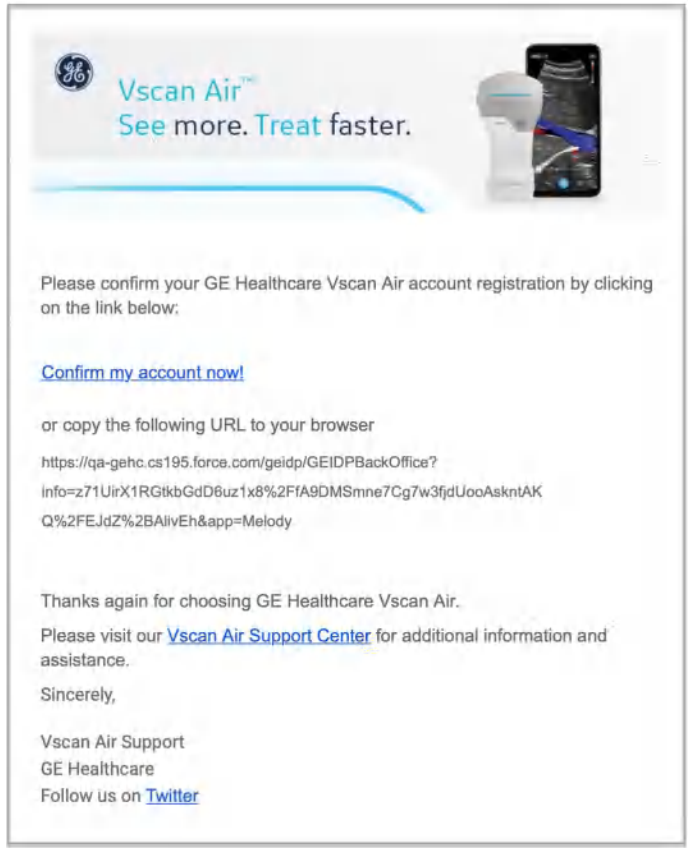


Figure 3-24. Email message

NOTE: Email shows example URL.

Create a Vscan Air account (continued)

14. Click the link in the email to validate the Vscan Air user account.
15. The account is activated. Sign into the new account.

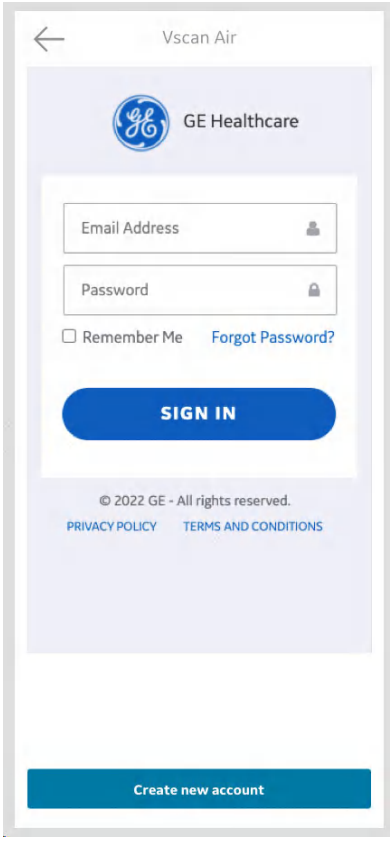


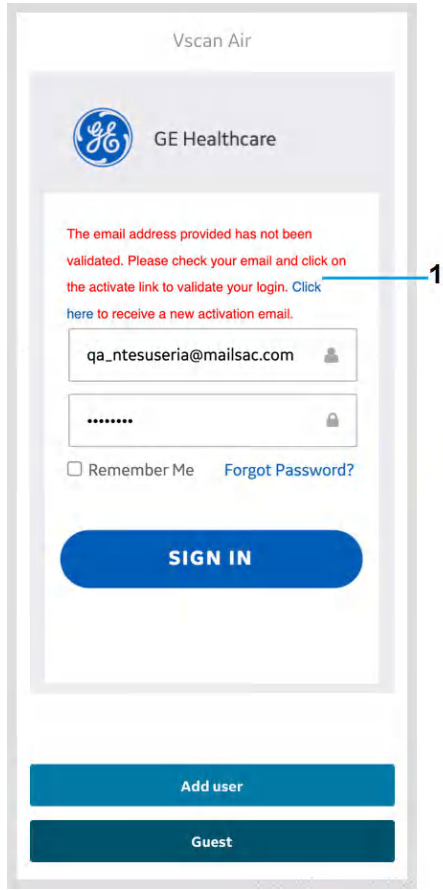
Figure 3-25. Sign in to the account

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)

16. 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 3-26. Resending activation mail

Create a Vscan Air account (continued)

17. Once email is validated, the app screen will show registration details. Click **Confirm** to proceed.

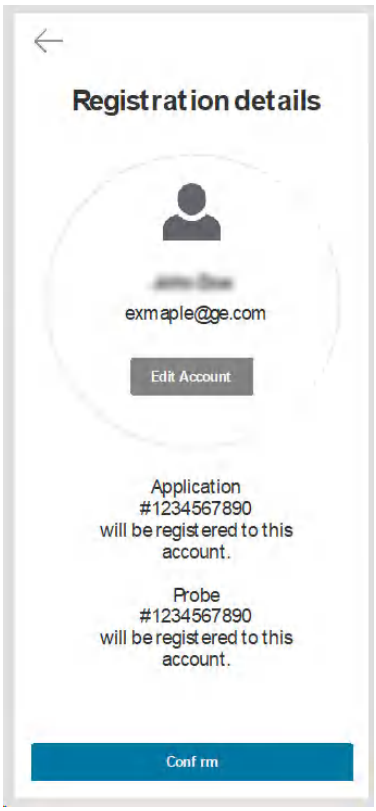


Figure 3-27. Confirm registration details

Create a Vscan Air account (continued)

18. 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**'.

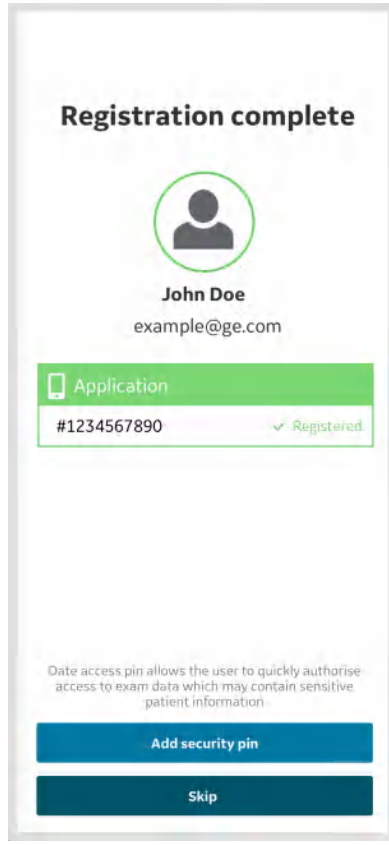


Figure 3-28. Registration complete

Create a Vscan Air account (continued)

19. To add a security PIN code after completing Vscan Air registration, see ‘Ask for data access PIN’ on *page 4-41* for more information.
20. The Vscan Air probe is now connected to the app.

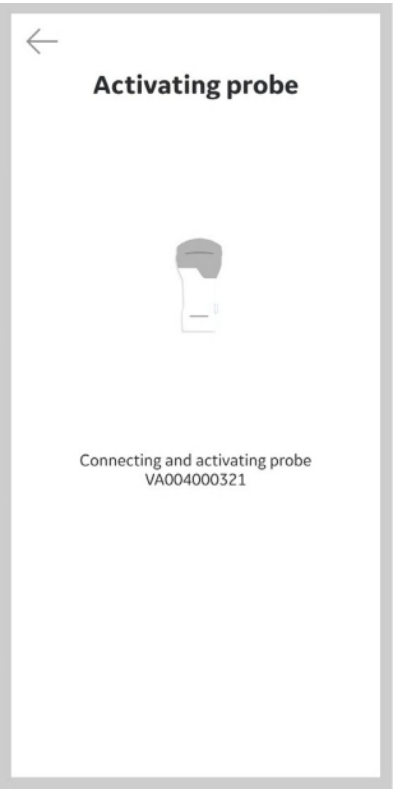


Figure 3-29. Vscan Air probe activation

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'.

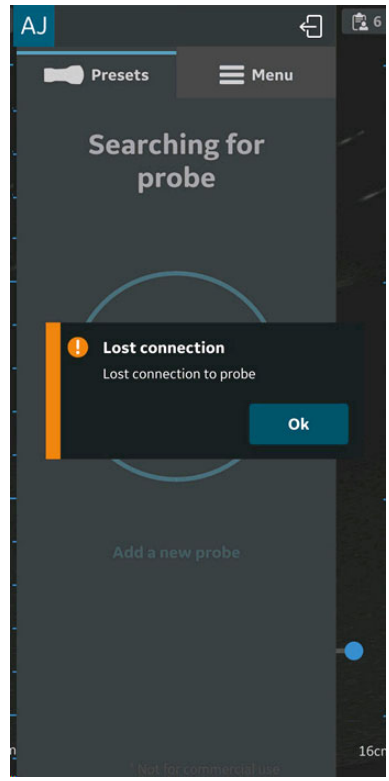


Figure 3-30. Vscan Air probe Connection Lost

New 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 3-31. Welcome screen

NOTE: The app can be explored by selecting 'Preview'. In this mode, scanning is disabled.

New Vscan Air app registration using an existing account (continued)

2. Enter the email address and password for your existing Vscan Air account.

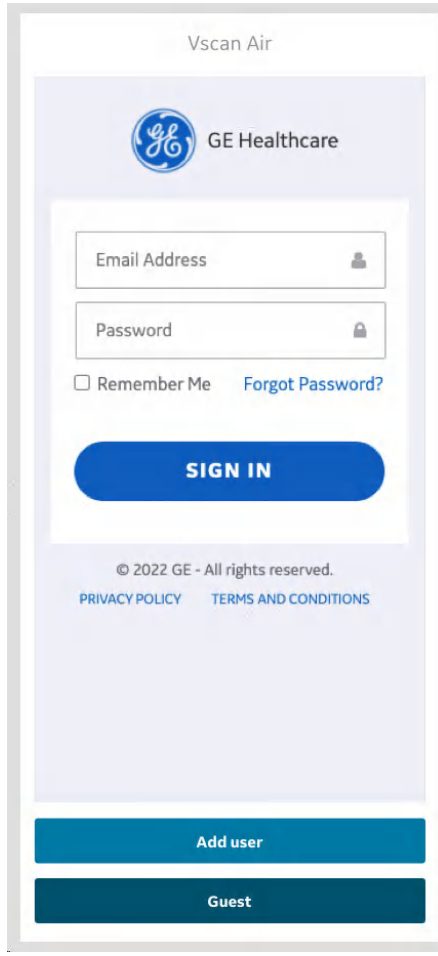


Figure 3-32. Sign in to the Vscan Air account

New Vscan Air app registration using an existing account (continued)

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

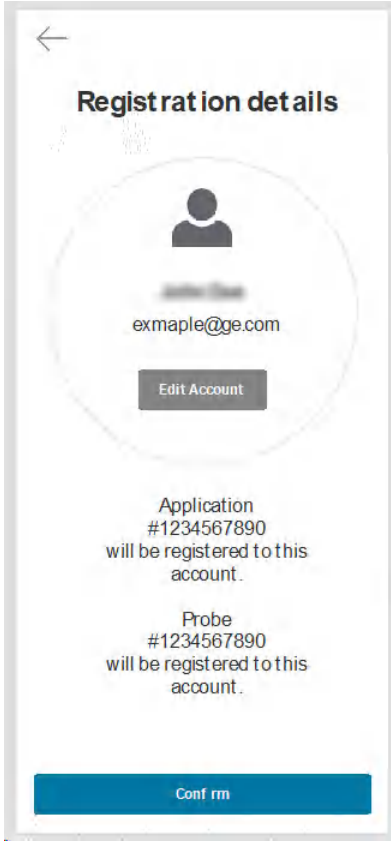


Figure 3-33. Confirm registration

New Vscan Air app registration using an existing account (continued)

4. On confirmation the registration completion screen is displayed.

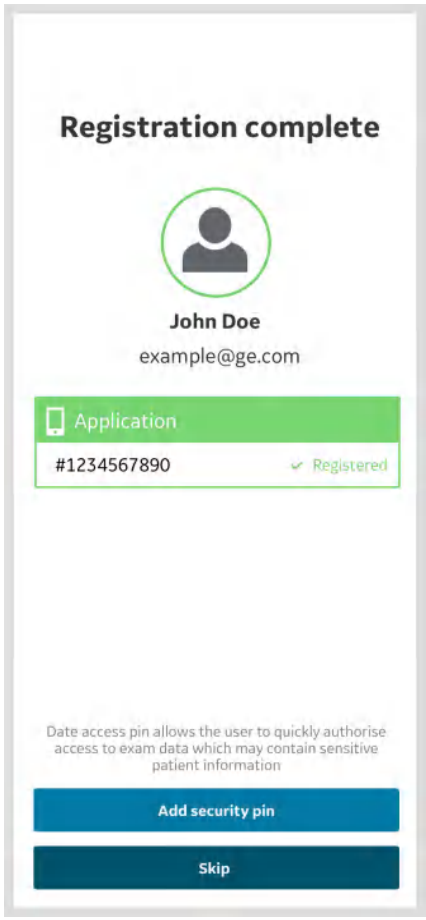


Figure 3-34. Registration complete

New 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 3-61*), where all the fields needed for device registration are not captured, then the registration screen will be displayed to update the remaining mandatory fields.

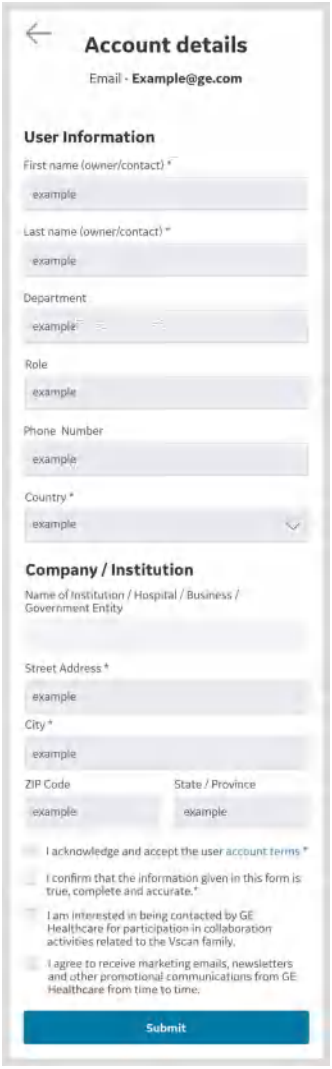


Figure 3-35. Registration with user information

New Vscan Air probe registration using existing account

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

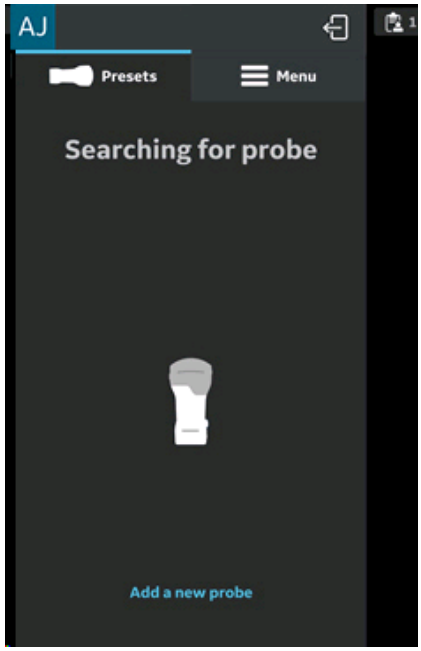


Figure 3-36. Search for Vscan Air probe

New Vscan Air probe registration using existing account (continued)

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

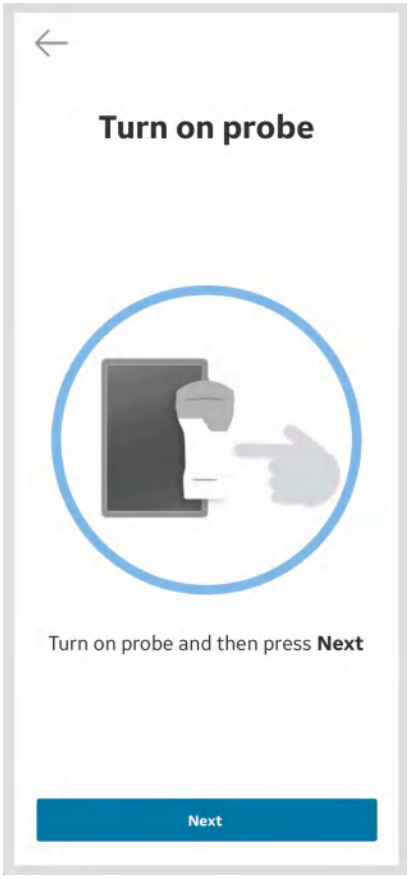


Figure 3-37. Turn On Vscan Air probe

New Vscan Air probe registration using existing account (continued)

4. Wait for initialization of Vscan Air probe.

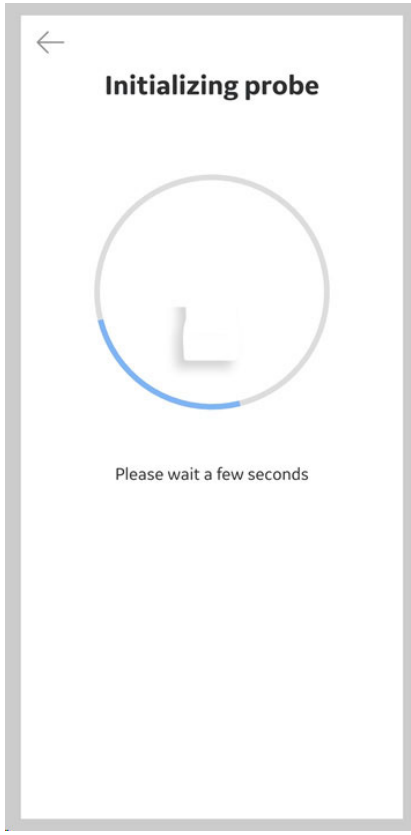


Figure 3-38. Initialization of Vscan Air probe

New Vscan Air probe registration using existing account (continued)

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

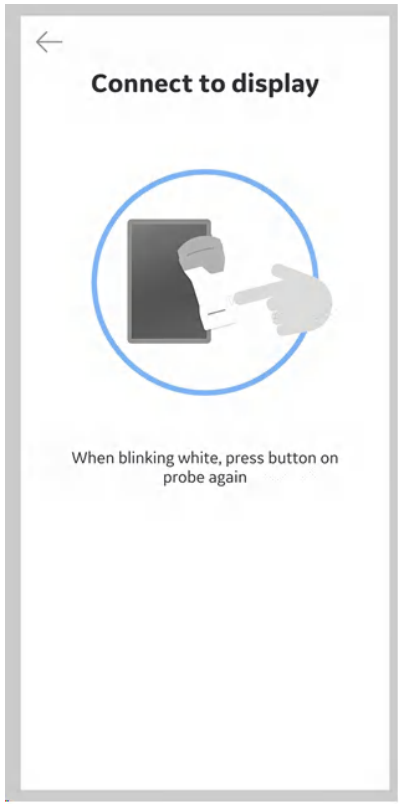


Figure 3-39. Connect to display

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

New 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.

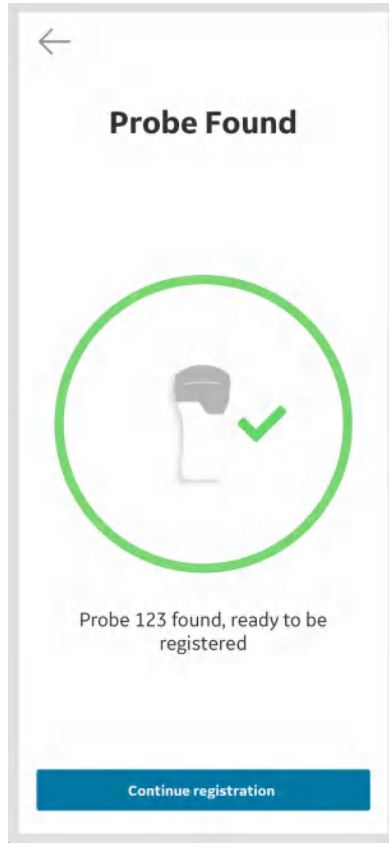


Figure 3-40. Vscan Air probe detected

New Vscan Air probe registration using existing account (continued)

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

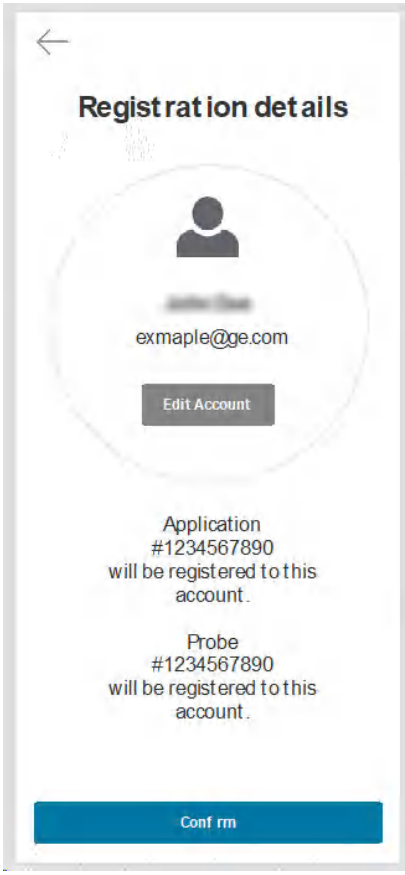


Figure 3-41. Confirm registration

New Vscan Air probe registration using existing account (continued)

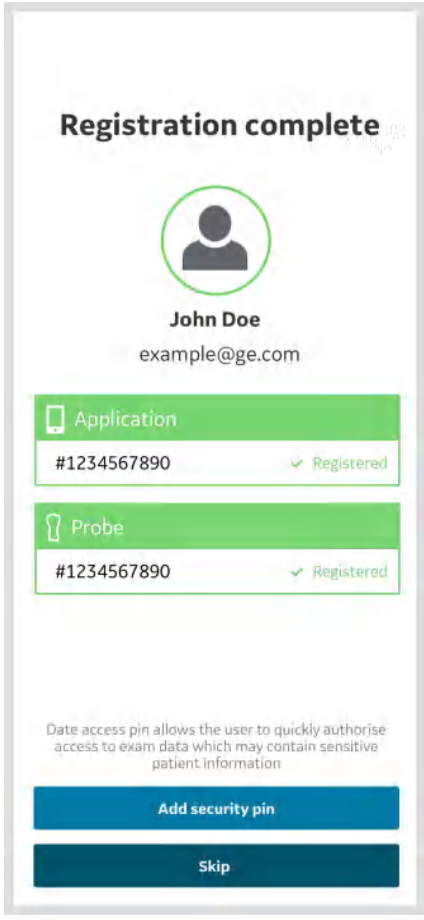


Figure 3-42. Registration complete

New Vscan Air probe registration using existing account (continued)

8. Registration is complete.

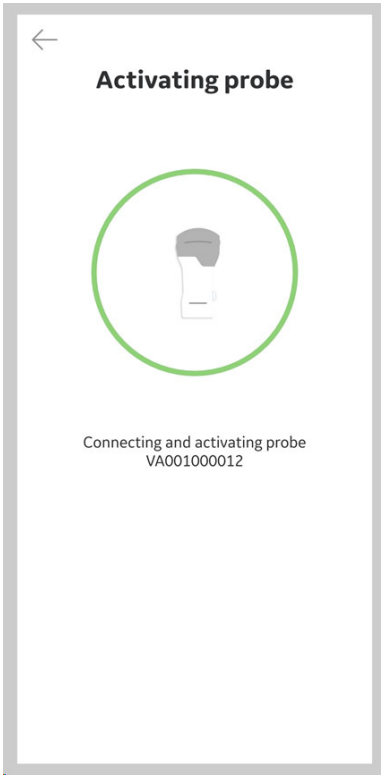


Figure 3-43. Vscan Air probe activation

New 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*".

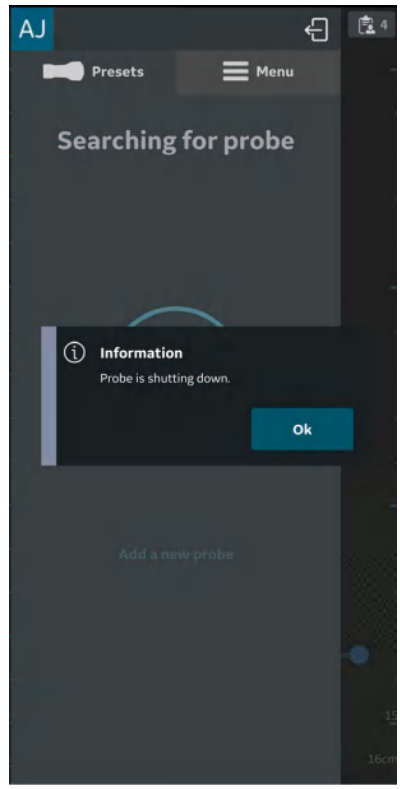


Figure 3-44. Probe shutting down

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.

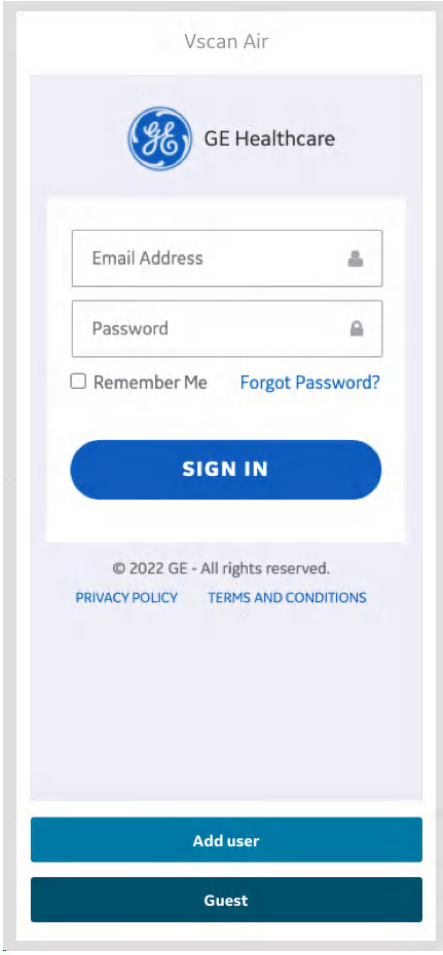


Figure 3-45. Add new user

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.

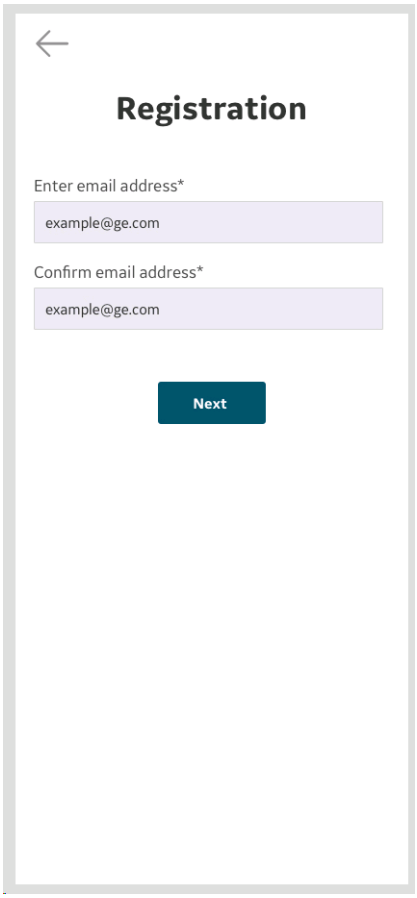


Figure 3-46. User registration

Adding users (continued)

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

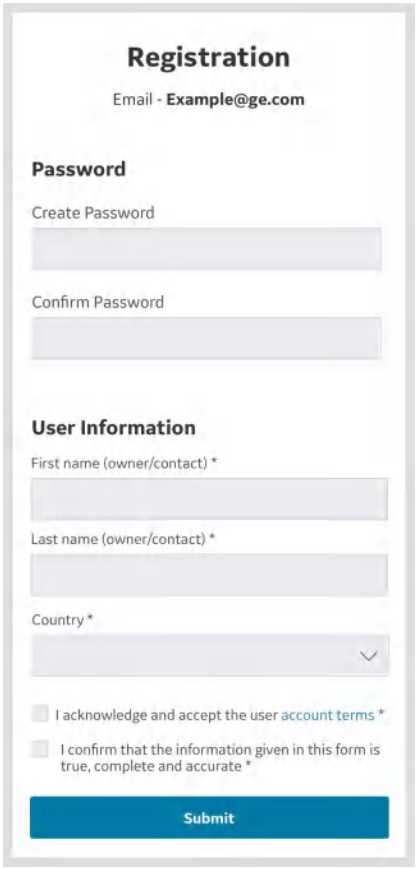


Figure 3-47. User registration

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.

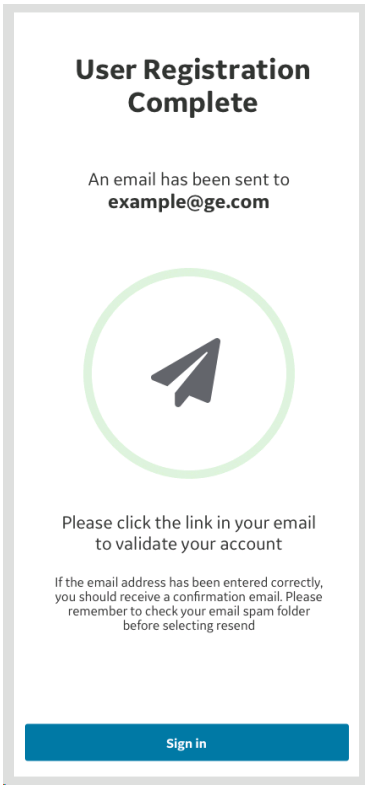


Figure 3-48. Email validation

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: 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.

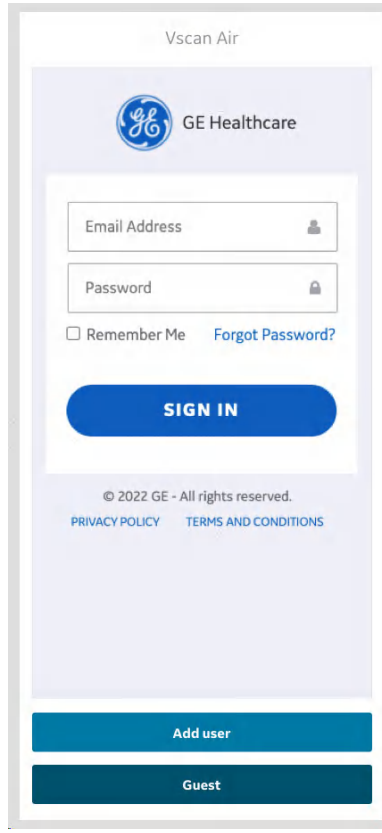


Figure 3-49. Scan as Guest

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.

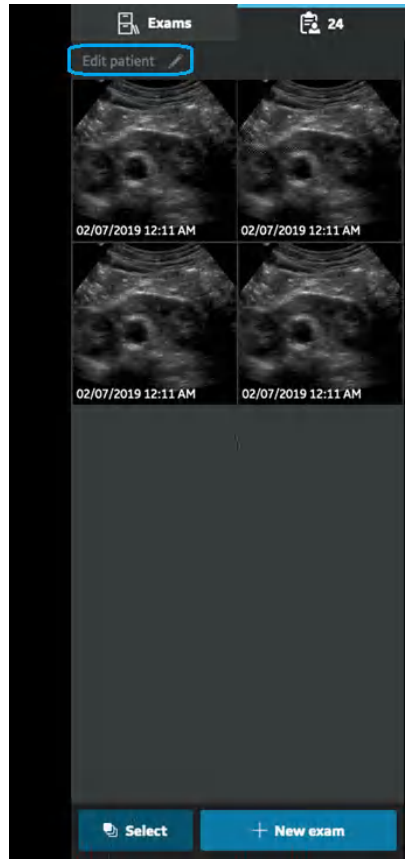
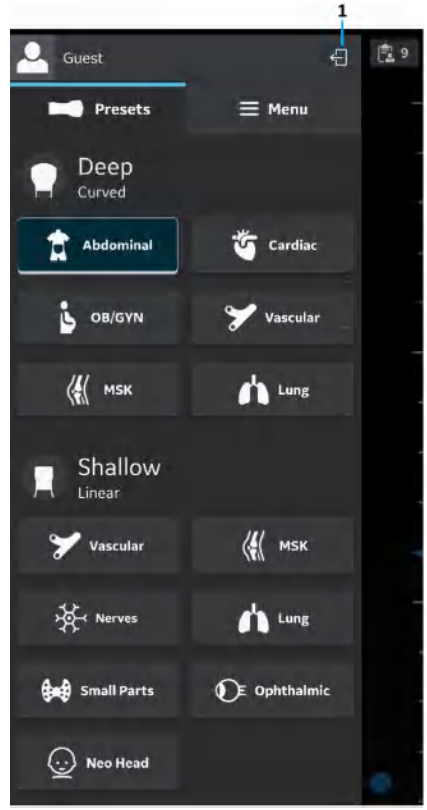


Figure 3-50. Current exam review screen

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 3-51. 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.

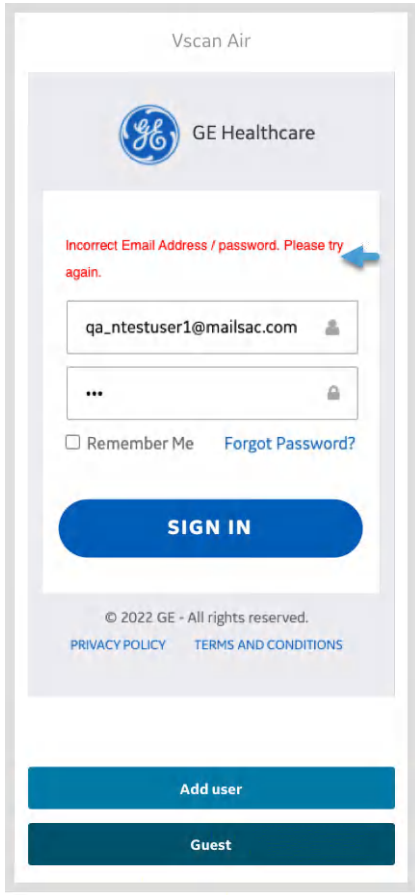
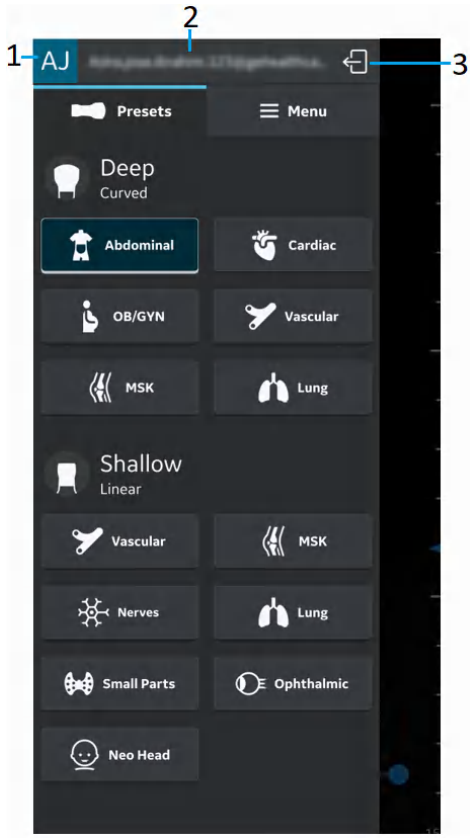


Figure 3-52. Incorrect credentials

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 3-53. Signed in user, displayed in the top of the left panel

User sign in / sign out (continued)

5. User will be taken back to the sign in screen on successful sign out.

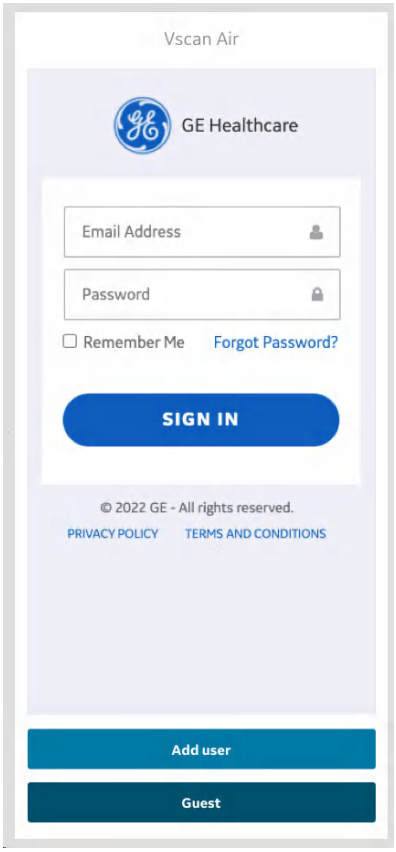


Figure 3-54. Sign in screen

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.

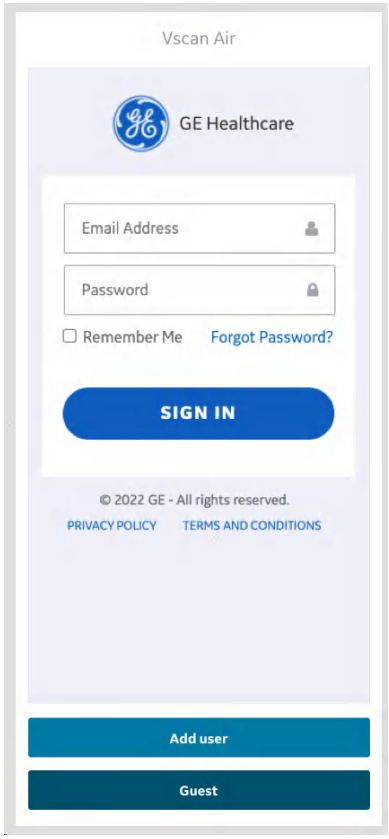


Figure 3-55. Sign in screen

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.

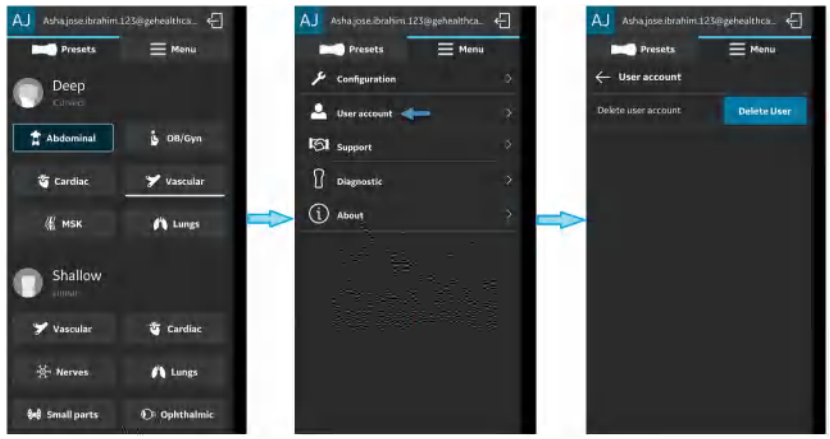


Figure 3-56. Delete user account

4. When clicking the delete user option, it will facilitate the delete user account workflow.

NOTE: 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.

NOTE: In the process of user account deletion, user will be prompted to unregister all the devices owned/registered/activated.

NOTE: 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 tools).

Multi 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. We 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

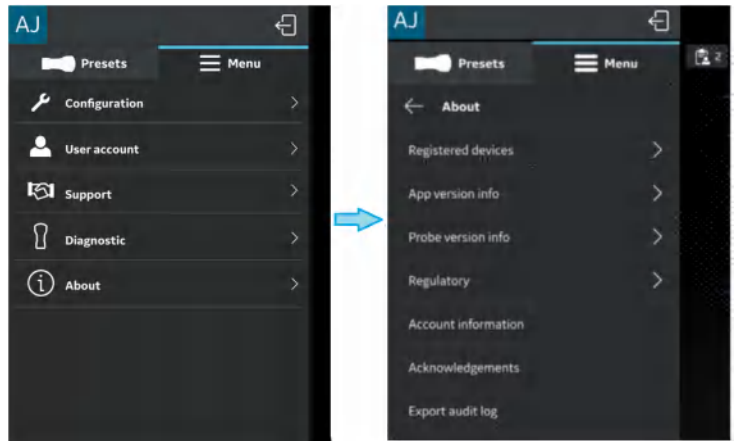


Figure 3-57. Registered devices

2. Press **Unregister** button on “Connected probe” tab on Registered devices screen to Unregister Vscan Air Probe.

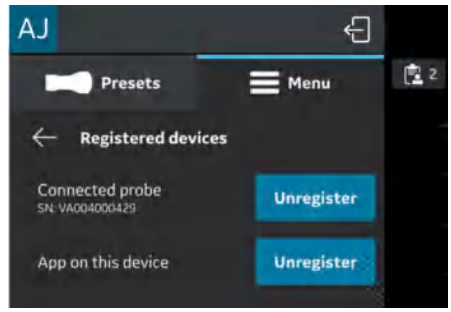


Figure 3-58. Unregister probe

Unregister Vscan Air Probe (continued)

3. After selecting **Unregister** button, the below message appear.

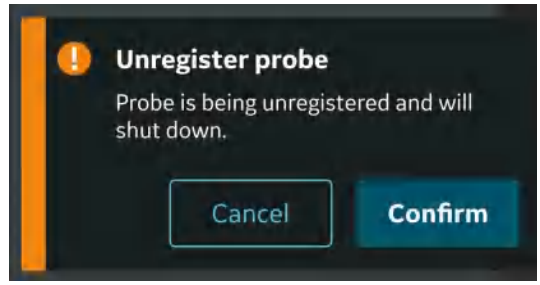


Figure 3-59. Unregister app warning

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.

Unregister Vscan Air app

To Unregister Vscan Air app, follow the procedure below:

1. Press Menu -> About -> Registered devices

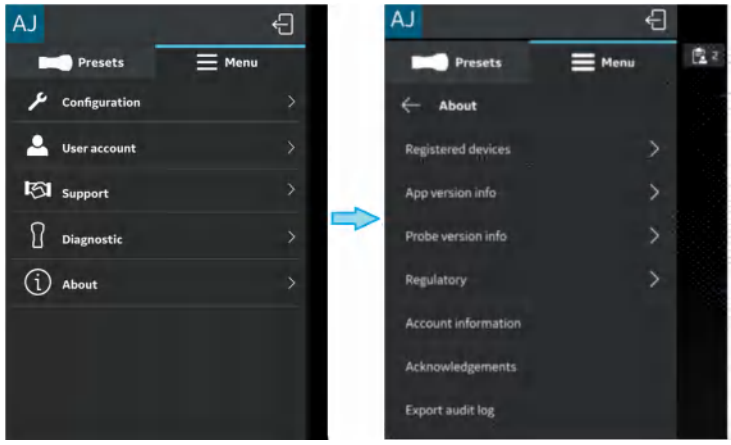


Figure 3-60. Registered devices

2. Press **Unregister** button on “App on this device” tab on Registered devices screen to Unregister Vscan Air app.

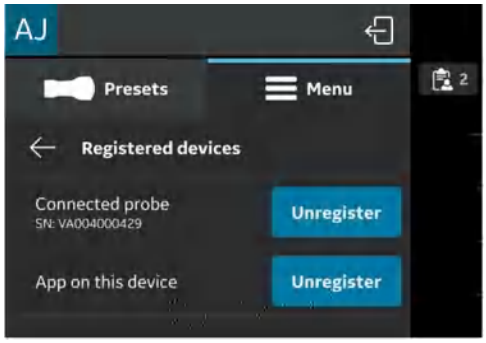


Figure 3-61. Unregister app

Unregister Vscan Air app (continued)

3. After selecting Unregister button, the below message appears. Press **Proceed** button after reading the message..

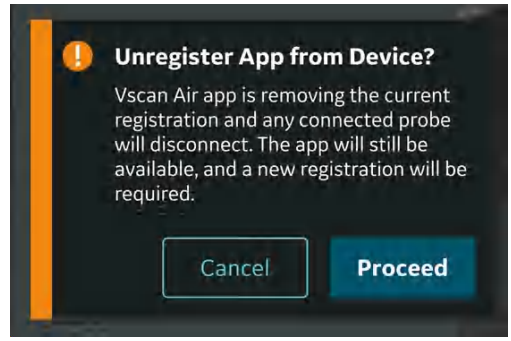


Figure 3-62. Unregister app warning

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.

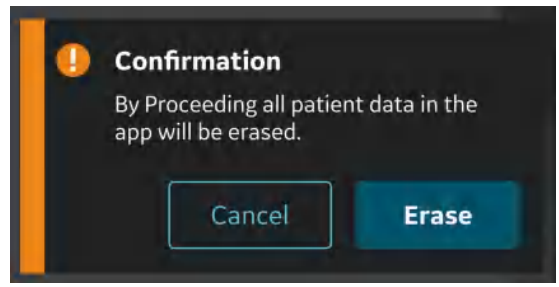


Figure 3-63. Erase data

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.

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 4-48*
3. ‘Support’ on *page 4-49*
4. ‘Diagnostics’ on *page 4-52*
5. ‘About’ on *page 4-54*

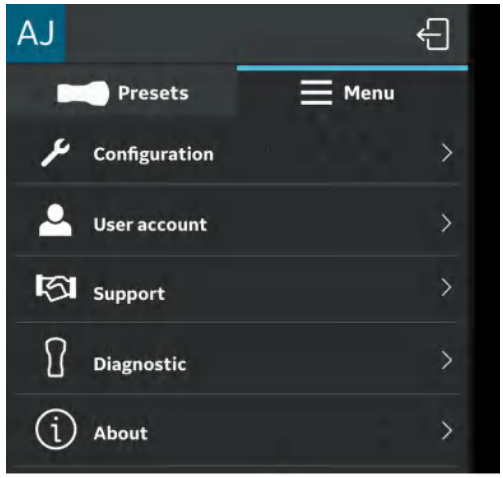


Figure 4-1. Menu

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 configration, Server settings, Security and* Automatic transducers check.

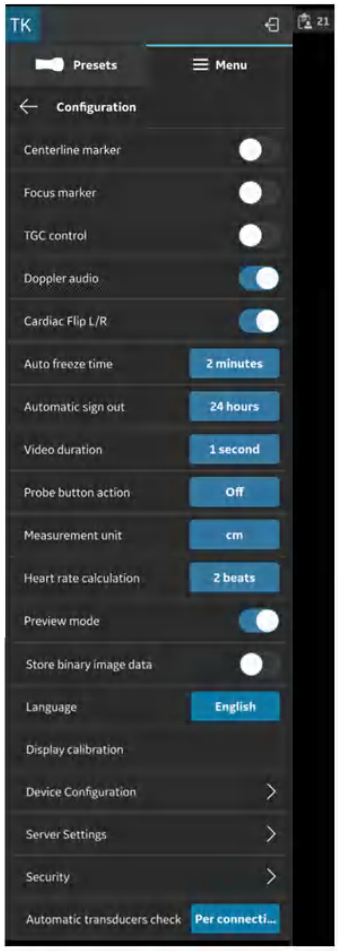


Figure 4-2. Configuration

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.

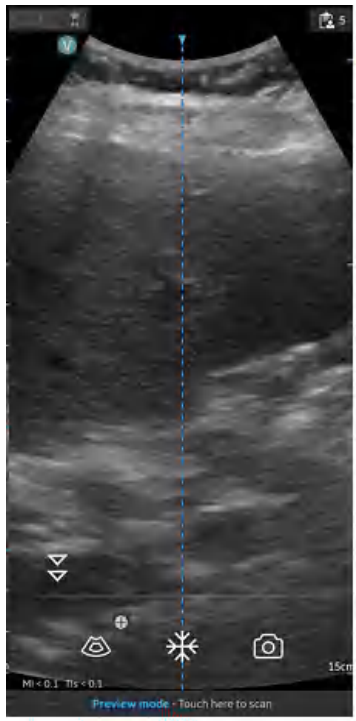


Figure 4-3. Centerline marker

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.

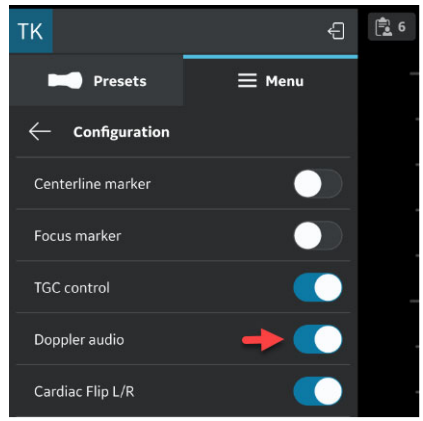


Figure 4-4. Doppler audio

NOTE: Check the display device audio settings if Doppler audio is enabled via the Vscan Air app configuration settings and there is no audio output. Make sure that the audio volume is set sufficiently high.

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.

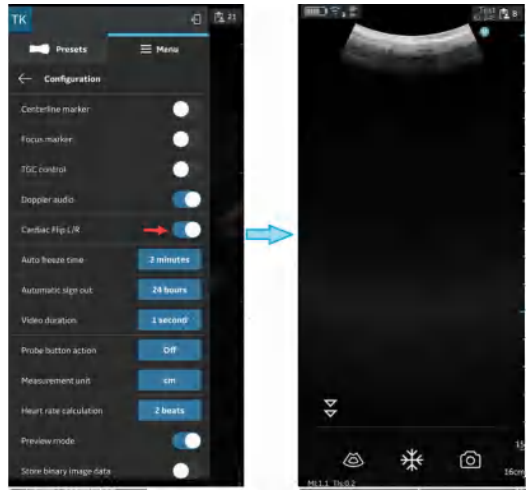


Figure 4-5. CLA-Cardiac (flip)

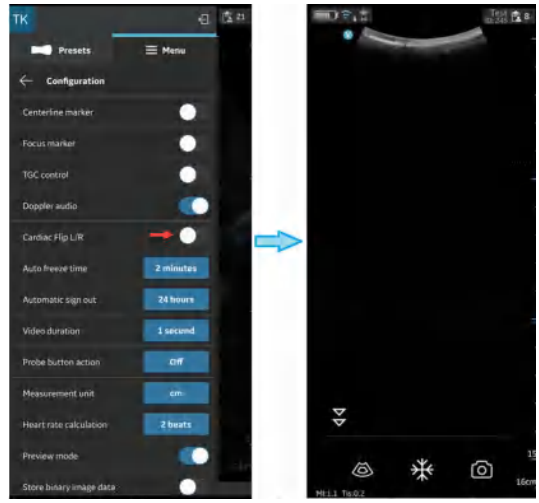


Figure 4-6. CLA-Cardiac (no flip)

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.

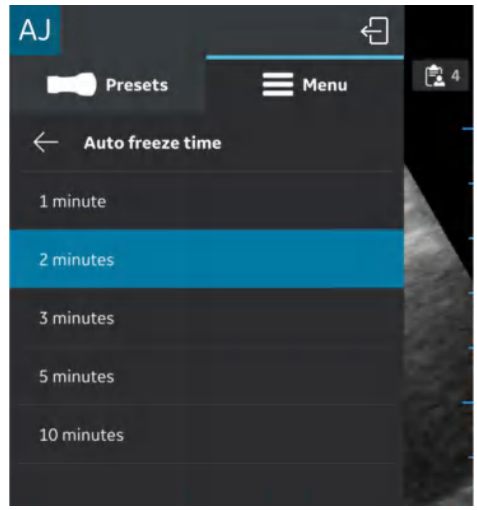


Figure 4-7. Auto freeze time

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.

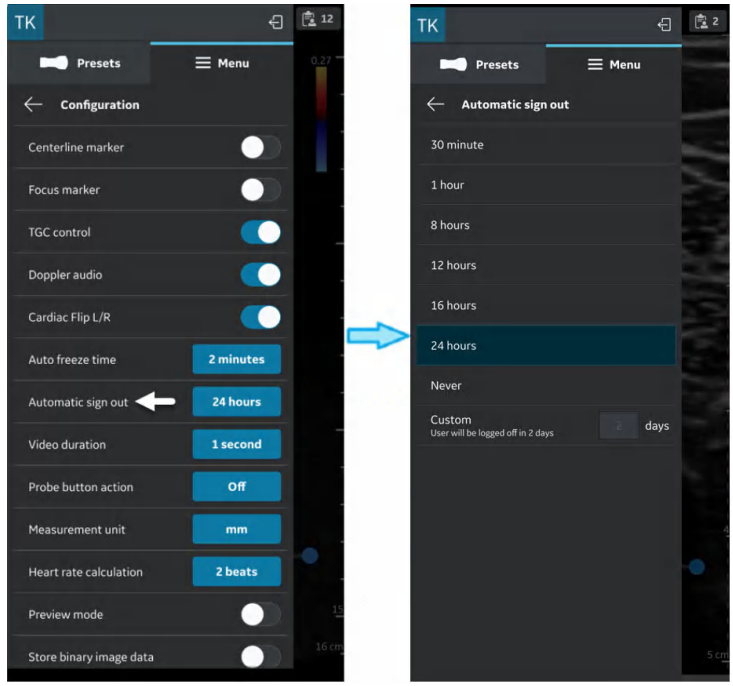


Figure 4-8. Automatic sign out

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.

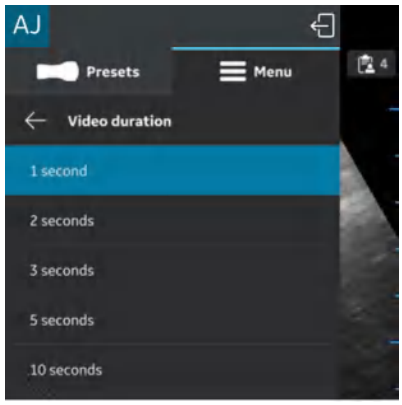


Figure 4-9. Video duration

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.

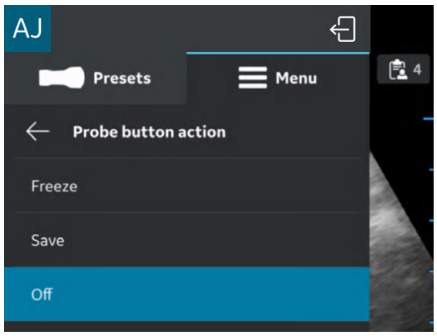


Figure 4-10. Probe button action

Configuration (continued)

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

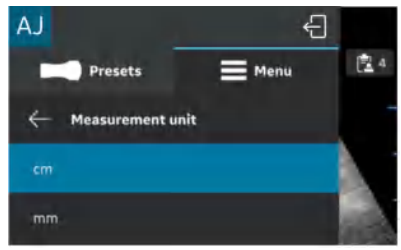


Figure 4-11. Measurement unit

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

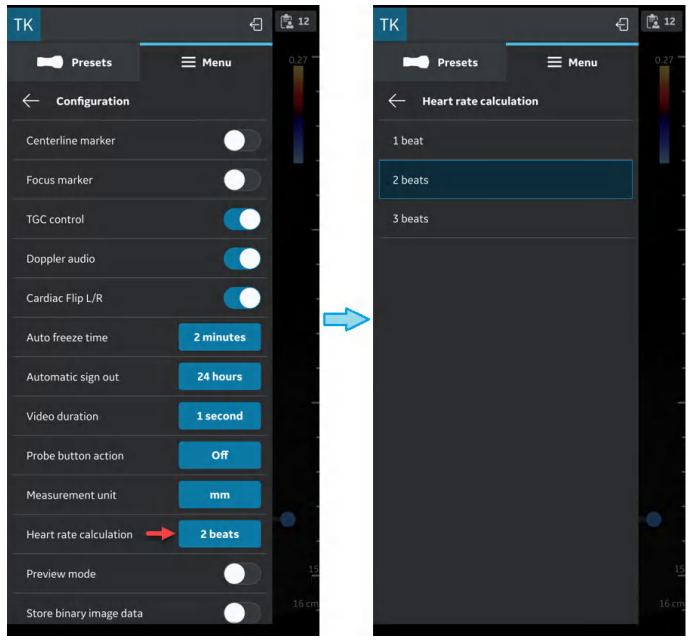


Figure 4-12. Heart rate calculation

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.

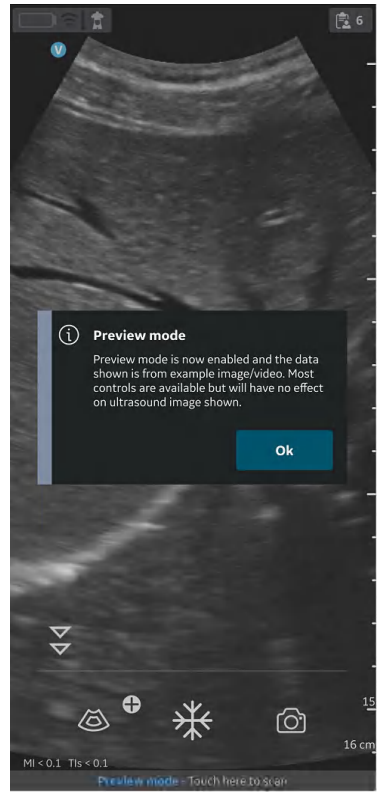


Figure 4-13. Preview mode pop-up

Configuration (continued)

13. **Store binary image data** (see ‘Configuration’ on *page 4-3*) - Tap the **ON/OFF** toggle switch to turn ON or OFF the binary image data. When turned ON, a pop-up message displays - “Binary image data storage is now enabled and unprocessed data will be stored together with video clips. This uses some additional storage space. Binary image data is useful for research and development in collaboration with GEHC.

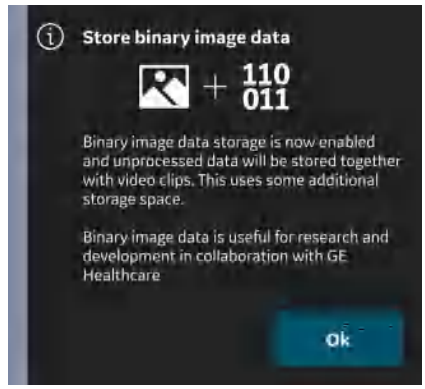


Figure 4-14. Binary image data store pop-up

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

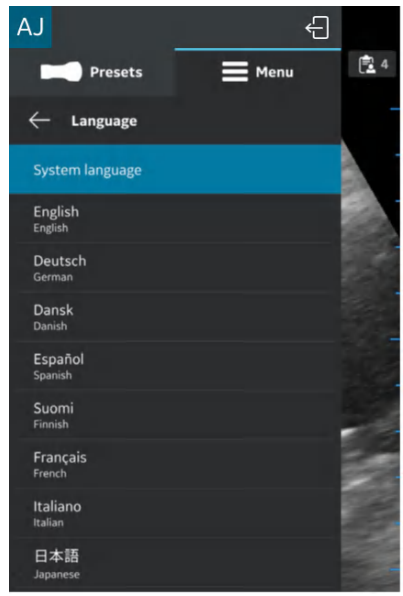


Figure 4-15. Language

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.

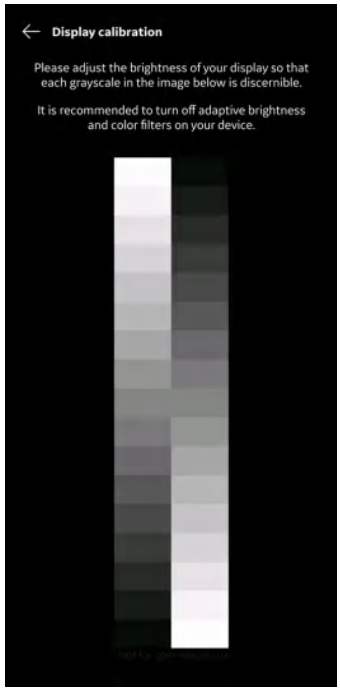


Figure 4-16. Display calibration

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.

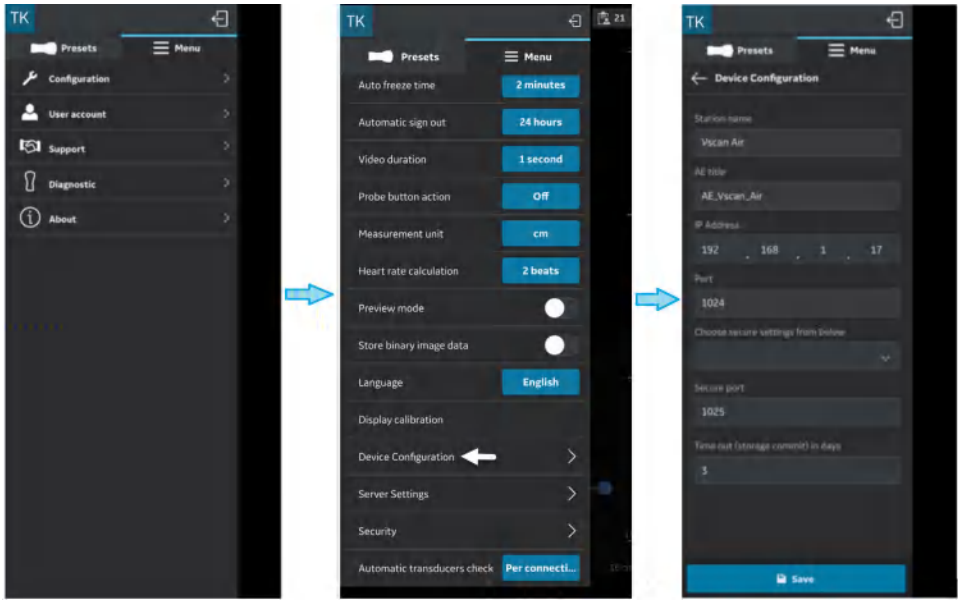


Figure 4-17. Device configuration

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.
    - **DICOM Image Server** - Remote store location for videos/images.
    - **Network Shared Folder** - Share images/videos to a shared folder on a PC.
    - **DICOM Web Server** - Exports data to a cloud based/ remote server using the DICOM Web protocol.

Configuration (continued)

18. **Security** (see ‘Configuration’ on *page 4-3*) - Choose for protecting exam and patient information, refer ‘Security’ on *page 4-40*.

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.

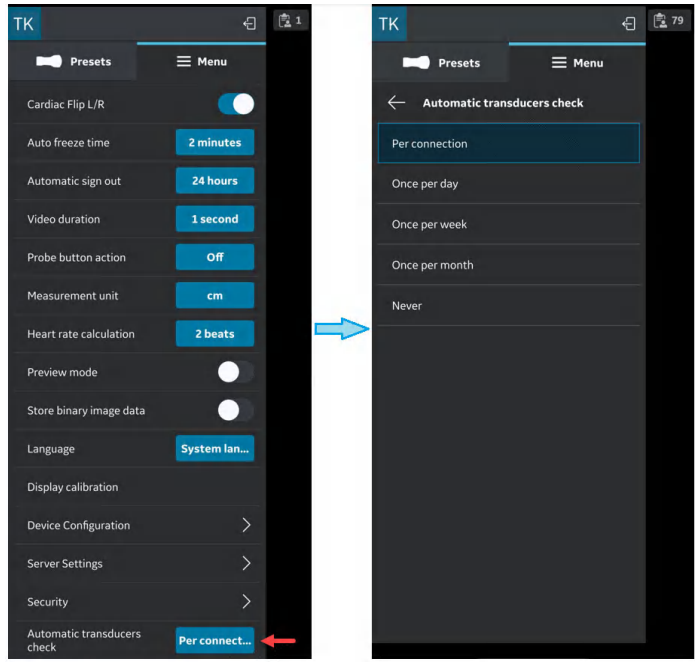


Figure 4-18. Automatic transducers check

Configure Modality Worklist Server

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

1. Press Menu -> Configuration -> Server Settings.

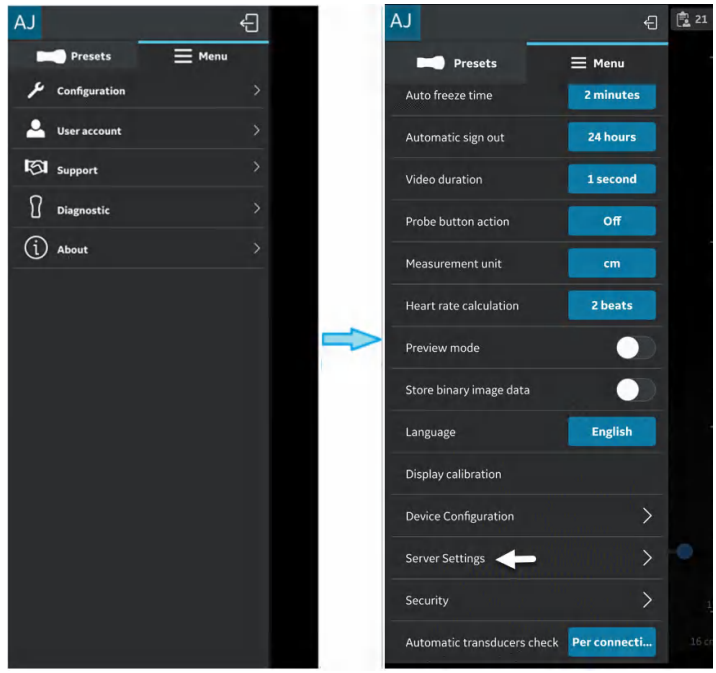


Figure 4-19. Server Settings

Configure Modality Worklist Server (continued)

2. Press **Add Server** in “Server Settings” screen.

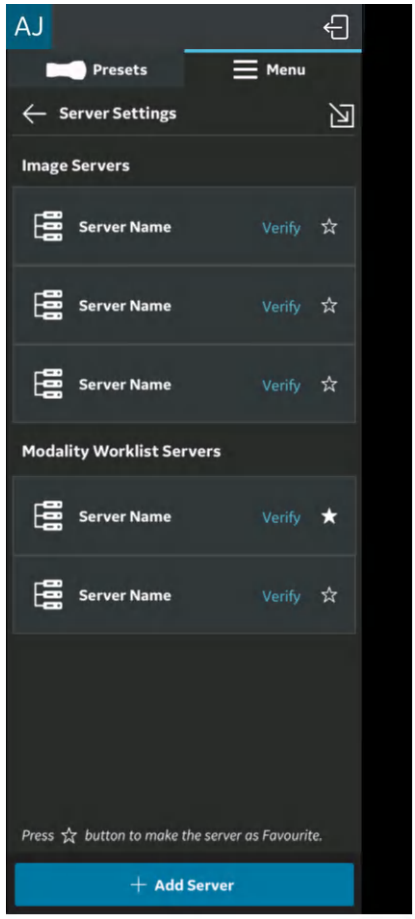


Figure 4-20. Add Server

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 5-110* for more information.

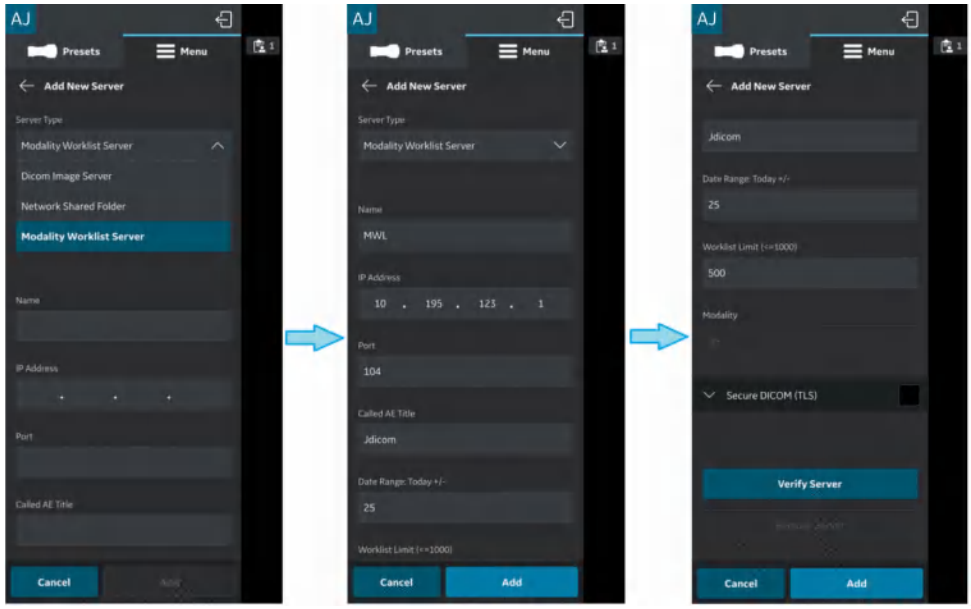


Figure 4-21. Enter configuration information.

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.

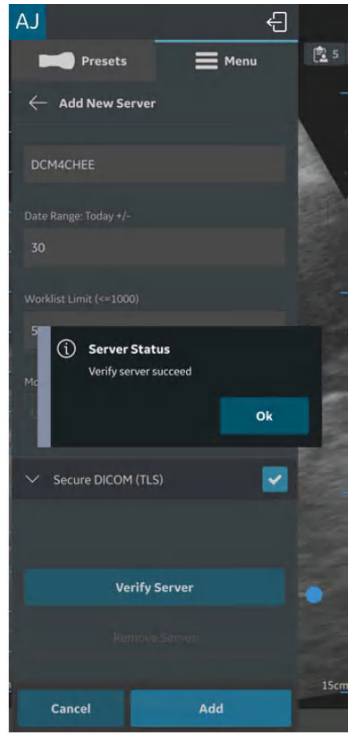


Figure 4-22. Verify server

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 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.

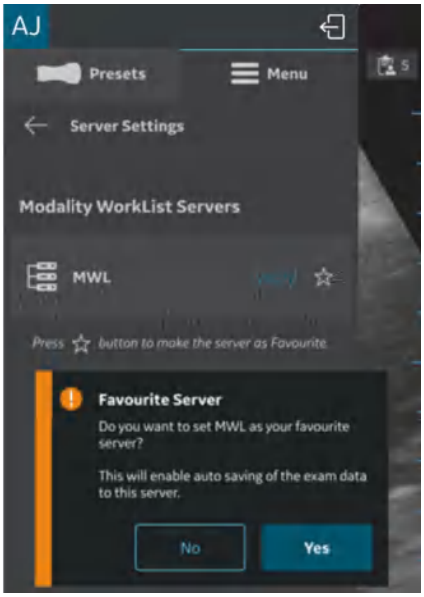


Figure 4-23. Worklist server as Favourite

Configure DICOM Image Server

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

1. Press Menu -> Configuration -> Server Settings.

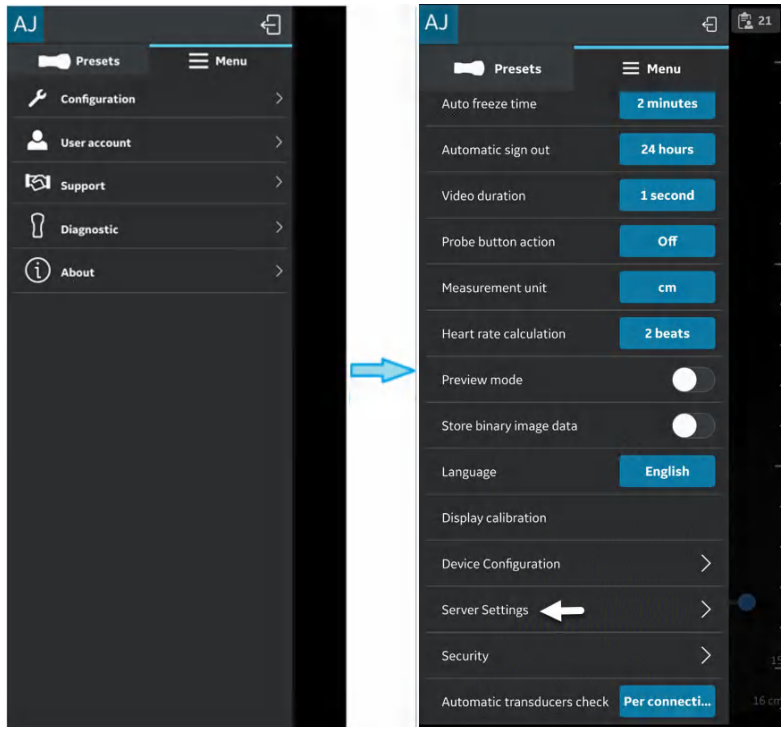


Figure 4-24. Server Settings

Configure DICOM Image Server (continued)

2. Press **Add Server** on the “Server Settings” screen.

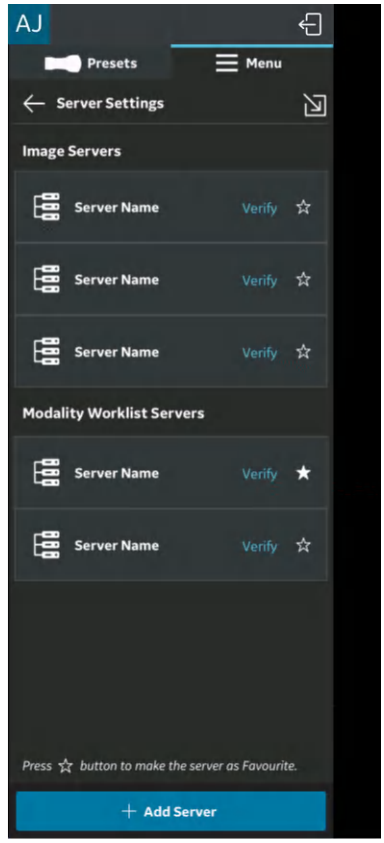


Figure 4-25. Add Server

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 5-110* for more information.

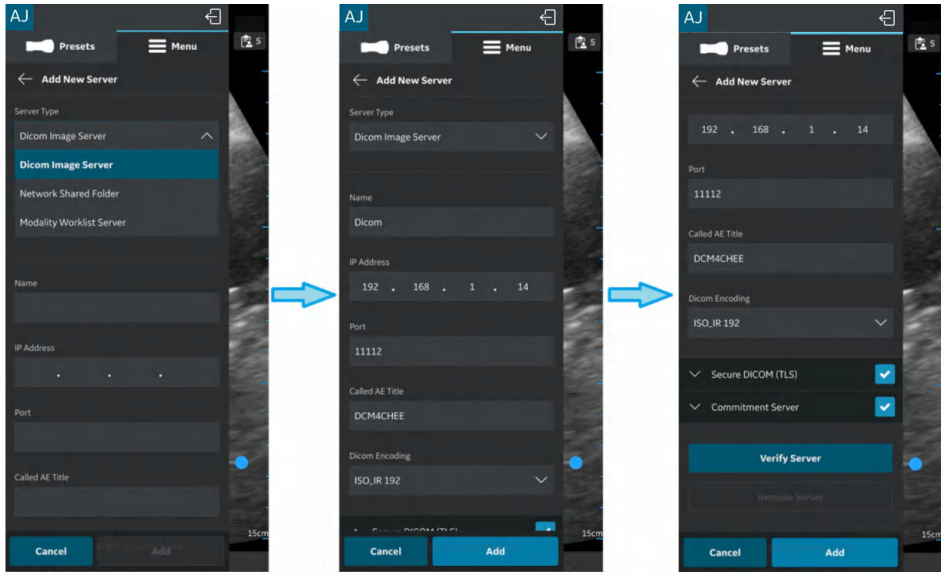


Figure 4-26. Enter Configuration Information

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.

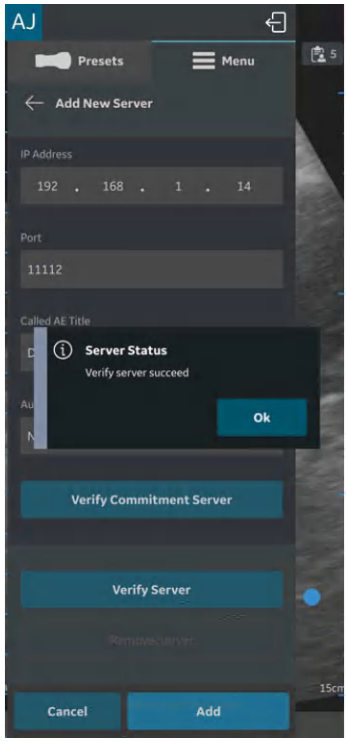


Figure 4-27. DICOM Image Server

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 favourite server. To set DICOM Image Server as favourite, tap on the respective star mark and press **YES** on the pop-up message screen.

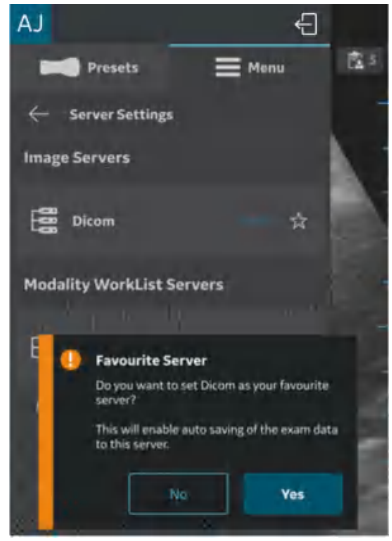


Figure 4-28. Select DICOM Image server as favourite

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.

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 4-22* 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.

Configure Network Shared Folder

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

1. Press Menu -> Configuration -> Server Settings.

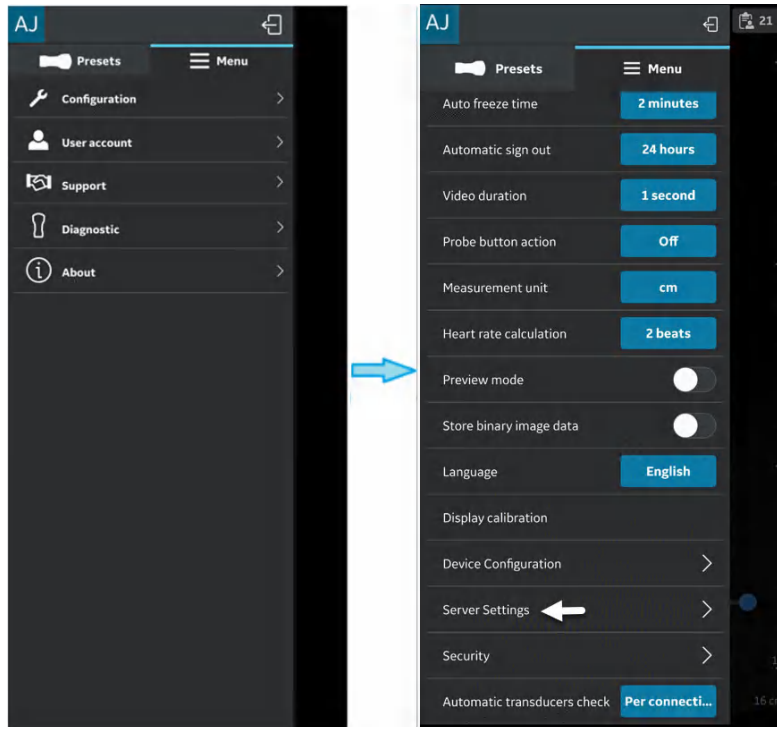


Figure 4-29. Server Settings

Configure Network Shared Folder (continued)

2. Press Add Server in “Server Settings” screen.

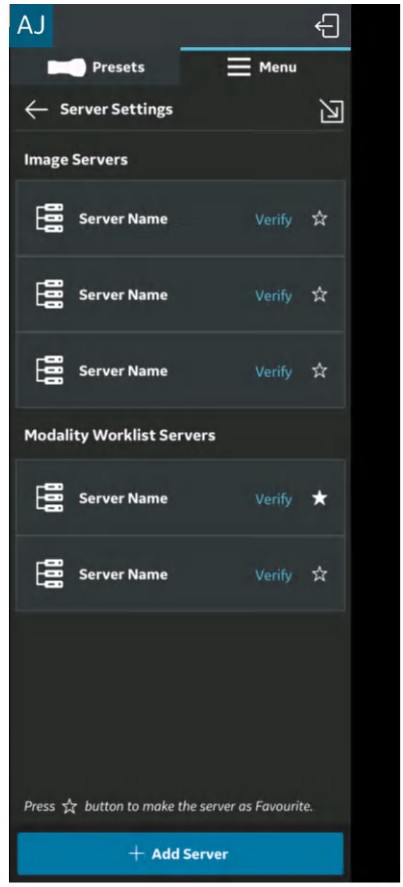


Figure 4-30. Add Server

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 *page 5-120* for more information.

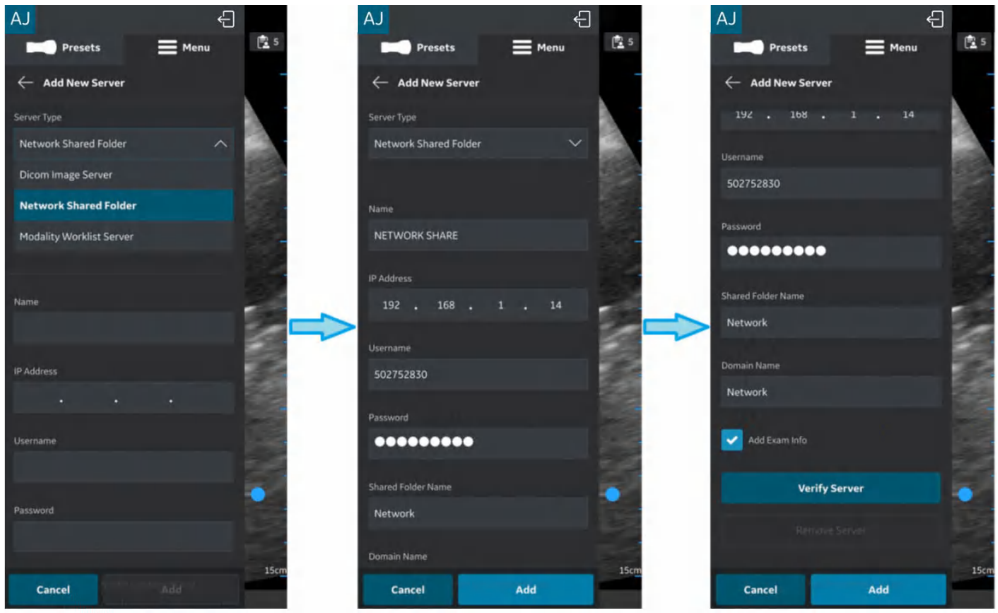


Figure 4-31. Enter Configuration Information

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.

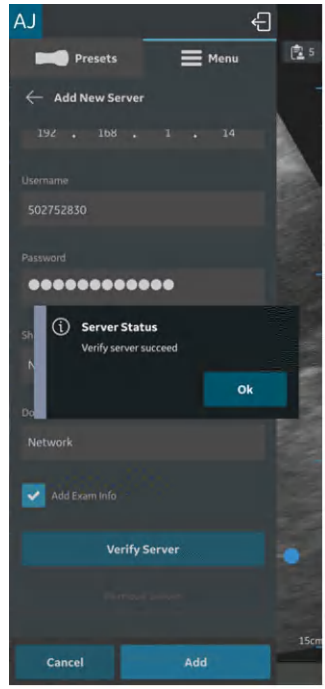


Figure 4-32. Verify network shared folder

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.

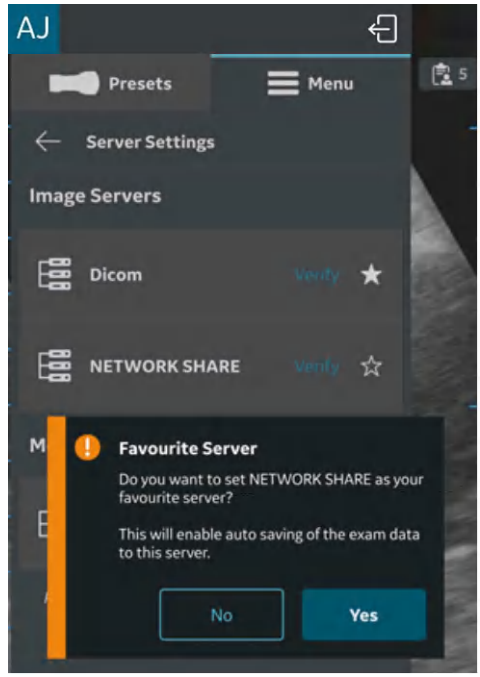


Figure 4-33. Network shared folder as favourite

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.

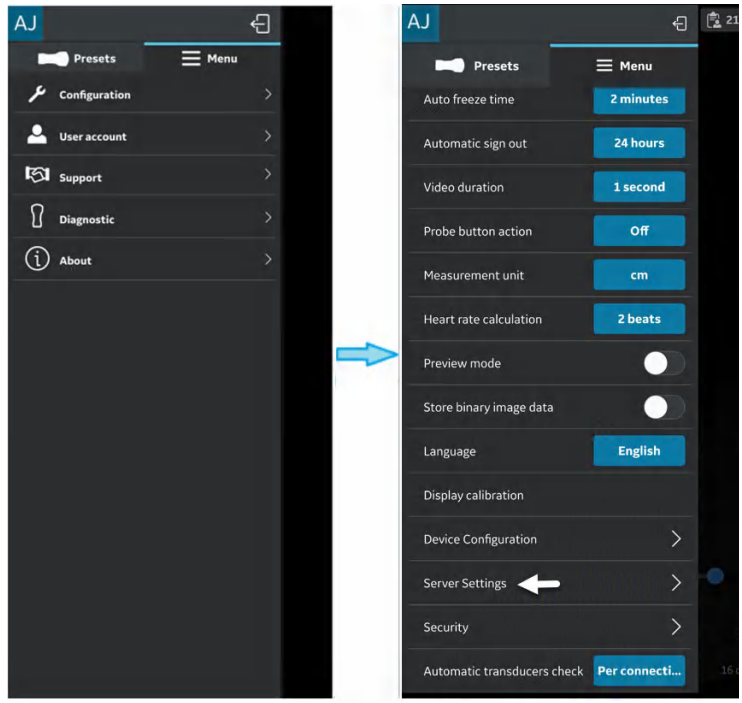


Figure 4-34. Server settings

Configure DICOM Web Server (continued)

2. Press Add Server on the “Server Settings” screen.

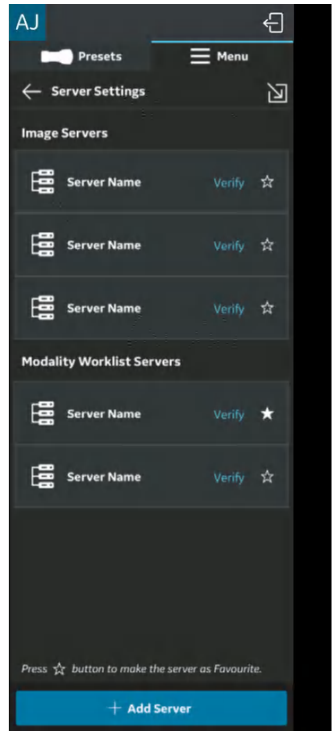


Figure 4-35. Add server

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.

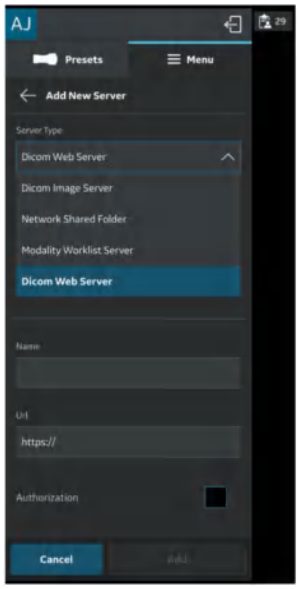


Figure 4-36. Add DICOM Web Server

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 5-110* 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.

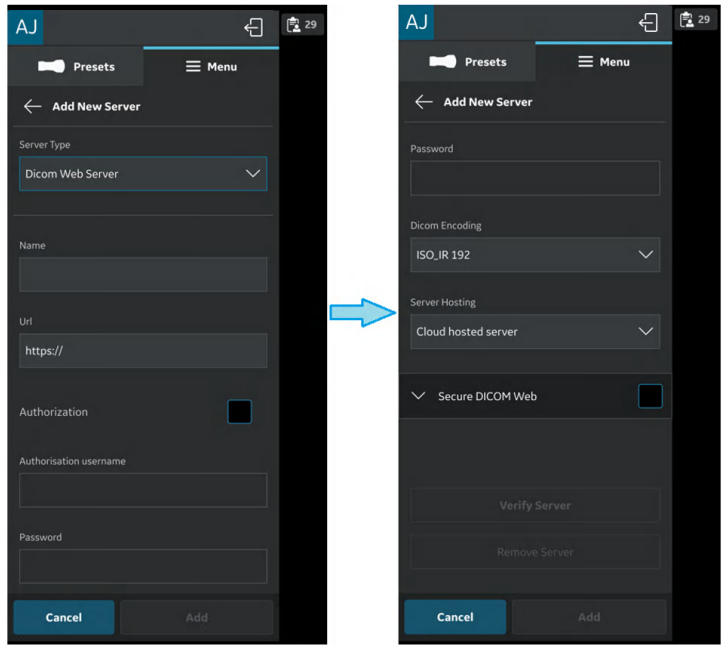


Figure 4-37. DICOM Web Server details

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.

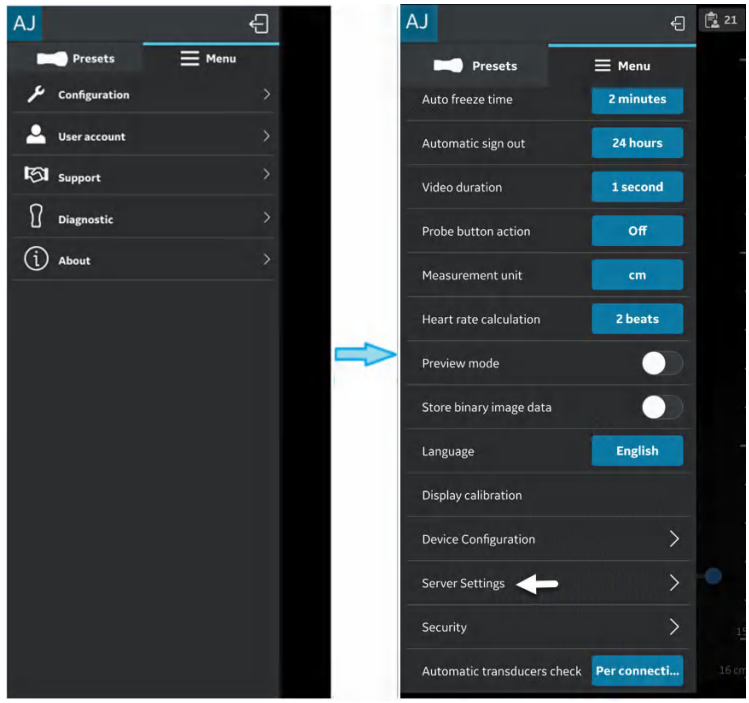


Figure 4-38. Server Settings

Remove Server (continued)

2. Press to select the desired server that needs to be removed.

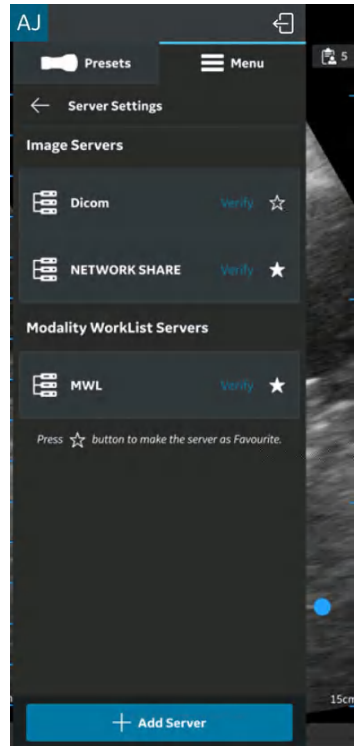


Figure 4-39. List of Servers

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.

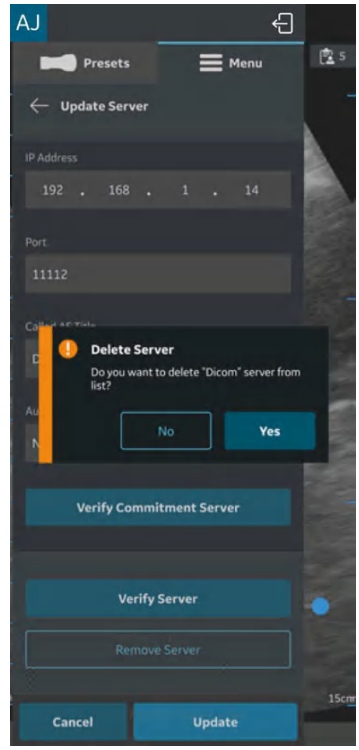


Figure 4-40. Remove Server

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.

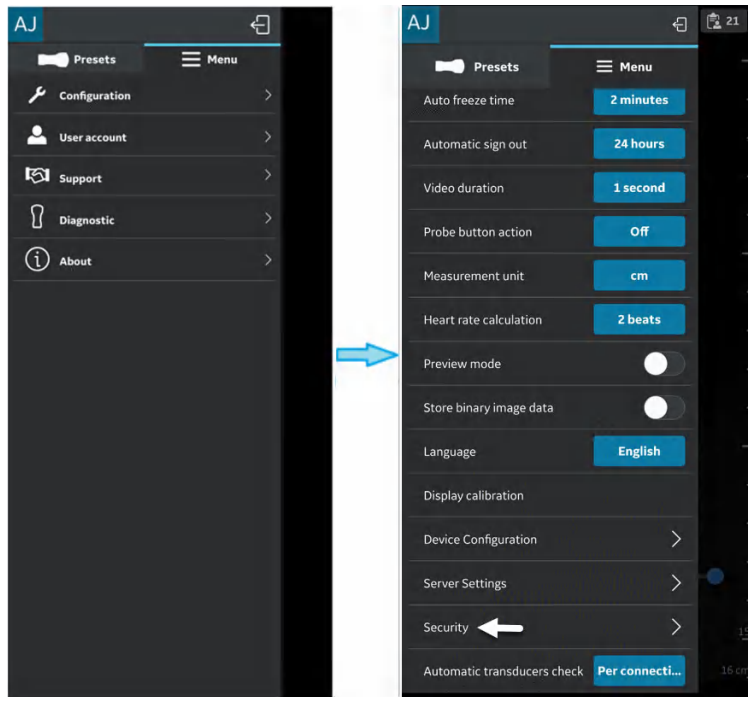


Figure 4-41. Security settings

Ask for data access PIN (continued)

2. Tap on the **Ask for data access PIN** button on the Security screen.

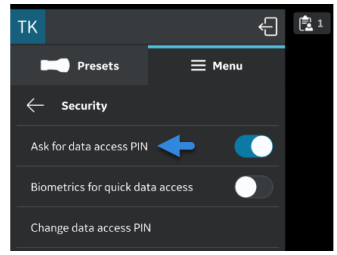


Figure 4-42. Tap on the Ask for data access PIN button

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

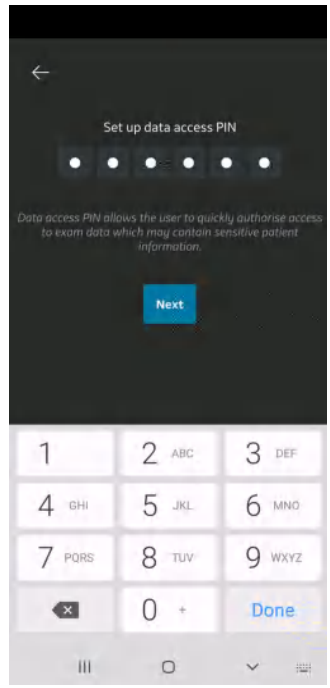


Figure 4-43. Enter data access PIN

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.

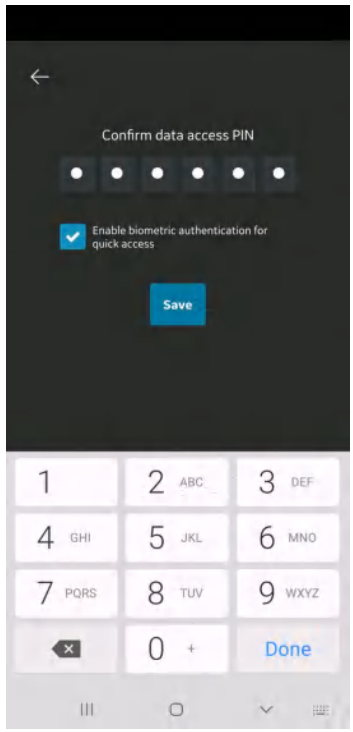


Figure 4-44. Confirm data access PIN

TouchID for quick data access (Biometric authentication)

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

1. Press Menu -> Configuration -> Security.

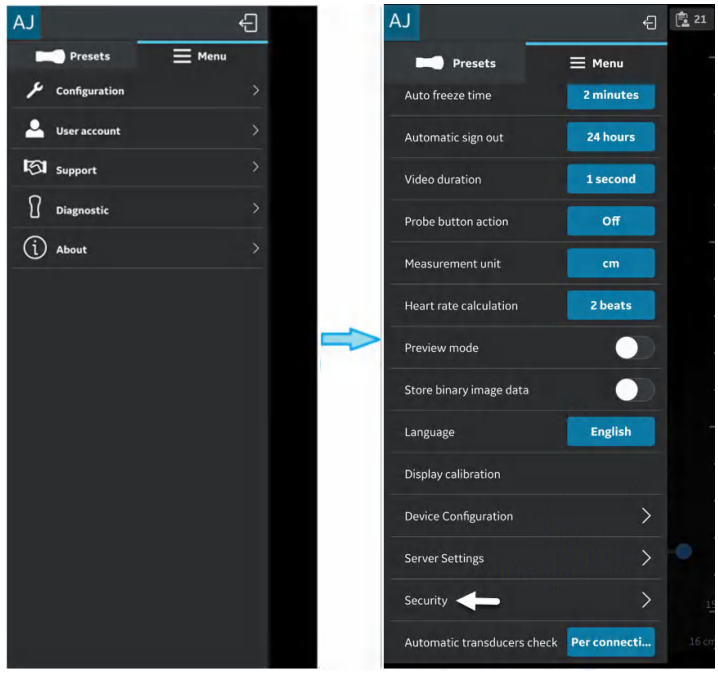


Figure 4-45. Security settings

2. Tap on the **TouchID for quick data access** button on the Security screen to activate biometric authentication.

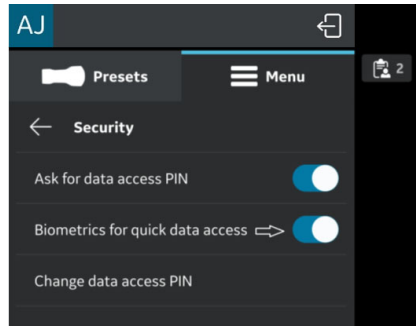


Figure 4-46. Activate Biometric Authentication

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.

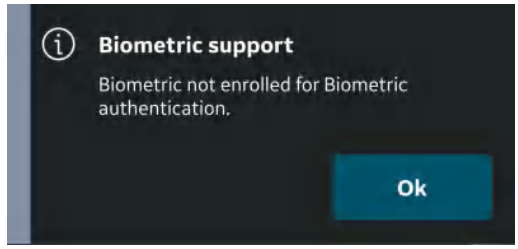


Figure 4-47. Biometric authentication error

Change data access PIN

Follow the procedure below to change the data access PIN.

1. Press Menu -> Configuration -> Security.

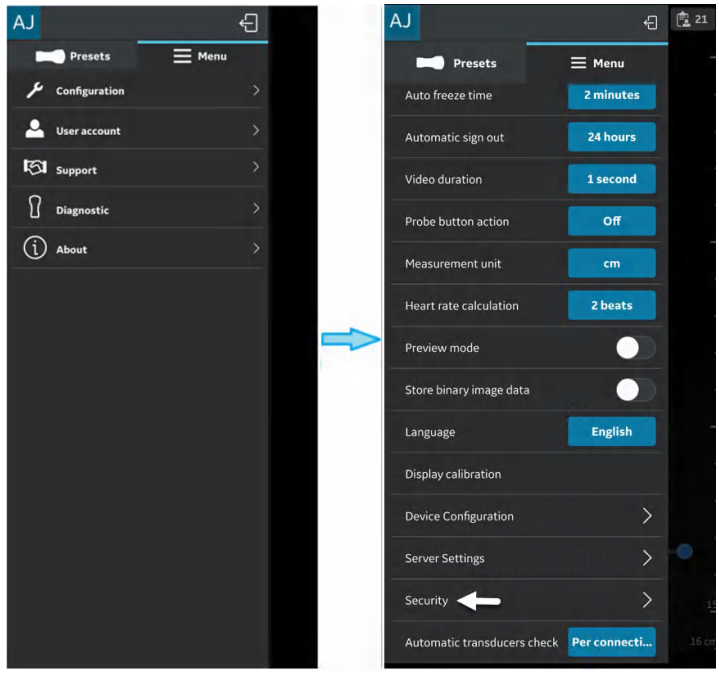


Figure 4-48. Security settings

Change data access PIN (continued)

2. Tap on Change data access PIN on the Security screen.

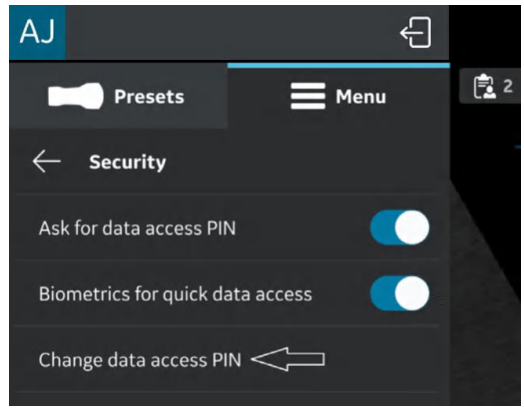


Figure 4-49. Change data access PIN

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.

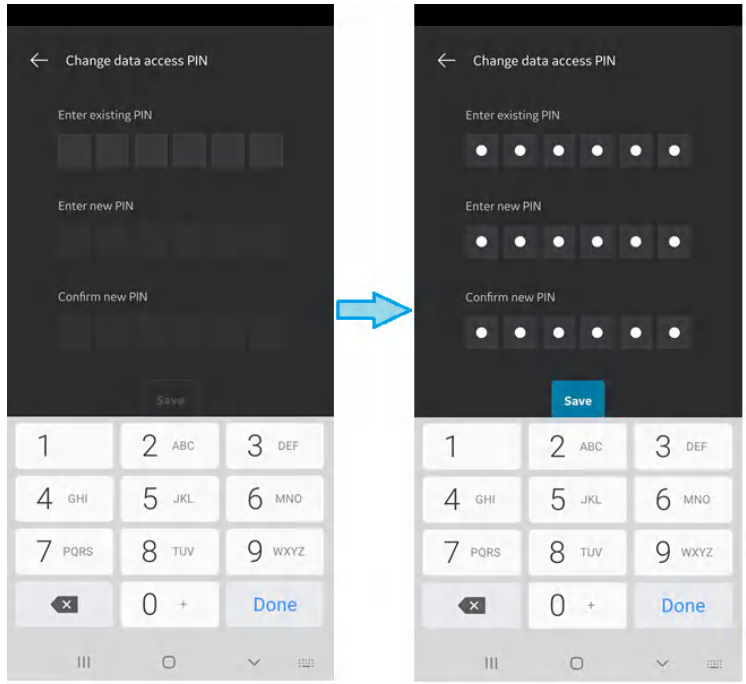


Figure 4-50. Confirm data access PIN

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**."

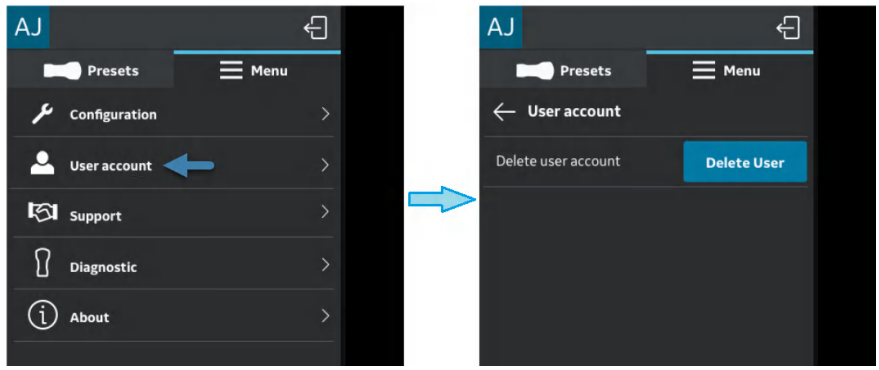


Figure 4-51. User account

User account deleted

A message is triggered when remote server call operation is initiated by a deleted account owner from Vscan Air application.

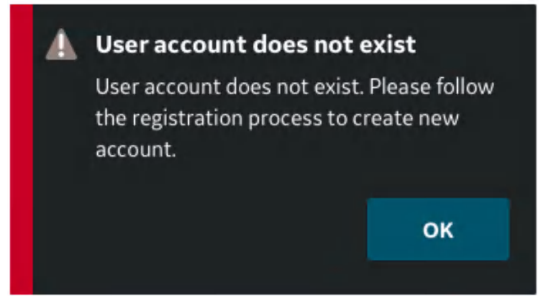


Figure 4-52. User account does not exist

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.

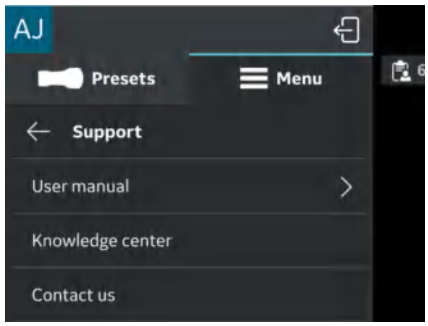


Figure 4-53. Support

- **User Manual** - To access the e-manual in the desired language.

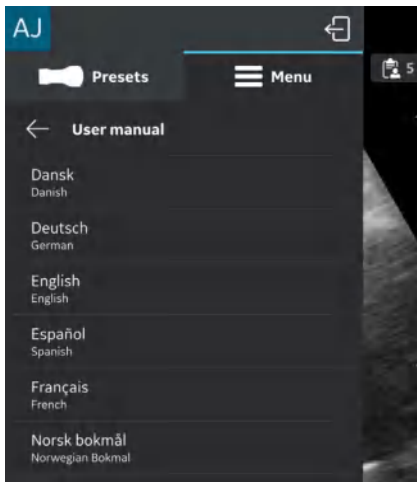


Figure 4-54. User manual

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

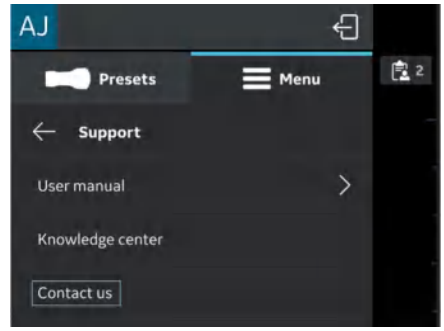


Figure 4-55. Contact us

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.

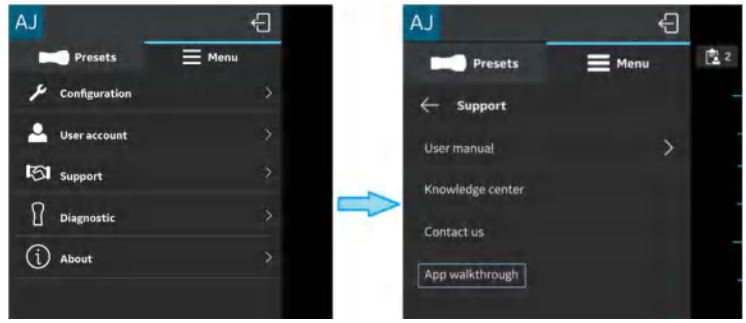
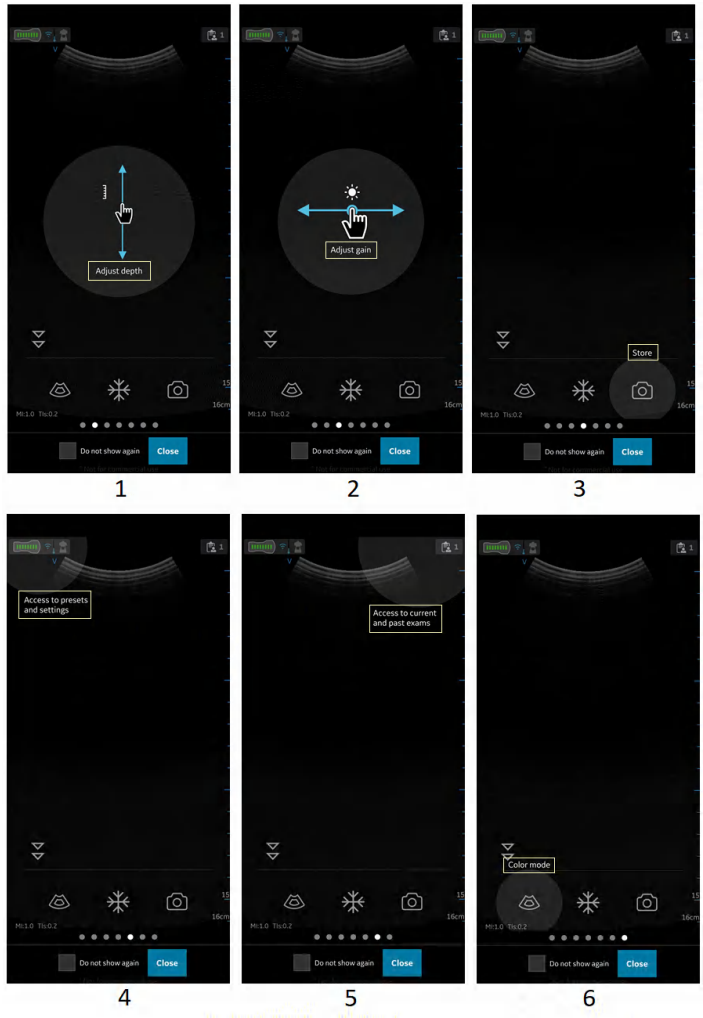


Figure 4-56. Vscan Air App walkthrough

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 4-57. App walkthrough functionality

Diagnostics

Diagnostics

The **Diagnostics** option displays - Run diagnostics and Send log.

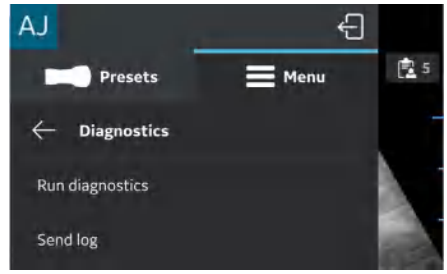


Figure 4-58. Diagnostics

- **Run Diagnostics** - To run all the Diagnostic tests refer the section ‘Diagnostics Test’ on *page 6-40*.

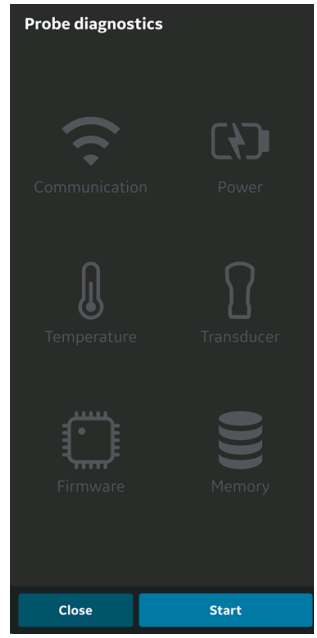


Figure 4-59. Run diagnostics