Technical Publications

Vscan Air

CE 0123

User Manual

GP092020-1EN - English

Rev 08

For USA: CAUTION- Investigational device. Limited by United States law to investigational use.

Operating Documentation

Regulatory requirement

Vscan Air ™

Vscan Air is a trademark of GE Healthcare.

This product complies with regulatory requirements of the following European Directive 93/42/EEC concerning medical devices.

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 A3, Vscan Air CL C1, Vscan Air CL C2, Vscan Air CL C3, Vscan Air CL I1, Vscan Air CL I2 and Vscan Air CL G1.

This manual is a reference for all 1.X software versions of Vscan Air for Android and all 1.X software versions of Vscan Air for iOS.

Manufacturer:
GE VINGMED ULTRASOUND AS
Strandpromenaden 45
3191 Horten, Norway
Tel.: (+47) 3302 1100 Fax: (+47) 3302 1350

Revision History

Reason for Change

REV	DATE DD Month YYYY	REASON FOR CHANGE
Rev 01	24 Dec 2019	Initial MyWorkshop release
Rev 02	31 Mar 2020	Activation and Registration Regulatory image, Registered devices, App version info, Appendix section. Probe version info, Vscan Air app version Wireless charger, Acoustic table Naming conventions, General description, Intended use, Indications for use, Clinical application not cleared for use in Japan Vscan Air app rating label versions Connection status dim/white battery outline, LED states Position and resize ROI, Recalled stored image, GE ultrasound transducers web site
Rev 03	15 May 2020	Vscan Air CL probe rating label versions Front page - copyright year Upgrade software - App version info Fig, Vscan Air CL probe software - Probe version info Fig Vscan Air CL probe software upgrade
Rev 04	28 May 2020	Vscan Air CL probe rating label versions, Vscan Air app rating label versions Regulatory, Indications for use, Indications Reference Guide
Rev 05	10 July 2020	Front page Product name -Vscan Air Display devices - validation, Element test Display device image quality verification Probe care card removed Regulatory page - SW & HW models separate para Vscan Air configuration list Minimum requirement spec

REV	DATE DD Month YYYY	REASON FOR CHANGE
Rev 06	10 Aug 2020	Chapter 1 updated Secion: - Attention - Intended use - Important Safety Considerations - Internet Chapter 2 updated Section: - Overview -> Note - Interference Caution -> Warning - Changing imaging modes - Vscan Air Labels -> Note Chapter 3 updated: - Anker PowerWave wireless charging pad package contents - System overview -> Note - Charging the battery - Supported Mobile Platforms - Display devices - validation - Display device image quality verification - Removed the Figure: Install Vscan Air app & Allow access from - Initial -> Power ON/OFF - Figure 3-22, Figurw 3-24 Chapter 4 updated: - Figure 4-7, Figure 4-15, Figure 4-19 Chapter 5 updated - Black and white imaging adjustments -> Note - Depth -> Note - Color Gain - Color Aliasing Chapter 6 updated Section: - Upgrade software - Vscan Air CL probe software - Cleaning with Wipes - Disinfection with wipes - Transducer Element test - Chemicals Used for Efficacy Validation Chapter 7 updated Section: - How to contact GE Chapter 8 updated Section: - The real-time display of acoustic output indices - Acoustic Output Reporting Tables for Track 3/EN/IEC 60601-2-37
Rev 07	14 Oct 2020	Chapter 1: Added Warning - Indications for use section Updated Indications for use Updated section Contact Information Chapter 2: updated- Accuracy of the displayed acoustic output and acoustic measurement uncertainties - Table 2-4 Chapter 3: Updated- Figure 3-8, 3-20. Registration Complete - Figure 3-26. Registration Complete Chapter 4: Updated Figure 4-17 Chapter 6: updated session - Cleaning and disinfection - Chemicals compatible with Vscan Air CL Chapter 8: Updated Table 8-1, Table 8-2, Table 8-3, Table 8-4

REV	DATE DD Month YYYY	REASON FOR CHANGE
Rev 08	06 Nov 2020	Chapter 3: Update: - Pre-requisites - Supported Mobile Platforms - Display device image quality verification - Figure 3-20. Registration Complete - Figure 3-26. Registration Complete Added session- Add security pin (data access pin) - TouchID for quick data access (Biometric authentication) - Change data access pin - Unregister Vscan Air Probe - Unregister Vscan Air app Chapter 4: Update: Figure 4-1. Menu - Figure 4-2. Configuration Added session- DICOM Client - Server Settings - Storage Commit - Configure Network Shared Folder - Remove Server - Security - TouchID for quick data access (Biometric authentication) Chaper 5: Added session - Resolution and Penetration setting - Protected Health Information (PHI) - Export data - Share individual images/videos - Share all images/videos from an exam - Share Exams - Export data to the Dicom Image Server - Export data to the Network Shared Folder - Export data to other apps (Social Networking Applications) Updated: - Pulse repetition frequency - Fast and slow flow (High and low velocity scale) Chapter 6: Updated: - Cleaning and disinfection - Chemicals Used for Efficacy Validation - Choosing a Disinfectant - Cleaning the protective case - Chemicals compatible with Vscan Air CL Added session- - Auto Deactivation of Vscan Air app due to inactivity - Inactivate duration reaches soft limit - Inactivate duration reaches hard limit Chapter 8: Updated session: - Specifications - Acoustic Output - The Acoustic Output Control Scheme figure writen into text format

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.

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Regulatory Requirements

Conformance Standards

The GEHC product families are tested to meet all applicable requirements in relevant EU Directives and European/ International standards. Any changes to accessories, peripheral units or any other part of the device must be approved by the manufacturer: GE Healthcare. 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
93/42/EEC	Medical Devices Directive (MDD) The CE label affixed to the product 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	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
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.

Table i-1: Regulatory Requirements (Continued)

Standard/Directive	Scope
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)
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.
* including national deviations	

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 probe has an internal battery which allows the operation during AC power absence.
- The AC adapter is Class II.

The Vscan Air CL probe is 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 particular 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

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

Importer information for Turkey does not have the font and font size normally used in the manual.

USA

- FCC ID: YOM-VSCANAIR

Canada

- IC: 9136A-VSCANAIR

Steps to access FCC ID and IC ID

1. To access FCC ID and IC ID information, select **Menu** icon on Vscan Air app.
2. 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: Please note that orders are based on the individually agreed upon specifications and may not contain all features listed in this manual.

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) 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 eDocumentation kit provides instructions on how to read the user documenation via electronic media. All user manuals are provided in electronic format. The eDocumenation media includes English and all other translations. The Vscan Air manuals are written for users who are familiar with basic ultrasound principles and techniques. They do not include sonographic training or detailed clinical procedures.

NOTE: The screen graphics in this manual are only for illustrational purposes. Actual screen output may differ.

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

Documentation (continued)

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

Table 1-1: Vscan Air CL configurations

Item	Vscan Air CL Part number	REF
1	GP000150	Vscan Air CL A1
2	GP000151	Vscan Air CL A2
3	GP000152	Vscan Air CL A3
4	GP000153	Vscan Air CL C1
5	GP000154	Vscan Air CL C2
6	GP000155	Vscan Air CL C3
7	GP000156	Vscan Air CL I1
8	GP000157	Vscan Air CL I2
9	GP000158	Vscan Air CL G1

NOTE: The Vscan Air CL probe comes with different AC adapter configuration and different labeling depending on which country or region it is shipped to, example: GP000150, only intended for USA.

Naming conventions

The following naming conventions are used throughout the user manual:

- Vscan Air CL – refers to the Vscan Air probe.
- 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 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, and 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.

Vscan Air customers have access to the Vscan Air web portal, including online access to product and clinical information.

Wireless Description

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

1	Wireless network protocols supported	IEEE 802.11a/b/g/n
2	Frequency bands of transmission / reception	2.4GHz and 5GHz(UNII-1 and UNII-3)
3	Preferred frequency or frequency band	5GHz
4	Bandwidth(s) supported	20MHz and 40MHz
5	FCC EIRP of 2.4GHz Wi-Fi	17.01 dBm
6	FCC EIRP of 5.0GHz Wi-Fi	13.59 dBm
7	FCC EIRP of BLE	7.61 dBm
8	ETSI EIRP of 2.4GHz Wi-Fi	17.81dBm
9	ETSI EIRP of 5.0GHz Wi-Fi	14.90 dBm
10	ETSI EIRP of BLE	7.38dBm

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 and imaging system 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), combined (B + Color Doppler) and Harmonic Imaging modes with both the curved and linear 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).

Table 1-3: Supported imaging modes

Vscan Air	Black/white imaging (B-mode)	Color flow (Color doppler)	Combined (B+ color doppler)	Harmonics
Curved array transducer	X	X	X	X
Linear array transducer	X	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.

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.

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 CL 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 Air web portal for reference materials.

Prescription Device

For USA only:

CAUTION

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

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 CL is a precision instrument. Handle Vscan Air CL and its accessories with care.
- Do not attempt to disassemble or alter any part of the unit including the Vscan Air CL, 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 pad and USB cable). Failure to do so may result in electrical shock or fire.
- Use the supplied wireless charging pad 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 charging pad 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.

Important Safety Considerations (continued)

- Keep good hand contact with Vscan Air CL 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 it is important that you read and understand the battery safety and environment information.

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

http://www.gehealthcare.com

http://www3.gehealthcare.com/en/Products/Categories/Ultrasound/Ultrasound_Probes

https://handheldultrasound.gehealthcare.com/

Vscan Air web portal: https://vscanair.com/

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

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.

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.

Contacting GEHC Ultrasound (continued)

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: (+54) 11-5298-2200
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	TEL: 3067-8010 FAX: (011) 3067-8280
CANADA	GE Ultrasound 9900 Innovation Drive Wauwatosa, WI 53226	TEL: (1) 800-668-0732 Customer Answer Center TEL: (1) 262-524-5698
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: (5) 228-9600 FAX: (5) 211-4631

Table 1-5: Americas (Continued)

USA	GE Ultrasound 9900 Innovation Drive Wauwatosa, WI 53226	TEL: (1) 800-437-1171 FAX: (1) 414-721-3865

For USA only: when contacting GE CARES you will have to provide your system ID. If system ID is unknown, please give the Temporary System ID “Vscan Air” to be properly routed for support.

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, Australia	TEL: 1300 722 229
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: +(91) 1-800-425-8025
KOREA	15F, 416 Hangang Dae ro, Chung-gu Seoul 04637, Korea	TEL: +82 2 6201 3114
NEW ZEALAND	8 Tangihua Street Auckland 1010 New Zealand	TEL: 0800 434 325
SINGAPORE	ASEAN 1 Maritime Square #13-01 HarbourFront Center Singapore 099253	TEL: +65 6291 8528

Table 1-7: Europe

AUSTRIA	General Electric Austria GmbH & Co OG EURO PLAZA, Gebäude E Technologiestrasse 10 A-1120 Vienna	TEL: (+43) 1 97272 0 FAX: (+43) 1 97272 2222
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 Vyskocilova 1422/1a 140 28 Praha 4	TEL: (+420) 224 446 162 FAX: (+420) 224 446 161
DENMARK	GE Healthcare Park Allè 295 DK-2605 Brøndby, Denmark	TEL: (+45) 43 295 400 FAX: (+45) 43 295 399
ESTONIA & FINLAND	GE Healthcare Finland Oy Kuortaneenkatu 2, 000510 Helsinki P.O.Box 330, 00031 GE Finland	TEL: (+358) 10 39 48 220 FAX: (+358) 10 39 48 221
FRANCE	GE Medical Systems SCS Division Ultrasound 24 Avenue de l'Europe - CS20529 78457 Vélizy Villacoublay Cedex	TEL: (+33) 1 34 49 52 70 FAX: (+33) 13 44 95 202
GERMANY	GE Healthcare GmbH Beethovenstrasse 239 42655 Solingen	TEL: (+49) 212-28 02-0 FAX: (+49) 212-28 02-380
GREECE	GE Healthcare 8-10 Sorou Str. Marousi Athens 15125 Hellas	TEL: (+30) 210 8930600 FAX: (+30) 210 9625931

Table 1-7: Europe (Continued)

HUNGARY	GE Hungary Zft. Division, Akron u. 2. Budaörs 2040 Hungary	TEL: (+36) 23 410 314 FAX: (+36) 23 410 390
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: (+44) 028 90229900 TEL: 1800 460 550 FAX: (+353) 1 686 5327
ITALY	GE Medical Systems Italia spa Via Galeno, 36, 20126 Milano	TEL: (+39) 02 2600 1111 FAX: (+39) 02 2600 1417
KAZAKHSTAN	«Дженерал Электрик Қазақстан» ЖШС Қазақстан, Алматы қаласы 050040, Тимирязев көшесі, 28В ү., 307 кеңсе.	T +7 727 3560020
LUXEMBORG	See Belgium.	
NETHERLANDS	GE Healthcare De Wel 18 B, 3871 MV Hoevelaken PO Box 22, 3870 CA Hoevelaken	TEL: (+31) 33 254 1290 FAX: (+31) 33 254 1292
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 FAX: (+47) 23 18 60 35 TEL: (+47) 33 02 11 16

Table 1-7: Europe (Continued)

POLAND	GE Medical Systems Polska Sp. z o.o., ul. Woloska 9 02-583 Warszawa, Poland	TEL: (+48) 22 330 83 00 FAX: (+48) 22 330 83 83
PORTUGAL	General Electric Portuguesa SA Avenida do Forte 6 - 6A Edifício Ramazzotti 2790-072 CARNAXIDE	TEL: (+351) 21 425 1300 FAX: (+351) 21 425 1343
RUSSIA	GE Healthcare Presnenskaya nab. 10 Block C, 12 floor 123317 Moscow, Russia	TEL: (+7) 4957 396931 FAX: (+7) 4957 396932
SPAIN	GE Healthcare España C/ Gobelas 35-37 28023 Madrid	TEL: (+34) 91 663 2500 FAX: (+34) 91 663 2501
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 (+46) 020-120 14 36
SWITZERLAND	GE Medical Systems (Schweiz) AG Europastrasse 31 8152 Glattbrugg	TEL: (+41) 1 809 92 92 FAX: (+41) 1 809 92 22
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
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 FAX: (+971) 4 429 6201

Table 1-7: Europe (Continued)

UNITED KINGDOM	GE Medical Systems Ultrasound Pollards Wood Nightingales Lane Chalfont St Giles Buckinghamshire HP8 4SP	TEL: (+44) 1494 544000 FAX: (+44) 1707 289742
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; FAX: (+47) 3302 1350

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 CL 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:

d  DANGER

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

- Severe or fatal personal injury
- Substantial property damage.

w  WARNING

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

- Severe personal injury
- Substantial property damage.

c  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.

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 CL probe.

Patient safety

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.

Diagnostic information (continued)

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

Equipment malfunction or incorrect settings can result in measurement errors or failure to detect details in the image. The user must become thoroughly familiar with the operation of the Vscan Air in order 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

DANGER

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 CL 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 CL, or to unplug it.
- If flammable substances are detected, evacuate and ventilate the area before turning off Vscan Air CL.

Electrical hazard

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

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

Electrical safety

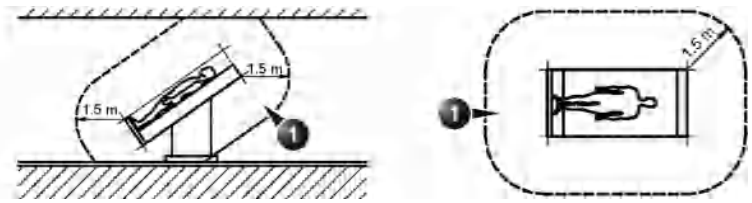
Device classifications

Vscan Air CL probe is an internally powered device, type BF.

The AC adapter is Class II.

External connection

CAUTION Charging of Vscan Air CL via the AC adapter and the wireless charger pad 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 CL probe 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 European Directive 93/42/EEC 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.

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.

Electromagnetic Compatibility (EMC) (continued)

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 2-7*).

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 European Union Medical Device Directive and FCC 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.

Electromagnetic Compatibility (EMC) (continued)

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 2-12*.

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

WARNING

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

WARNING

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

WARNING

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

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

FCC compliance statements

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 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.

FCC compliance statements (continued)

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.

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.*

Electromagnetic emissions

Table 2-1: Electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions.		
The Vscan Air CL probe is intended for use in the electromagnetic environment below. The customer or the user of the Vscan Air CL should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emission EN55011	Group 1	The Vscan Air CL 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 CL 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.
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 CL probe is intended for use in the electromagnetic environment below. The customer or the user of the Vscan Air CL 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.

Table 2-2: Electromagnetic immunity (Part 1) (Continued)

Guidance and manufacturer's declaration – electromagnetic immunity.			
The Vscan Air CL probe is intended for use in the electromagnetic environment below. The customer or the user of the Vscan Air CL should assure that it is used in such an environment.			
Immunity test	EN/IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
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 CL is 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 CL probe is intended for use in the electromagnetic environment below. The customer or the user of the Vscan Air CL 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 CL is:

- 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 indicies as aid for safe use of the Vscan Air CL.

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: Particular 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 limits 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 CL is 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 3-11*.

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 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) and Color flow (Color 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)

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.				

Table 2-6: Recommended maximum scanning times (Neonatal- Transcranial and Spinal 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.

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 5-15* and ‘Color flow (Color doppler)’ on *page 5-19*.

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 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.

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 Vscan Air CL temperature

Probe	Max Temp (°C) (Simulated use)	Max Temp (°C) (Still air)
Vscan Air CL – Curved array transducer (for deep scanning)	38.7	44.5
Vscan Air CL – Linear array transducer (for shallow scanning)	37.7	41.9

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

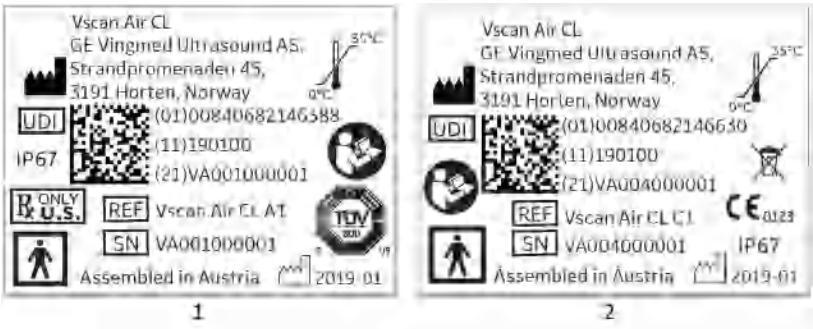
- Thermocouple was placed at the geometric center of the lens.
- Thermal phantom at not less than 33°C or in the range 20-33°C for external probes. Maximum Vscan Air CL temperature rise is measured and added to 33°C. Maximum Vscan Air CL temperature (Simulated use) is <43°C.
- With Vscan Air CL transmitting in air, temperature rise is measured and added to 23°C. Maximum Vscan Air CL temperature (Still air) is <50°C. Lens temperature is monitored for 30 minutes.

NOTE: Vscan Air CL placed in contact with a thermal phantom made of tissue-mimicking material is referenced in IEC60601-2-37, Ed2.1

- Auto-freeze capability is disabled during these measurments.

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 CL probe – EU Version

Figure 2-2. Vscan Air CL probe rating label versions

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

NOTE: The labels shown in Figure 2-2, Figure 2-3, and Figure 2-4 are samples. The label content will vary based on country requirements and AC adapter configuration.

Figure 2-5. Battery label

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

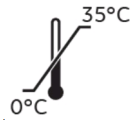
Label	Purpose	Location	Standard
CE 0123	Indicates that the product is in compliance with all relevant European Directives and under surveillance by Notified Body 0123.	Vscan Air app Vscan Air CL probe	N/A - by certification body
	This symbol indicates that the waste of electrical and electronic equipment 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 CL 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 CL probe Battery	ISO 7010-M002
	TÜV SÜD NRTL Certification Mark	Vscan Air CL 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 CL 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 CL probe	FDA guidance
	Type BF Applied Part symbol (see ‘Classifications’ on *page i-8*)	Vscan Air CL probe	IEC 60417-5333
	Manufacturer name and address	Vscan Air CL probe Vscan Air app	ISO 7000-3082

Table 2-8: Label Icons

Label	Purpose	Location	Standard
	Manufacturing date (year-month)	Vscan Air CL probe Vscan Air app	ISO 7000-2497
	Brand and model identifier.	Vscan Air CL probe Vscan Air app	ISO 7000-2493
	Serial number	Vscan Air CL 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 CL 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 CL probe	N/A- by GEHC
	Push button (power switch)	Vscan Air CL probe	IEC 60417-5010
FCC ID: IC ID:	Federal Communications Commission IDentification number. IC ID The Canadian certification ID number relating to radio apparatus and broadcasting equipment	Vscan Air app	FCC Part 15:Subpart CRSS-247
IP67	Vscan Air can be completely submerged upto 1m in water.	Vscan Air CL probe	IEC 60529
LOT	Batch or lot code	Vscan Air app	ISO 7000-2492

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 2-9: Hazardous substances

Component Name	Hazardous Substances' Name					
	Pb	Hg	Cd	Cr^{6+}	PBB	PBDE
Probe & Cable	X	O	O	O	O	O
Main unit	O	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 CL for Use

Contents:

Package contents

Vscan Air CL shipment box contents

Vscan Air CL product box

Make sure all items listed below are included in the package.

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

Figure 3-1. Vscan Air CL product box contents

NOTE: The Protective case protects the Vscan Air CL from scratches when it is not being used.

Anker PowerWave wireless charging pad package contents

1. Package contents with front and back cover
2. Instruction booklet
3. Package contents with PowerWave Pad and USB cable
4. Unboxing of the Contents
5. USB cable (1.2m)
6. Anker PowerWave charging pad

Figure 3-2. Anker PowerWave charging pad package contents

How to charge the Vscan Air CL

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

2. Connect the AC adapter into the wall outlet.

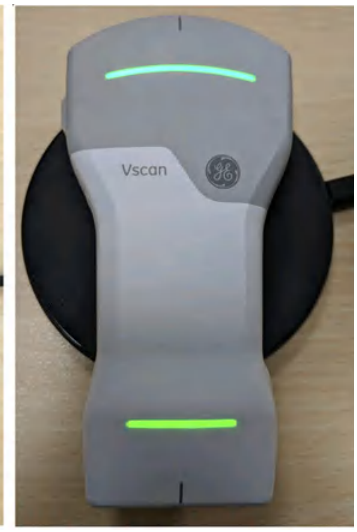
How to charge the Vscan Air CL (continued)

3. Place the Vscan Air CL on the charging pad with the GE logo up. Ensure the probe is centred on the charging pad.

4. The Vscan Air CL lights up and starts charging.

How to charge the Vscan Air CL (continued)

5. Vscan Air CL gets wirelessly charged with the Anker PowerWave charging pad. Yellow light on both LEDs indicates the Vscan Air CL is charging. Green light on both LEDs indicates the Vscan Air CL is fully charged 90-100% (see ‘Vscan Air CL LED indication’ on *page 3-16*).



Environmental requirements

Environmental requirements for Vscan Air CL

Table 3-1: Environmental requirements

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

Transient operating conditions

NOTE: Permissible transient environmental operating conditions:

- Temperature range of -20 to +50 degrees
- Device will function for a minimum of 20 minutes when placed in an environment with temperatures ranging from -20°C to 50°C after storage at room temperature (20 ± 2°C)
- Following storage at temperatures ranging from -20°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 6-4.

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 CL to acclimate for approximately 10 minutes, if stored at temperatures ranging from -20°C to +50°C.

Allow the Vscan Air CL to acclimate for approximately 30 minutes, if stored at temperatures outside the transient environmental operating conditions -20°C to +50°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 CL is not certified for being mounted or fixed inside a road- or air ambulance.
- The Vscan Air CL can be used in emergency medical services environments. See ‘Environmental requirements for Vscan Air CL’ on *page 3-7 for more information.*
- The Vscan Air CL probe is 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-6*. Additional regulations might apply

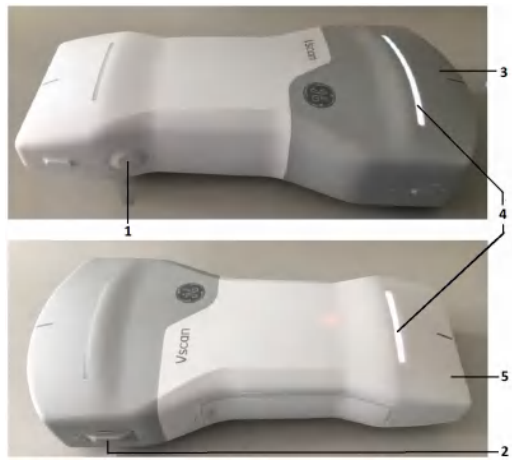
** The Vscan Air ultrasound system is compliant to IEC 60601-1-12 and EN1789 as stated in ‘Regulatory Requirements’ on *page i-6*. Additional regulations might apply.

System description

System overview

The Vscan Air CL is a dual headed battery-operated ultrasound device. The Vscan Air CL 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 button
2. Manufacturing port - sealed
3. Curved array
4. LED indicator
5. Linear array

Figure 3-3. Vscan Air CL

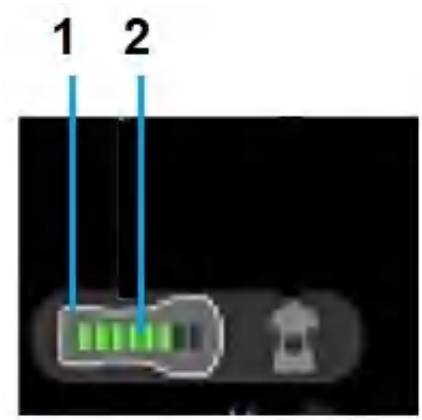
NOTE: To charge Vscan Air CL refer 'How to charge the Vscan Air CL' on page 3-4

Display screens

Connection and probe battery status

- No out-line of the probe and no battery charge indication - NOT CONNECTED TO PROBE

- White out-line of the probe and battery charge indication - CONNECTED TO PROBE



1. White out-line of the probe
2. Battery charge indication

Display screens (continued)

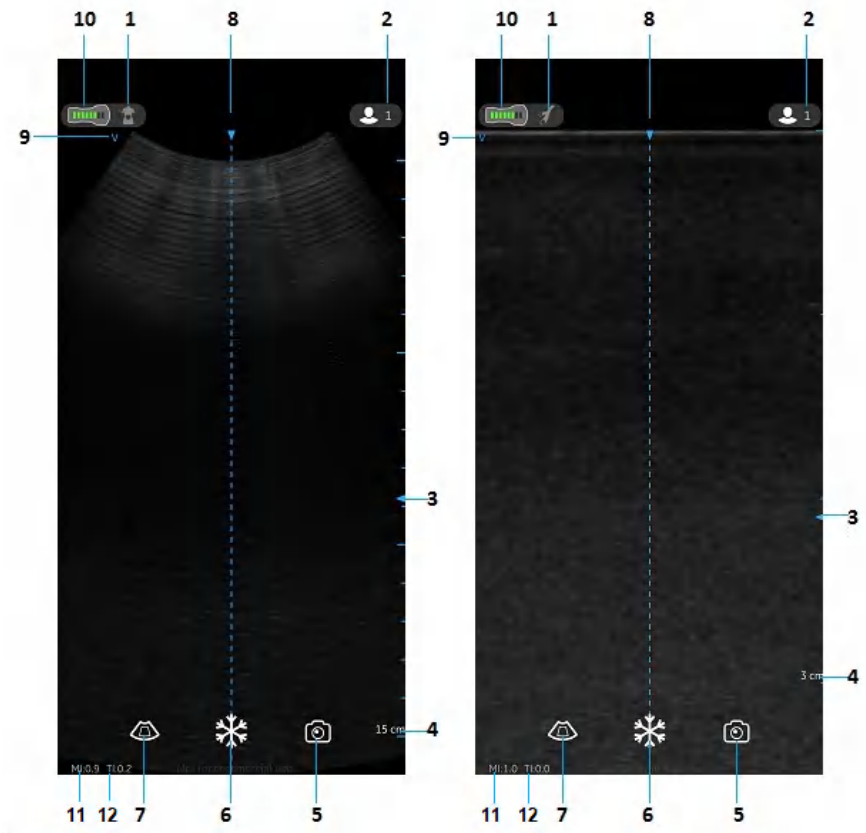


Figure 3-4. Black/white imaging mode (B-mode)

Curved array (deep scanning) transducer
1. Selected preset
2. Exam number
3. Focus marker
4. Depth
5. Store
6. Freeze
7. Color flow
8. Center line marker
9. Image orientation marker
10. Vscan Air CL battery status indicator
11. Mechanical Index (MI)
12. Thermal Index (TI)

Linear array (shallow scanning) transducer
1. Selected preset
2. Exam number
3. Focus marker
4. Depth
5. Store
6. Freeze
7. Color flow
8. Center line marker
9. Image orientation marker
10. Vscan Air CL battery status indicator
11. Mechanical Index (MI)
12. Thermal Index (TI)

Accessories

Optional accessories

Table 3-2: International AC Adapter

Accessory	Figure
AC Adapter - Type C	
AC Adapter - Type G	
AC Adapter - Type A	
AC Adapter - Type I	

NOTE: Details about types of AC power plugs are included in 'Power plugs' on page 3-14

Vscan Air CL Battery

Battery

The Vscan Air CL probe is 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 CL probe as described in the section ‘How to charge the Vscan Air CL’ on *page 3-4*

The battery specification is shown in the below table.

Battery specification

Table 3-3: Battery specification

Items		Unit	Value	Description
Basic	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 CL probe is not certified for being charged inside a road- or air ambulance.

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

Power plugs

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

Figure 3-5. Power plugs

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

Voltage requirements

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

CAUTION

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

Charging the battery

Place the Vscan Air CL probe on the wireless charging pad as shown in ‘How to charge the Vscan Air CL’ on *page 3-4*

Battery level indicator

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

Table 3-4: 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 LED indication

1. Booting
2. Searching
3. Display found
4. Connected
5. Active array
6. Charging
7. Fully charged
8. Occupied
9. Error

Figure 3-6. LED states

- A blinking white light switching between Vscan Air CL ends indicates the Vscan Air CL is booting.

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

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

- A steady blue light on both LEDs indicates the Vscan Air CL is connected.

- A steady blue LED on one Vscan Air CL side indicates the active array on the Vscan Air CL.

- A blinking yellow light on both LEDs indicates a Vscan Air CL charging issue.

- A steady yellow light on both LEDs indicates the Vscan Air CL is charging.

- A steady green light on both LEDs indicates the Vscan Air CL is fully charged.

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

- A steady red on both LEDs indicates an error.

Battery specifications

Table 3-5: 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	About 1 hour while continuously scanning
Lifetime	At least 500 charges

In order to get maximum charging capacity with your Vscan Air CL 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 CL probe outside the specified temperature range.

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 9, 10 or 11, 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 13 or 14
- 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 BLE 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.

Display devices - validation

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

- iPad
- iPad mini
- iPhone 11

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

- Samsung Galaxy S6
- Samsung Galaxy S10
- Samsung Galaxy Tablet S6
- Samsung Galaxy S20
- Google Pixel 4

Please visit the Vscan Air web page for additional information on validated 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.

Following can be done to adjust the display brightness of the device for adequate visualization.

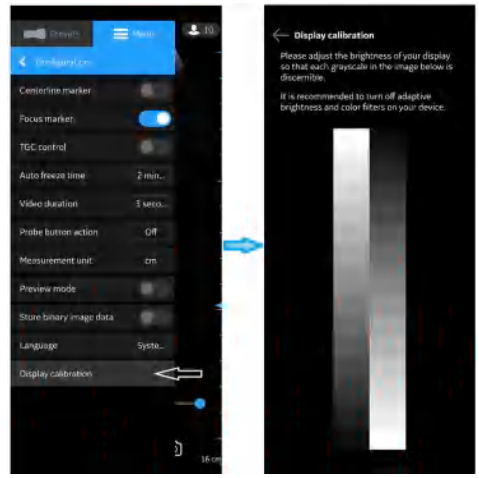


Figure 3-7. Display calibration

Display device image quality verification (continued)

There are example reference images available in the ‘Preview mode’. These images can be used to adjust the brightness level of the device, so that a full range of grey scale level is visible.

Recommended example images: Abdominal preset on Curved and MSK preset on Linear transducer.

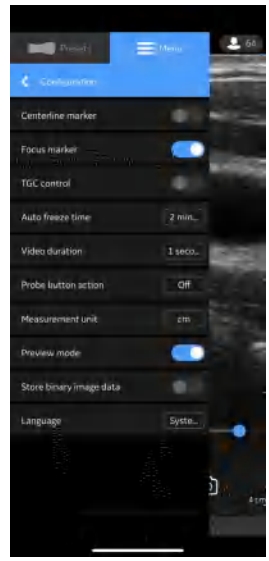


Figure 3-8. Screen with preview mode

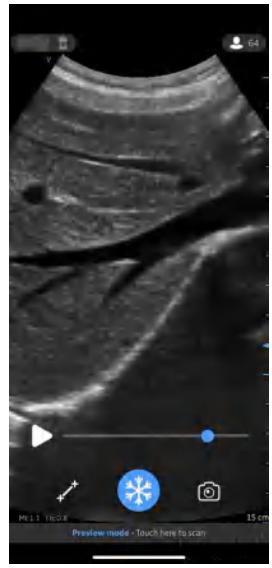


Figure 3-9. Abdominal preset with curved

Display device image quality verification (continued)

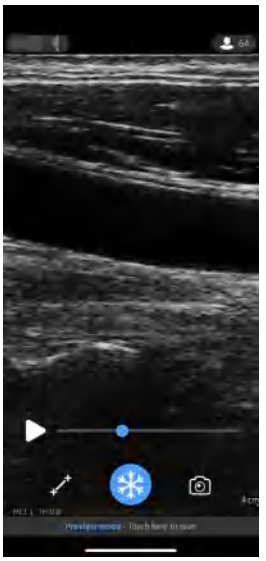


Figure 3-10. MSK preset with linear

It is also 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 CL probe on the wireless charging pad as shown in ‘How to charge the Vscan Air CL’ on *page 3-4*

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

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

Vscan Air App Version

Table 3-6: App Version

App Version (Revision)
1.0 (1.0.1.12345)

NOTE: This is an example of display format for App Version (Revision).

Activation and Registration

Each Vscan Air device needs to be registered to a user account on the Vscan Air product registration server to be activated and ready for use. The account will hold the user contact information in addition to information on devices registered to the account.

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.

Create a Vscan Air user account

1. Click on the Vscan Air app icon on the display device to start the app.
2. Press **Register** to start registration

Figure 3-11. Start registration

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

First time registration (continued)

3. Select **Create**.

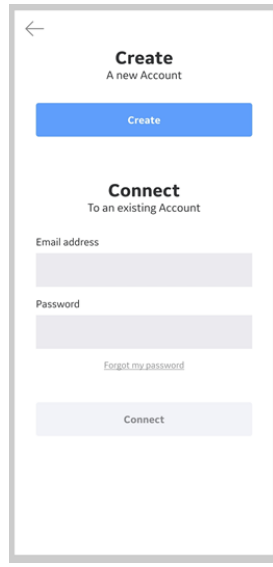


Figure 3-12. Register the Vscan Air app

4. **Turn on** Vscan Air CL.

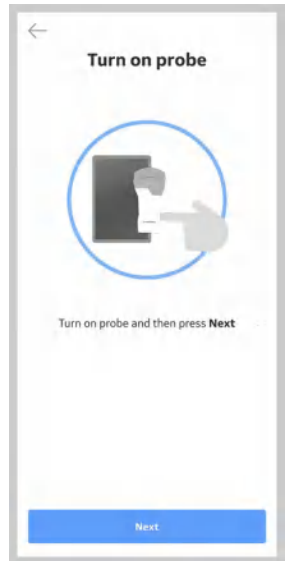


Figure 3-13. Search for Vscan Air CL

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'.

First time registration (continued)

5. Wait for initialization of Vscan Air CL.

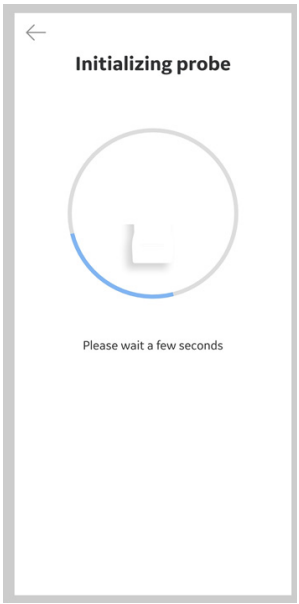


Figure 3-14. Initialization of Vscan Air CL

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

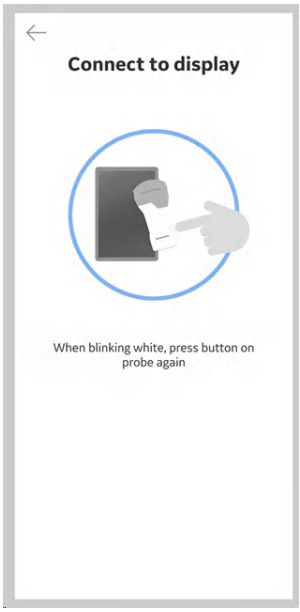


Figure 3-15. Connect to Display

First time registration (continued)

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

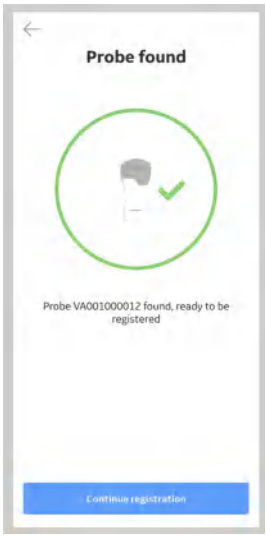


Figure 3-16. Vscan Air CL Detected

8. Enter the required information.
9. Confirm that given information is correct.
10. Check desired options to either participate in collaborative GEHC activities or to receive special offers and promotions.
11. Press **Submit**.

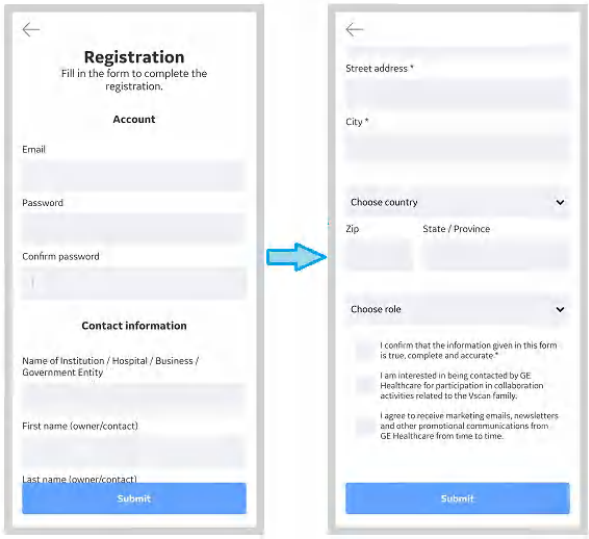


Figure 3-17. Registration Submission

First time registration (continued)

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

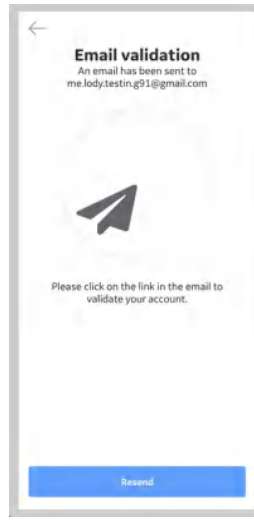


Figure 3-18. Email validation

NOTE: Please check your spam folder if not receiving the email for validating your user account.

13. Click the link in the email to validate the Vsacn Air user account.
14. **Confirm** registration details.

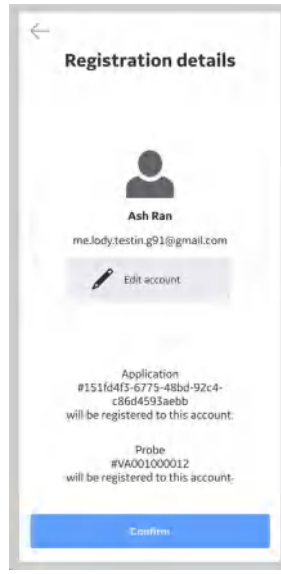


Figure 3-19. Confirm Registration

First time registration (continued)

15. Registration is complete. Security PIN can be set for secure data access by selecting '**Add security PIN**' or proceed to scanning by selecting '**Start scanning**'.

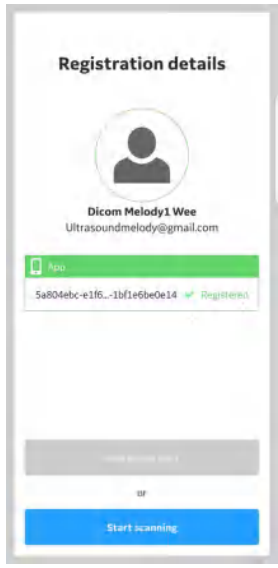


Figure 3-20. Registration Complete

16. To add a security PIN code after completing Vscan Air registration, See 'Add security PIN (data access PIN)' on *page 3-36* for more information.
17. The Vscan Air CL is now connected to the app.

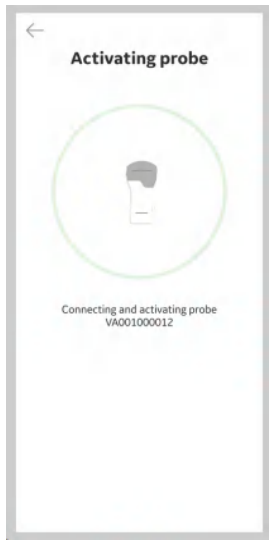


Figure 3-21. Vscan Air CL Activation

First time registration (continued)

NOTE: When the Wi-Fi connection to the paired probe is unexpectedly lost, the Vscan Air App shows warning message as 'Lost connection to Probe' (see the Figure 3-22 below).

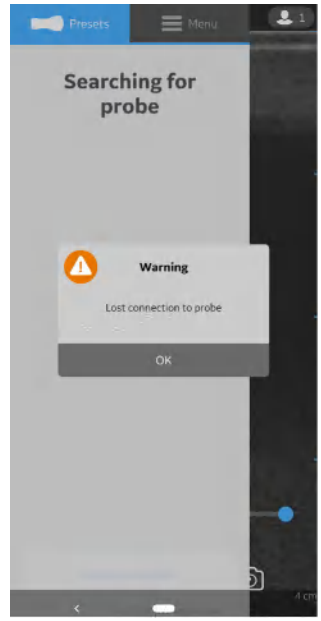


Figure 3-22. Vscan Air CL Connection Lost

New Vscan Air app Registration using an Existing Account

Use the below steps to register a new Vscan Air app on another display device with your existing Vscan Air account.

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

Figure 3-23. Welcome Screen

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

2. Choose **Connect** to an existing account option and enter the email address and password for your existing Vscan Air account.
3. Press **Connect**.

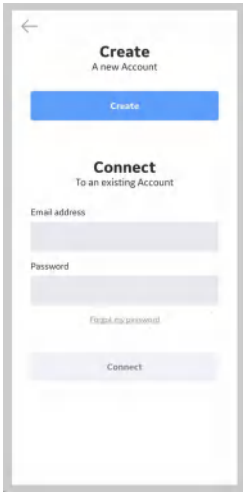


Figure 3-24. Vscan Air Account Login

New Vscan Air app Registration using an Existing Account (continued)

4. **Confirm** that registration details are correct or **edit** if incorrect.

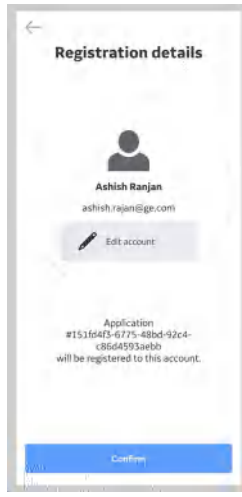


Figure 3-25. Registration Confirmed

5. Registration is complete. Security PIN can be set for secure data access by selecting '**Add security PIN**' or proceed to scanning by selecting '**Start scanning**'..

Figure 3-26. Registration Complete

6. To add a security PIN code after completing Vscan Air registration, See ‘Add security PIN (data access PIN)’ on *page 3-36* for more information.

New Vscan Air CL probe registration using existing account

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

Figure 3-27. Search for Vscan Air CL probe

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

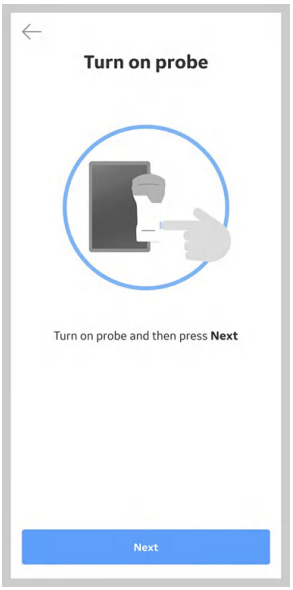


Figure 3-28. Turn On Vscan Air CL probe

New Vscan Air CL probe registration using existing account (continued)

4. Wait for initialization of Vscan Air CL.

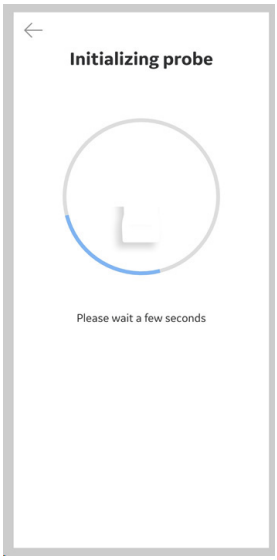


Figure 3-29. Initialization of Vscan Air CL

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

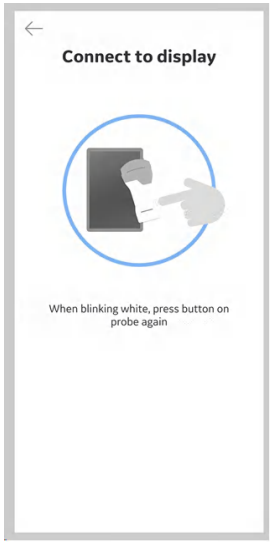


Figure 3-30. Connect to Display

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

New Vscan Air CL probe registration using existing account (continued)

6. Once Vscan Air CL is found, press “**Continue registration**' and ‘**Connect**’ to an existing Vscan Air user account.

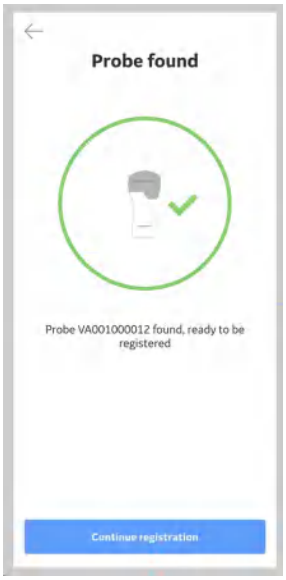


Figure 3-31. Vscan Air CL Detected

7. Enter the email address and password to your existing Vscan Air account. Press **Connect**.

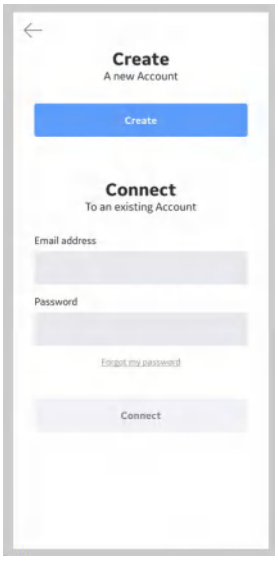


Figure 3-32. Confirm Registration

New Vscan Air CL probe registration using existing account (continued)

8. **Confirm** that registration details are correct or **edit** if incorrect.

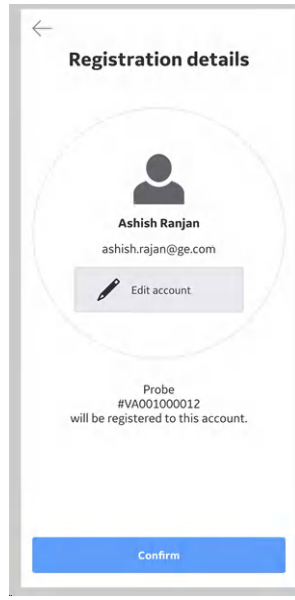


Figure 3-33. Confirm Registration

Figure 3-34. Registration complete

New Vscan Air CL probe registration using existing account (continued)

9. Registration is complete. Press **Start scanning** to begin using your Vscan Air CL device.

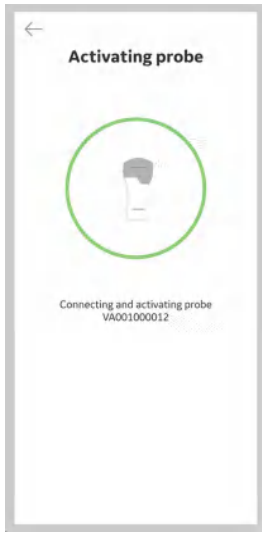


Figure 3-35. Vscan Air CL activation

10. When the scanning is over switch off the probe. The Vscan Air app on screen displays the message '*Probe is shutting down*".

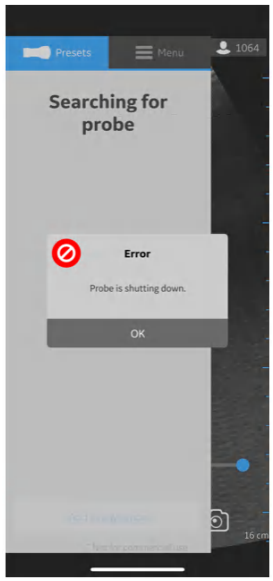


Figure 3-36. Probe shutting down

Security

Exam Information/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.

- To enable a data access PIN, See ‘Ask for data access pin’ on *page 4-25* for more information.
- To additionally enable biometric authentication, See ‘TouchID for quick data access (Biometric authentication)’ on *page 3-38* for more information.

Add security PIN (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. From Registration Details screen, Press **Add security PIN** button.

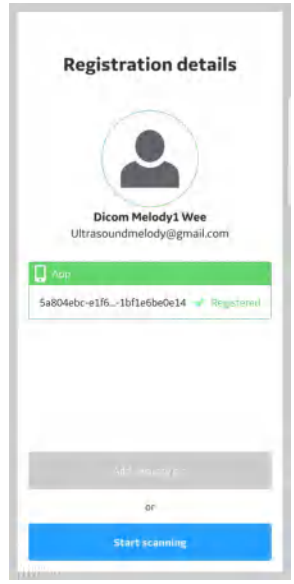


Figure 3-37. Add security PIN

Add security PIN (data access PIN) (continued)

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

Figure 3-38. Enter data access PIN

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

3. 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.

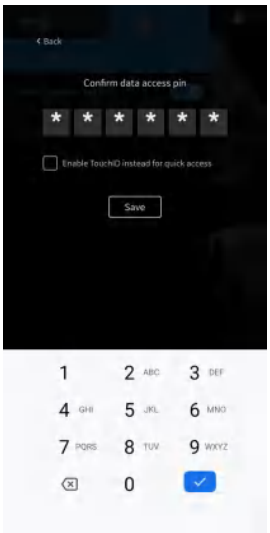


Figure 3-39. Confirm data access PIN

TouchID for quick data access (Biometric authentication)

To enable biometric authentication for quick data access, See ‘TouchID for quick data access (Biometric authentication)’ on *page 4-27* for more information.

Change data access PIN

To change the data access PIN, See ‘Change data access PIN’ on *page 3-38* for more information.

Multi Vscan Air probes detection

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

When there are two Vscan Air CL devices (for example A and B) in the vicinity of the display device, the closest one is detected. If you wish to use Vscan Air CL A, turn OFF Vscan Air CL B or put it far away from the display device. Press the power button on Vscan Air CL 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 CL probe has no ability to connect to Vscan Air App while in Preview mode. You can explore 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 CL 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 CL.

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 CL probe is lost.

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

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

NOTE: The display device shall be encrypted and user authentication enabled (password or PIN with sufficient complexity) before the user can store or access any already stored images or videos.

Unregister Vscan Air Probe

To Unregister Vscan Air Probe, follow the procedure below:

1. Press Menu -> About -> Registered devices

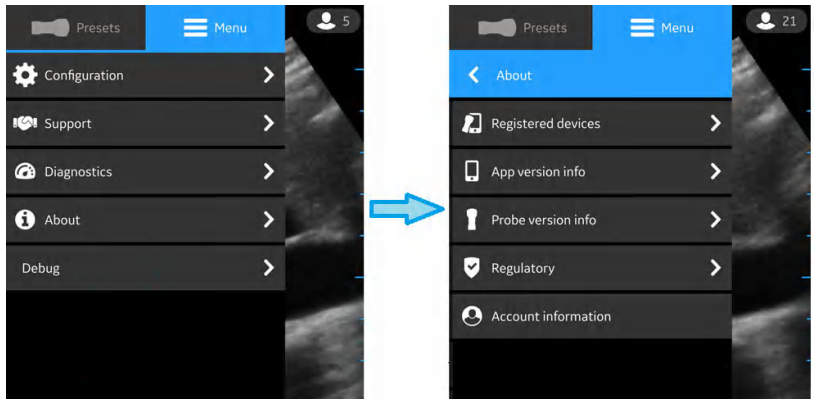


Figure 3-40. Registered devices

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

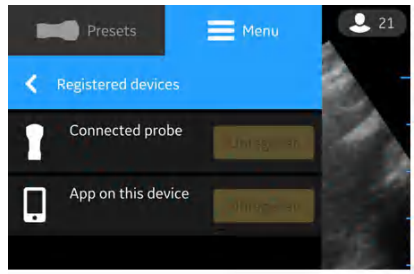


Figure 3-41. Unregister Probe

Unregister Vscan Air app

To Unregister Vscan Air app, follow the procedure below:

1. Press Menu -> About -> Registered devices

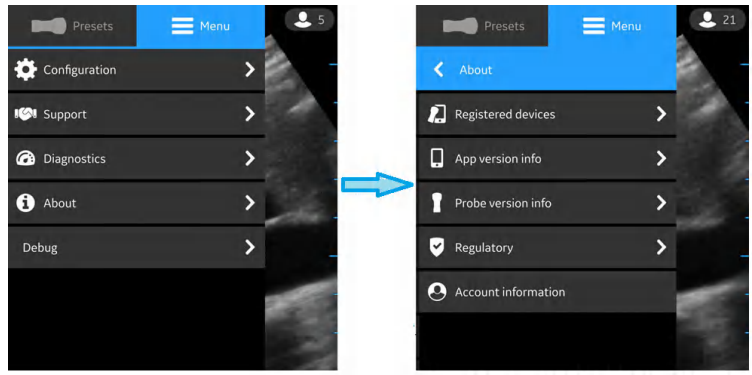


Figure 3-42. Registered devices

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

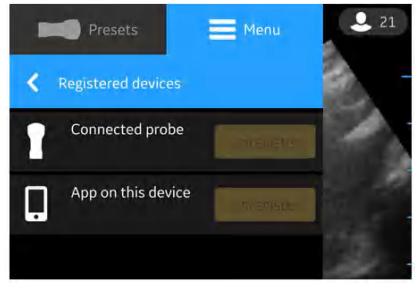


Figure 3-43. Unregister app

Unregister Vscan Air app (continued)

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

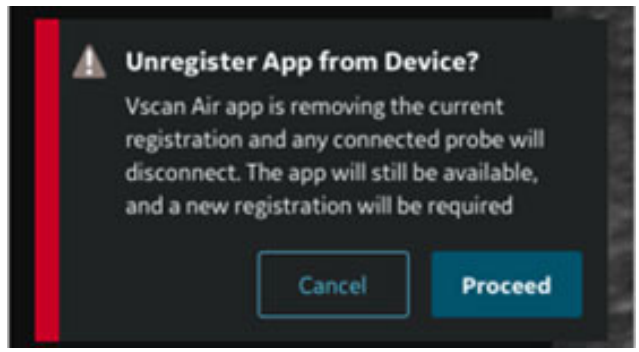


Figure 3-44. Unregister app warning

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.

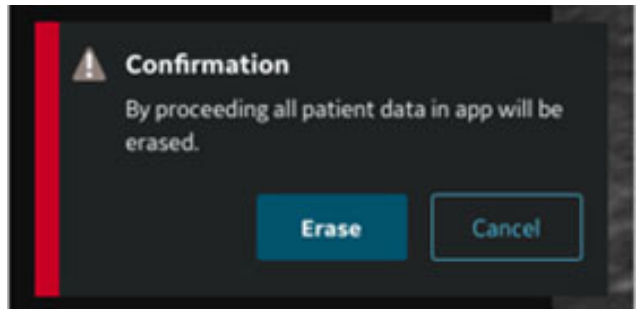


Figure 3-45. Erase data

Chapter 4

Vscan Air Configuration (for iOS and Android)

Contents:

Configuration

The following functions are available under the main menu.

1. Configuration
2. Support
3. Diagnostics
4. About

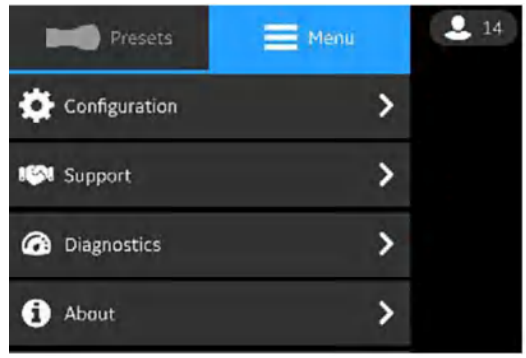


Figure 4-1. Menu

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.

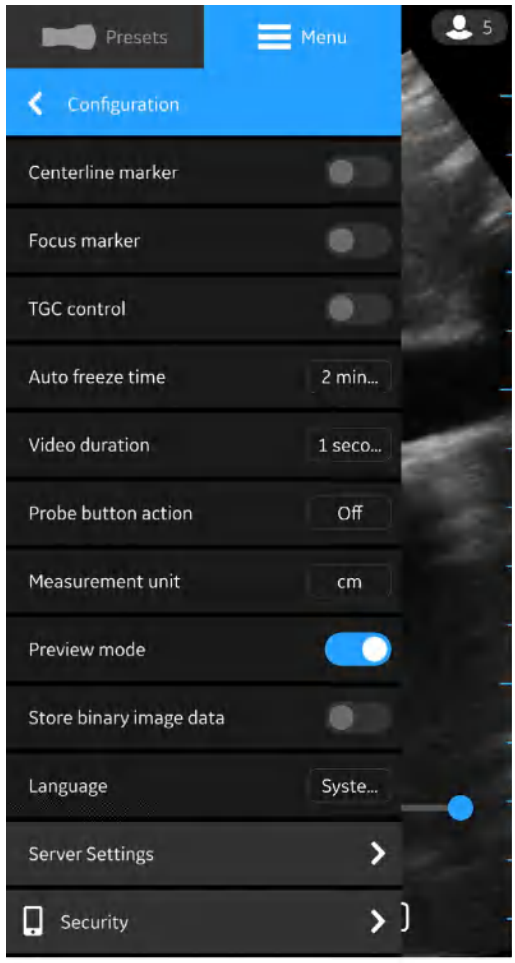


Figure 4-2. Configuration

Configuration (continued)

- **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.

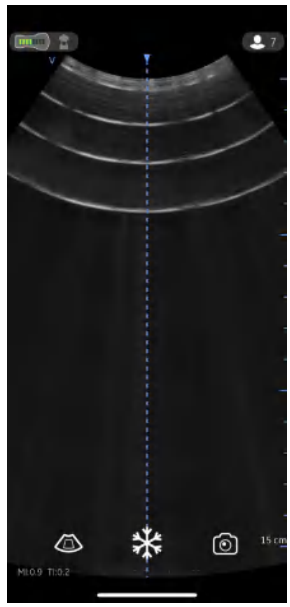


Figure 4-3. Centerline marker

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.

- **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 B-mode Focus Marker, color scanning, in freeze and replay.

Configuration (continued)

- **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 or landscape layouts.

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

- **Auto Freeze Time**
  - 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.

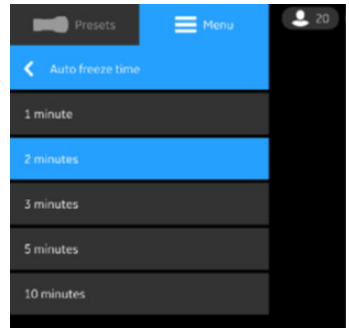


Figure 4-4. Auto freeze time

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)

- **Video duration**
  - 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.

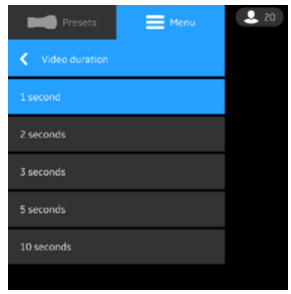


Figure 4-5. Video duration

- **Probe Button Action**
  - Press Probe Button Action.
  - Tap to choose either Freeze or Save or Off to configure with no action with the Probe button press.

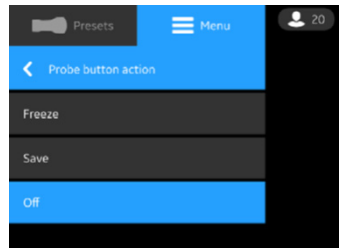


Figure 4-6. Probe button action

- **Measurement Unit** - Tap to choose either cm or mm.

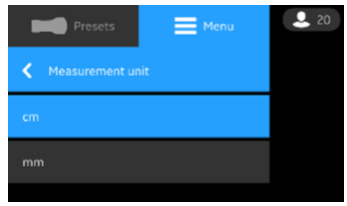


Figure 4-7. Measurement unit

Configuration (continued)

- **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.

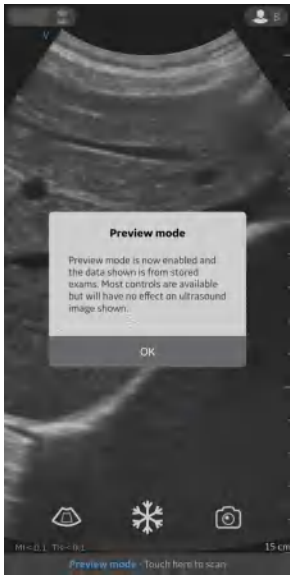


Figure 4-8. Preview mode

Configuration (continued)

- **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 4-9. Binary image data store pop-up

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

- **Language** - Choose the desired language

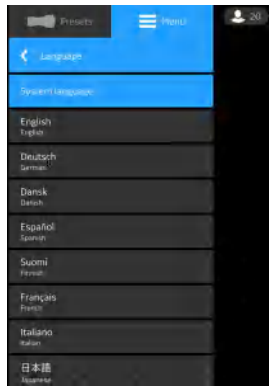


Figure 4-10. Language

CAUTION

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

DICOM Client

1. Follow the procedure below to configure DICOM Client.
   Press Menu -> Configuration -> DICOM Client.

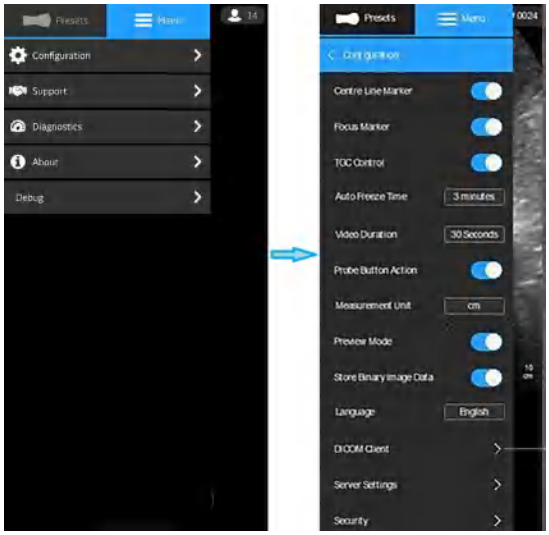


Figure 4-11. DICOM Client

2. Specify or update the default values of DICOM Client (Vscan Air) information in the respective fields on DICOM Client screen to establish communication with DICOM servers.

Figure 4-12. DICOM Client (Vscan Air)

Server Settings

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 the desired path in a PC.

Configure Modality Worklist Server

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

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

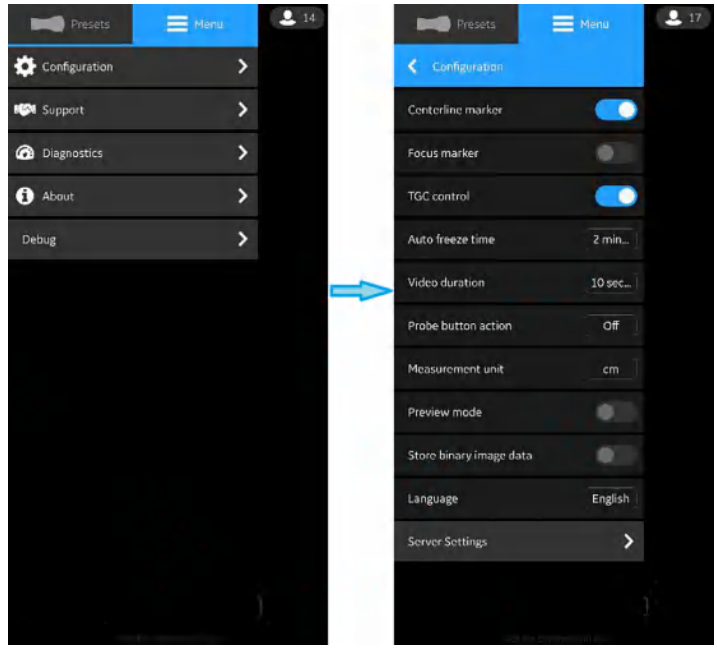


Figure 4-13. Server Settings

Configure Modality Worklist Server (continued)

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

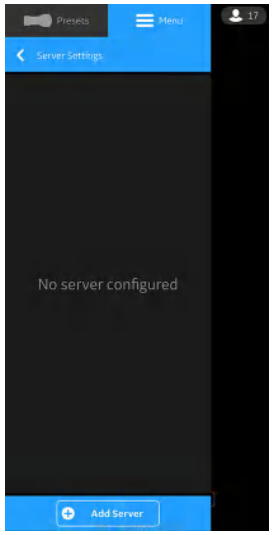


Figure 4-14. Add Server

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 5-61* for more information.

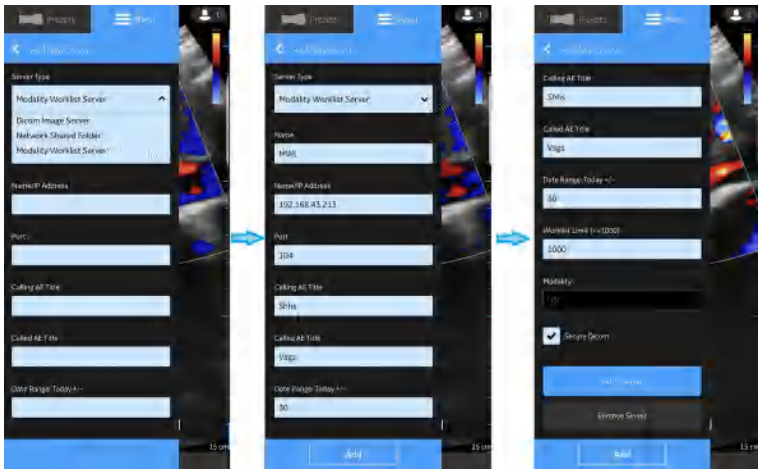


Figure 4-15. Enter Configuration Information.

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 ok.

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

   If communication fails, check the server settings and make necessary corrections.

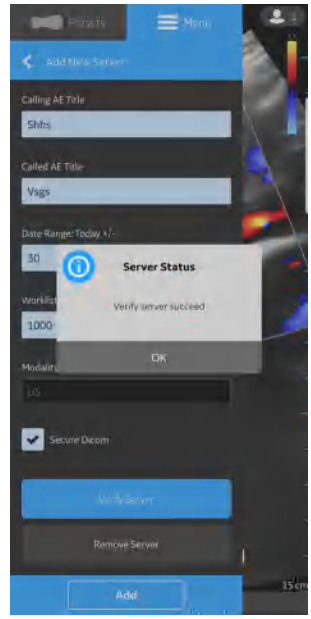


Figure 4-16. Verify Worklist Server

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

Configure Modality Worklist Server (continued)

5. Once the Modality Worklist Server is added, the server name will be available under Server Settings. If this is the first MWL server that is added, it will be the favorite server. If there are more than one MWL/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.

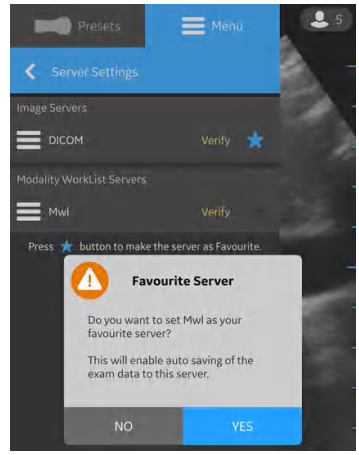


Figure 4-17. Worklist server as Favourite

Configure Dicom Image Server

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

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

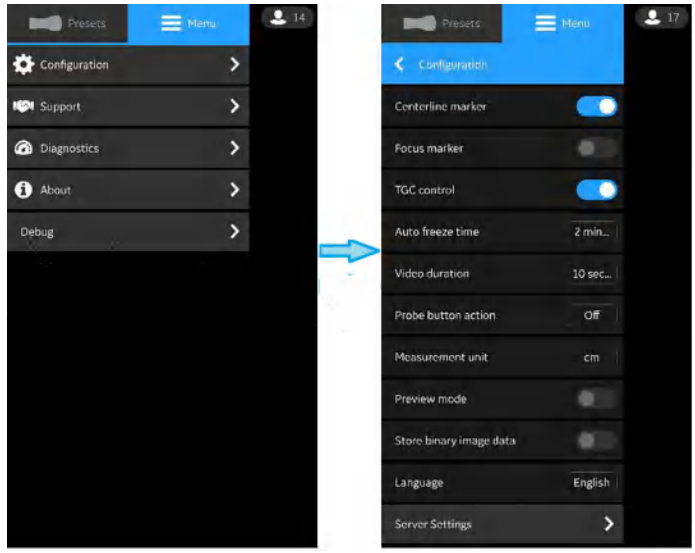


Figure 4-18. Server Settings

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

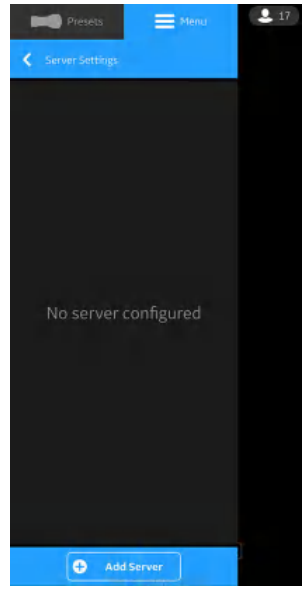


Figure 4-19. Add Server

Configure Dicom Image Server (continued)

3. In “**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 Dicom Image Server.

   If Dicom Image Server is of Secure Dicom (TLS communication), select the check box “Secure Dicom”. See ‘Secure Dicom’ on *page 5-61* for more information.

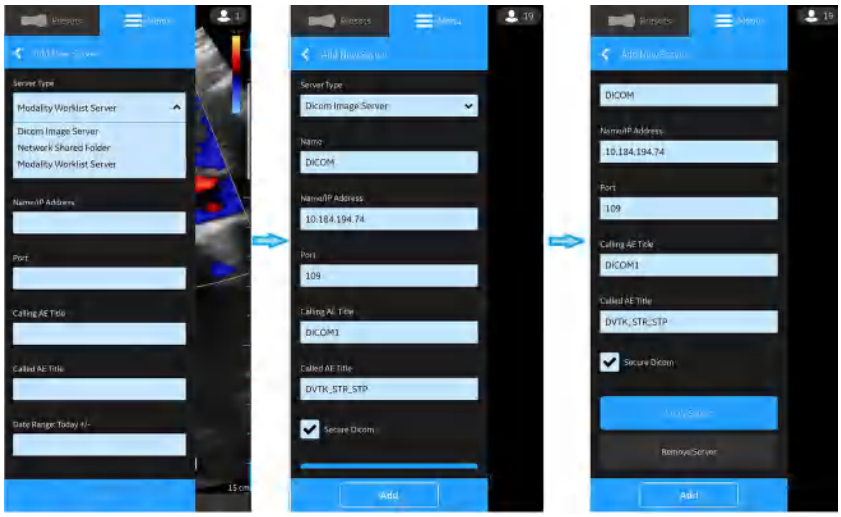


Figure 4-20. Enter Configuration Information

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 ok.

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

   If communication fails, check the server settings and make necessary corrections.

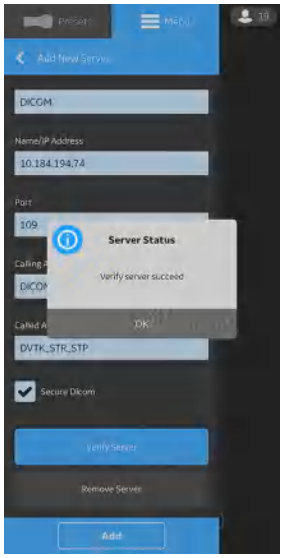


Figure 4-21. DICOM Image Server

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 this is the first Dicom Image Server that you are adding, by default it will be the favourite server. If there are more than one Dicom Image Servers, you have to choose the desired Dicom Image Server as 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 4-22. Select DICOM Image server as favourite

Storage Commit

Storage Server

Storage Server is nothing but the Dicom Image Server that recieves and stores the Exam data from Vscan Air app.

Commitment Server

Commitment Server sends confirmation to the Vscan Air app when the Storage Server successfully recieves 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 deisplay device after exporting it to that particular Dicom Image Server.

To enable “Auto Delete” functionality, follow the procedure below:

1. While configuring the Dicom Image Server, tap on the Commitment Server drop-down button. See ‘‘Configure Dicom Image Server’ on *page 4-14* 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 commotment server.

“Verify server succeed” pop-up message displays if the communication with the Server is ok.

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.

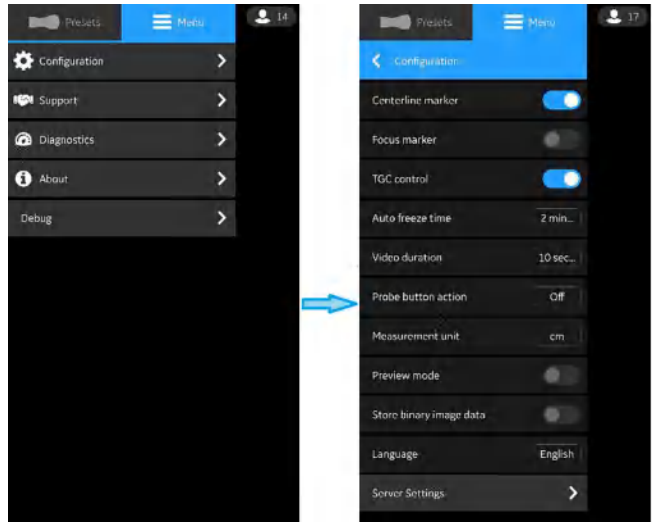


Figure 4-23. Server Settings

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

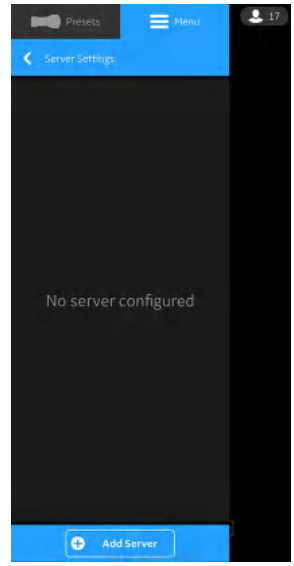


Figure 4-24. Add Server

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 comprehensive exam info**". See ‘Comprehensive exam info’ on *page 5-69* for more information.

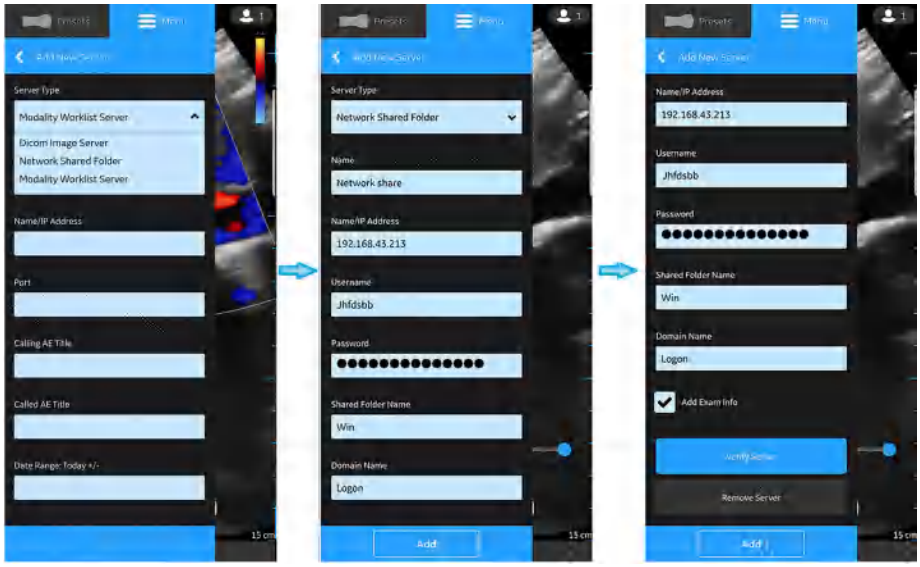


Figure 4-25. Enter Configuration Information

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 ok.

   Press **OK** and then Press “**Add**” to add the Network Shared Floder.

   If communication fails, check the server settings and make necessary corrections.

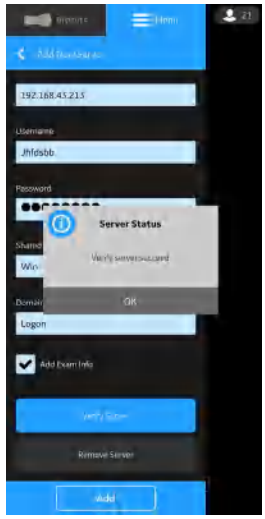


Figure 4-26. Verify Network Shared Folder

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 this is the first Network Shared Folder that you are adding, by default it will be the favorite server. If there are more than one Network Shared Folder, then one of them have 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.

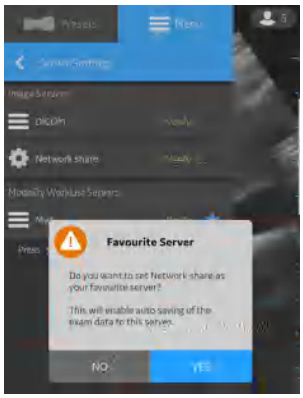


Figure 4-27. Network Shared Folder as Favourite

Remove Server

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

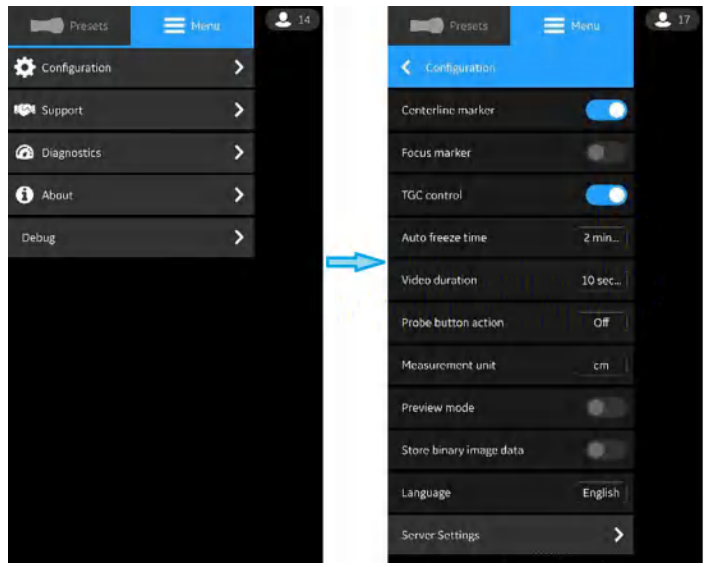


Figure 4-28. Server Settings

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

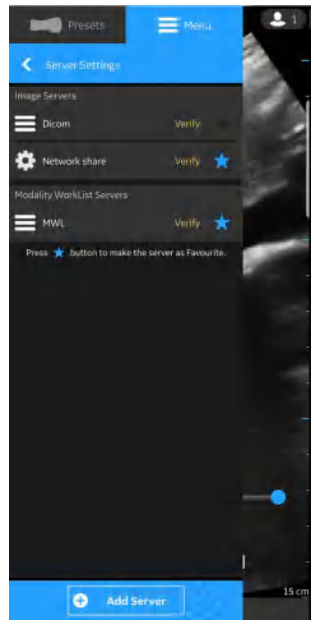


Figure 4-29. List of Servers

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.

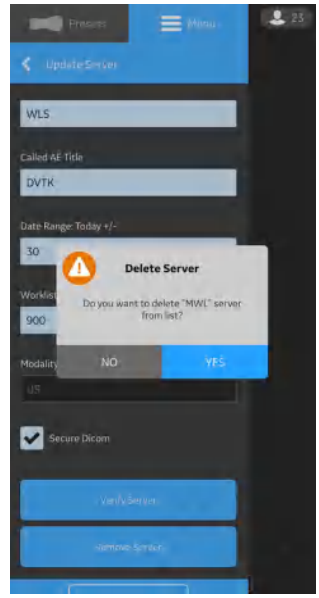


Figure 4-30. Remove Server

Security

Exam Information/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.

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.

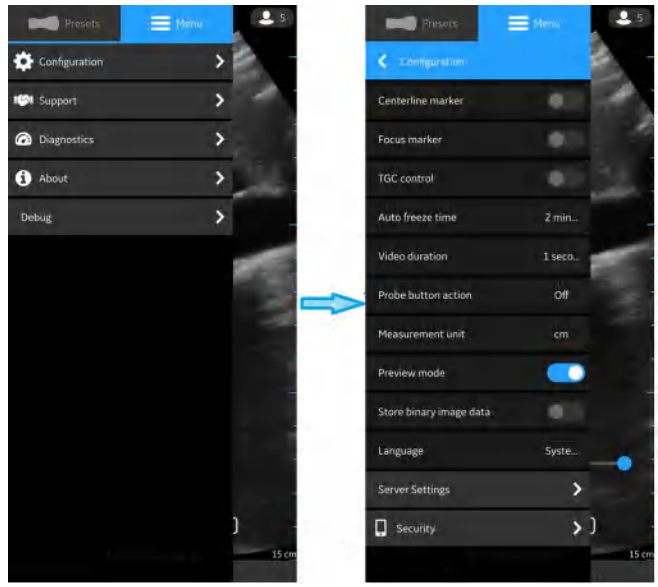


Figure 4-31. Security settings

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

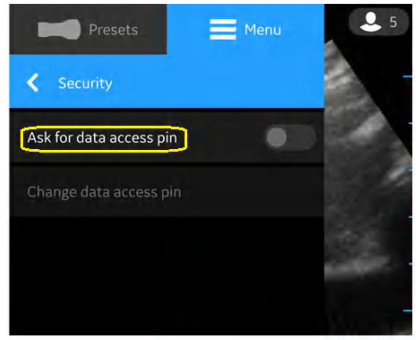


Figure 4-32. Tap on the Ask for data access pin button

Ask for data access pin (continued)

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

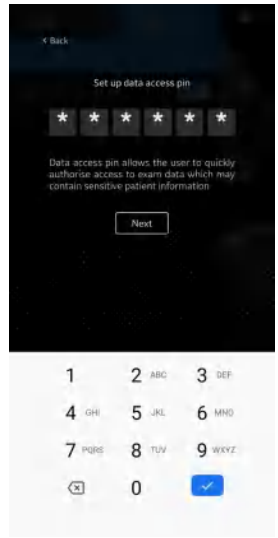


Figure 4-33. Enter data access pin

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

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.

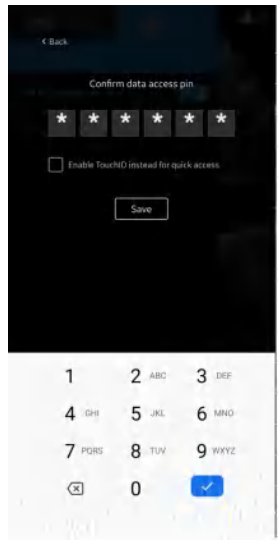


Figure 4-34. Confirm data access pin

TouchID for quick data access (Biometric authentication)

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

1. Press Menu -> Configuration -> Security.

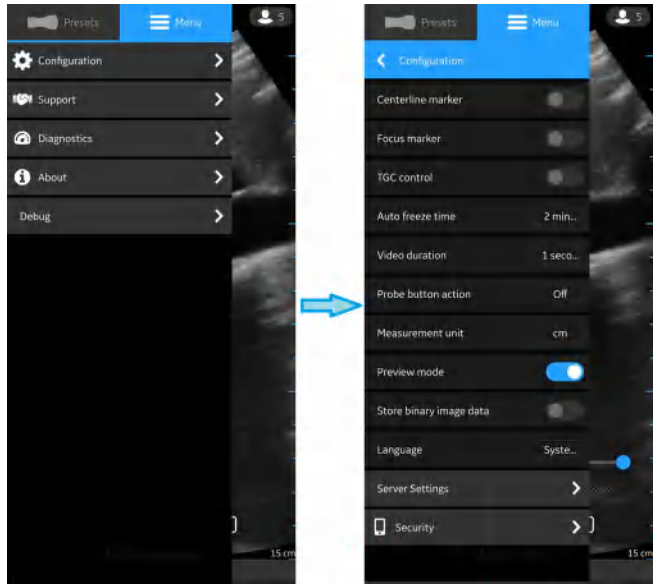


Figure 4-35. Security settings

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

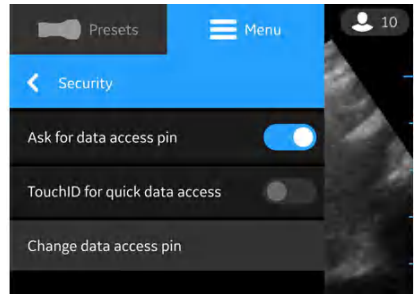


Figure 4-36. Activate Biometric Authentication

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.*

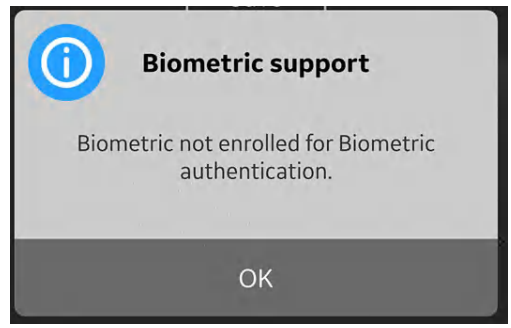


Figure 4-37. Biometric authentication error

Change data access pin

Follow the procedure below to change the data access pin.

1. Press Menu -> Configuration -> Security.

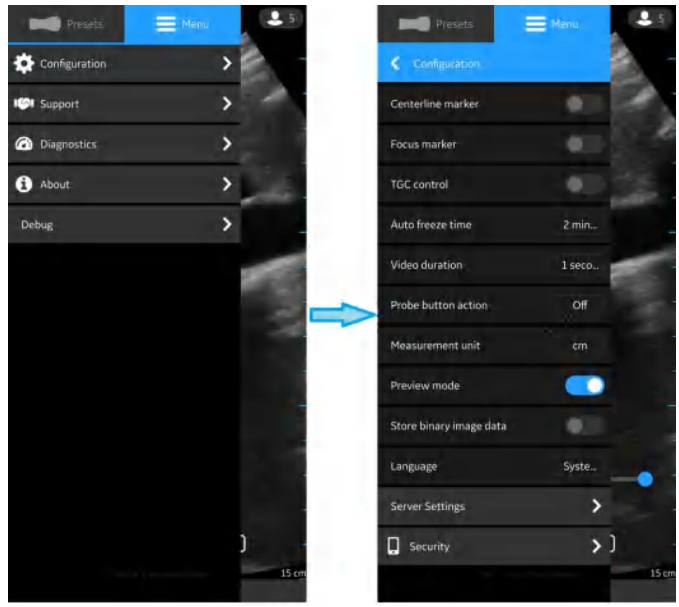


Figure 4-38. Security settings

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

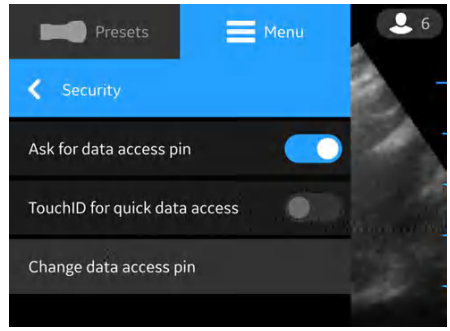


Figure 4-39. Change data access pin

Change data access pin (continued)

3. Under the “Change data access pin” screen, enter your **existing pin**, then enter **new pin** and Confirm the new pin.

   Press **Save** button. After successful set up of new data access pin, application takes you to the Security screen.

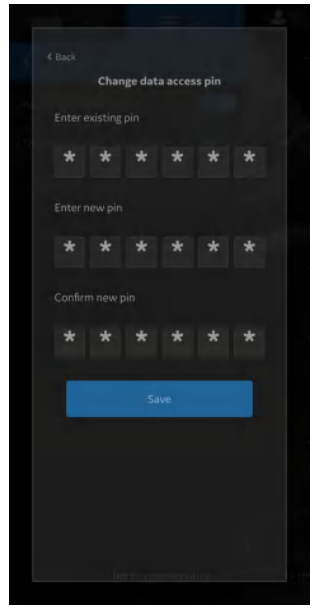


Figure 4-40. Confirm data access pin

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

Support

Support

The **Support** option displays - User manual, Hotline, Case library and Tutorials.

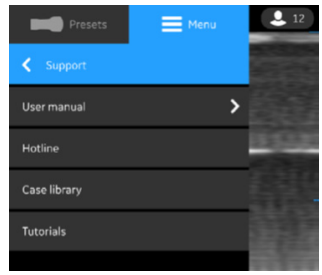


Figure 4-41. Support

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

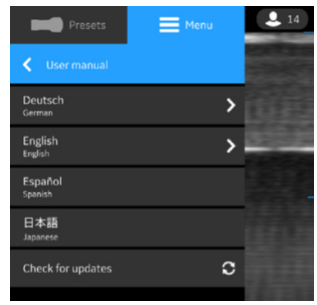


Figure 4-42. User Manual

- **Hotline** - To access list of GEHC Service Centre contact numbers
- **Case Library** - Vscan Air web page that provides access to reference image and case examples.
- **Tutorials** - Directs to the Vscan Air web page that provides access to multiple video tutorials to learn more about using Vscan Air.

Diagnostics

Diagnostics

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

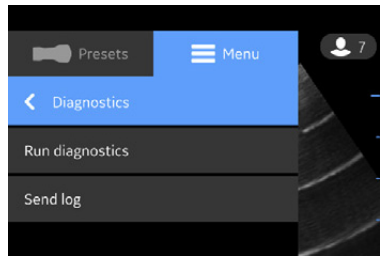


Figure 4-43. Diagnostics

- **Run Diagnostics** - To run all the Diagnostic tests refer the section ‘Diagnostics Test’ on *page 6-21*.

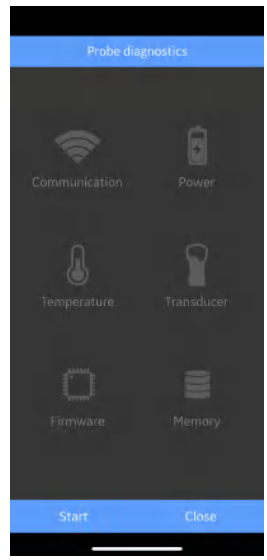


Figure 4-44. Run Diagnostics

Diagnostics (continued)

- **Send log** - On selecting the send log button, the device will send diagnostics logs and system logs to the server.

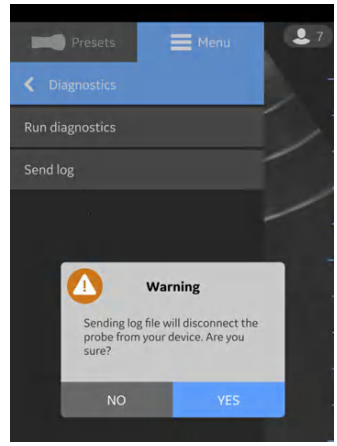


Figure 4-45. Send log warning - iOS

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

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

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

About

About

The **About** option displays - Registered devices, App version info, Probe version info, Regulatory, Account information and Acknowledgements.

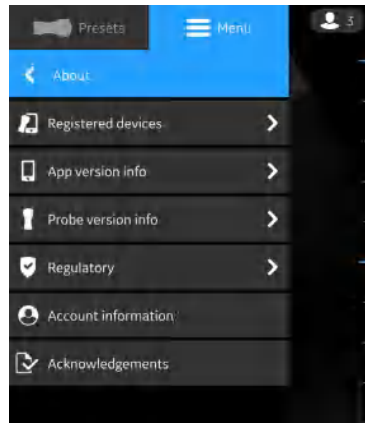
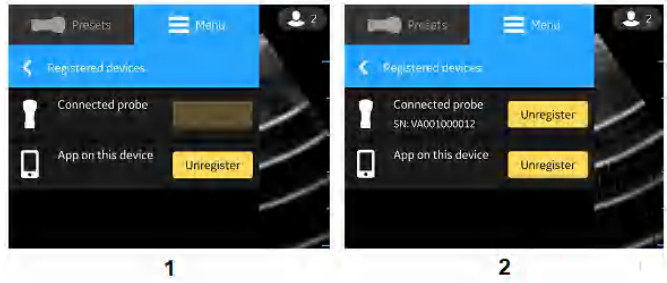


Figure 4-46. About

About (continued)

App Details

- **Registered devices** - Displays Connected Probe and App on this device.



1. Unregistered Probe
2. Registered Probe

Figure 4-47. Registered devices

- **Unregister:**

  To unregister Vscan Air CL probe or Vscan Air App, you select "**Unregister**" and confirm.

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

  If unregistered, Vscan Air App current registration and any connected probe will disconnect. The app will still be available, and a new registration will be required.

About (continued)

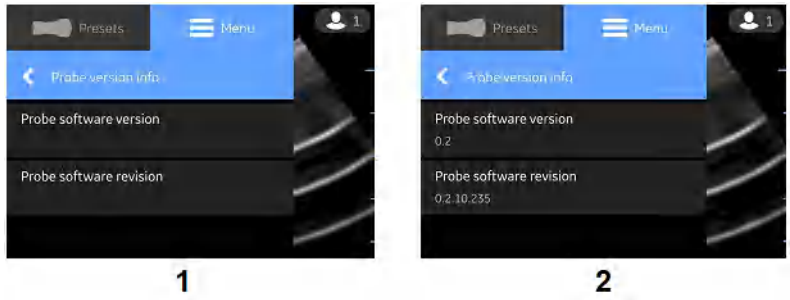
- **App version info**

  App version info - Displays App software version and App software revision.

Figure 4-48. App version info (example)

- **Probe version info**

  Probe version info - Displays Probe softwre version and Probe software revision



1. Unregistered Probe
2. Registered Probe

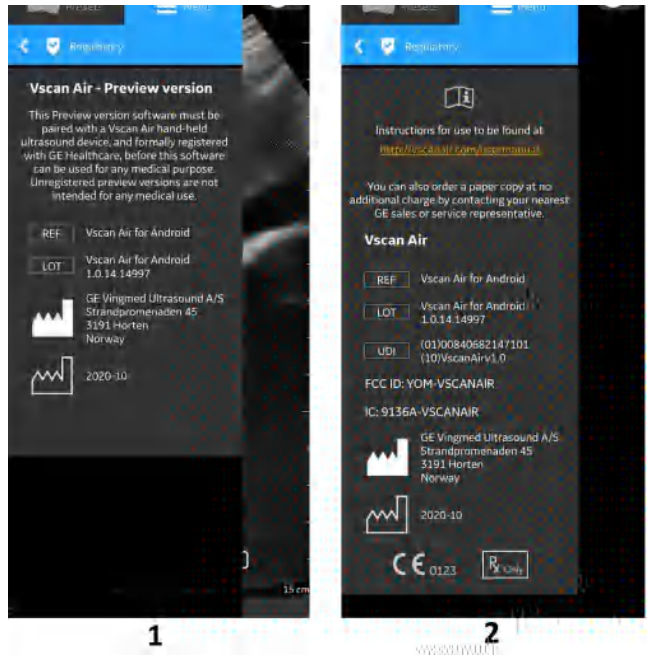
Figure 4-49. Probe version info (example)

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

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

About (continued)

- **Regulatory**



1. Before registration
2. After registration

Figure 4-50. Regulatory

- **Account information**

1. Press the Account information tab.

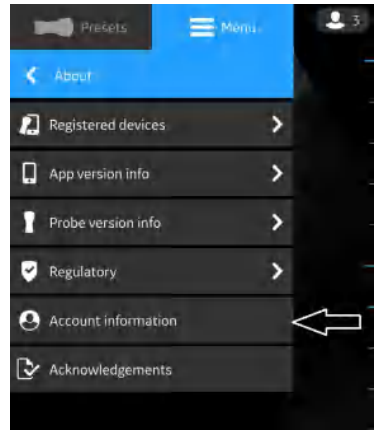


Figure 4-51. Account Information

About (continued)

2. Use the existing Vscan Air user account email and password to log in.

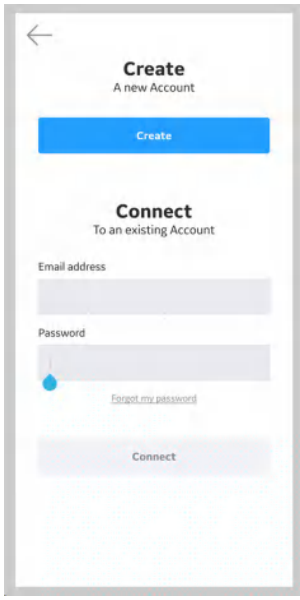


Figure 4-52. Connect to existing account

3. Update the account details if needed.

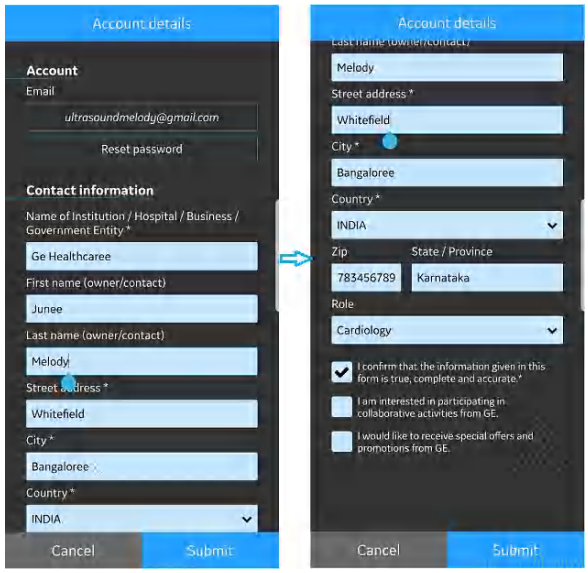


Figure 4-53. Account details

About (continued)

4. Check to confirm the given information.
5. Press **Submit**, to update the Account details.

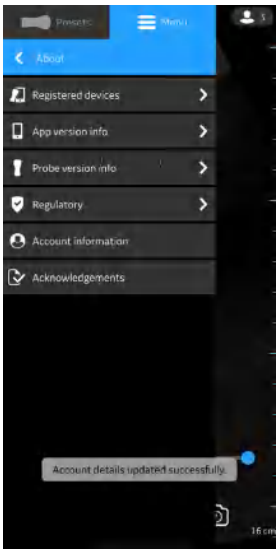


Figure 4-54. Account details Updated

- **Acknowledgements** - Displays the third party software licience.

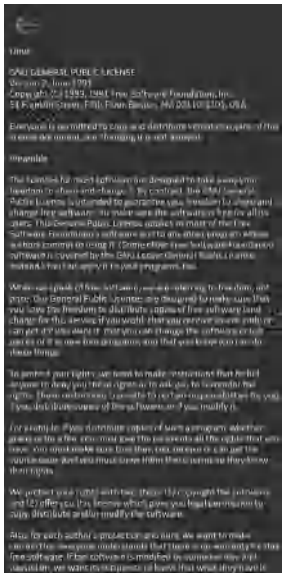


Figure 4-55. Acknowledgements

Chapter 5

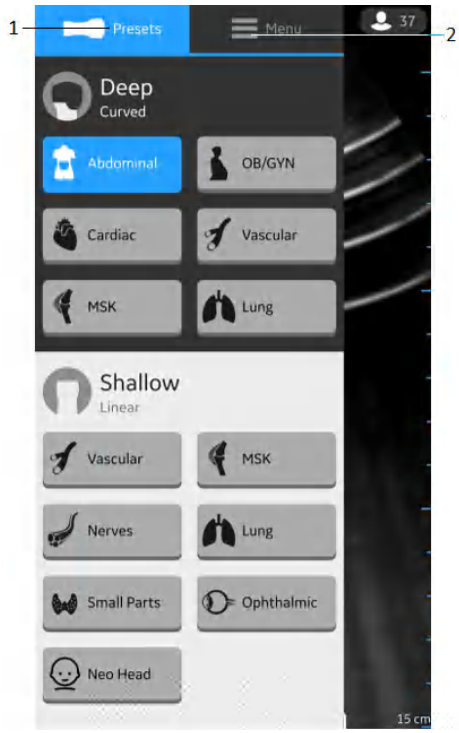
Using Vscan Air CL

Contents:

Display Features

Left panel

Swipe left to right or tap on the Vscan Air CL probe icon on left hand top corner to access presets and menu options.



1. Presets
2. Menu

Figure 5-1. Left panel

See ‘Probe and Presets’ on *page 5-9 for more information.*

Right panel

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

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

Figure 5-2. Right Panel

- Start a new exam - Press **New Exam** on right corner at the bottom of the screen to start a new exam.
- Current exam - Displays the current exam number
- Exams - Displays a list of previously saved exams that can be selected to access stored images and videos.

Scanning

General scanning recommendations

Before each use:

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

After Each Use

- Inspect the Vscan Air CL (see ‘Inspection’ on *page 6-3*)
- Clean the Vscan Air CL (see ‘Cleaning and disinfection’ on *page 6-4*).
- If required, disinfect the Vscan Air CL (see ‘Cleaning and disinfection’ on *page 6-4*).

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

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

Use of Gel

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

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

Use of Gel (continued)

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

Table 5-1: Compatible Gels

	
Aquasonic	Parker Laboratory Inc.
Clear Image	Sonotech Inc.
Scan	Parker Laboratory Inc.
Sonogel	Sonogel Vertriebs GmbH
Wavelength	National Therapy Products Inc.

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

Other recommendations

Like most high frequency computing devices, the electronic components of Vscan Air CL will generate some heat while operating normally and as intended. Vscan Air CL is equipped with safety mechanisms which will automatically reduce computing speed (frame rate), and ultimately shut down the device, before any risk of overheating occurs. Vscan Air CL is verified to comply with harmonized safety standards (see ‘Conformance Standards’ on *page i-6*) under any operating condition described in this user manual (see ‘Environmental requirements for Vscan Air CL’ on *page 3-7*). To help keeping the Vscan Air CL operating temperature at an optimal functional level, and to ensure longer scanning time with maximum frame rate, it is recommended to hold the Vscan Air CL such that there is good contact between the device and the hand.

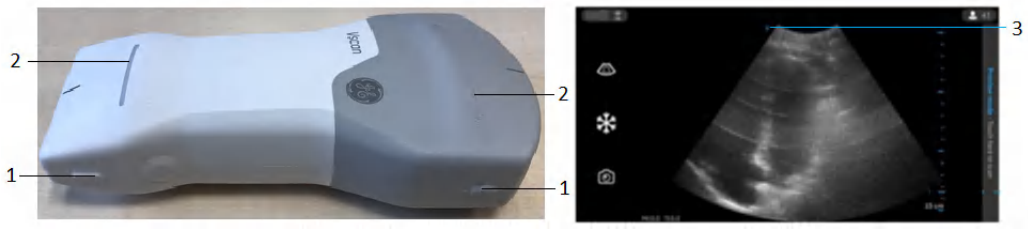
For patient and personnel safety, be aware of biological hazards. To avoid the risk of disease transmission:

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

Probe orientation

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

A steady blue LED light on one end of the Vscan Air CL indicates which transducer head is active.



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

Figure 5-3. Vscan Air CL Orientation

Patient examination

Creating a new exam

A new exam can be created in two ways:

1. Automatically - when the Vscan Air CL is turned ON and paired successfully with the Vscan Air app.
2. Manually - Create a New Exam from the right panel.
   - Swipe from right to left or tap the 'icon' on the right upper corner to bring out the right panel.
   - Press **New Exam** on the bottom right corner of the screen.

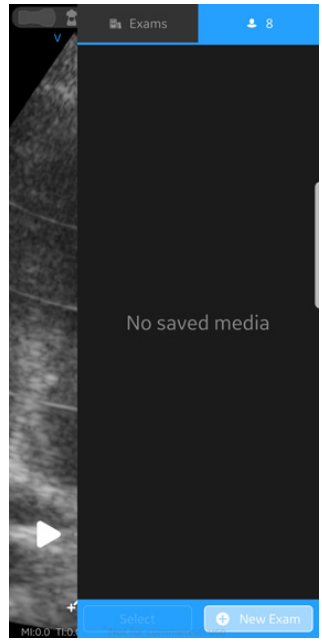


Figure 5-4. New exam

NOTE: A new exam also gets created everytime a Vscan Air CL connects with the app.

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

WARNING

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

Storing an image/video

Refer to sections ‘Storing an image’ on *page 5-26* and ‘Storing a video’ on *page 5-27*.

Probe and Presets

Use of presets

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

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

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

		OB/Gyn	• Obstetrics
			  • Uterus
			  • Fetus
			  • Placenta
			  • Amniotic fluid
			• Gynecology
			  • Uterus including cervix
			  • Ovaries and adnexa

		Vascular	• Abdominal aorta • IVC • Other veins and arteries
		Lung	• Thoracic/Pleural motion • Lung tissue • Fluid detection

Use of presets (continued)

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

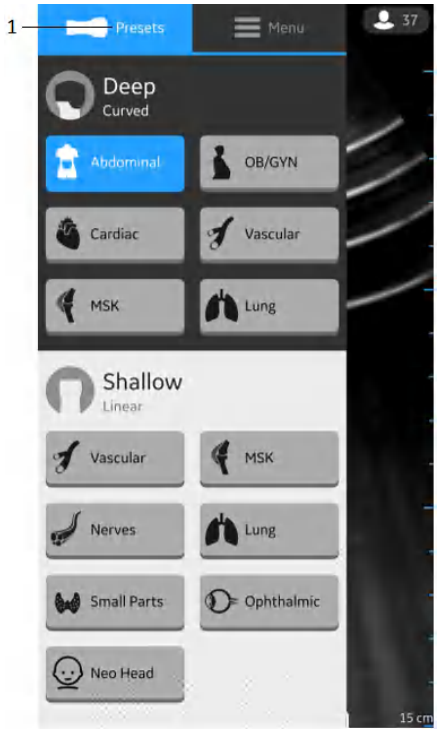
Linear array transducer	Preset		Optimized for
		Vascular	• Veins • Arteries
		Nerves	Peripheral nerves
		Small Parts	• Small organs • Pediatric (recommended minimum weight: 4 kg) • Soft tissue
		MSK	Musculoskeletal superficial • Joints • Long bones • Muscles • Tendons • Ligaments
		Lung	• Thoracic/Pleural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

To change the preset and probe

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

   All presets available for Vscan Air CL are displayed.

   Presets are grouped according to the deep scanning (Curved array) and shallow scanning (Linear array) ability of the Vscan Air CL.



1. Presets

Figure 5-5. Preset menu

2. Select the desired preset.

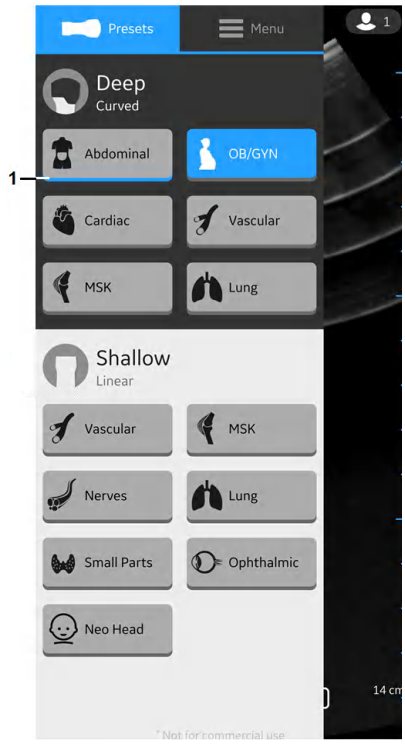
   The preset selected automatically activates the transducer for that preset.

3. To change the preset, swipe from right to left again. Choose the desired preset.
4. Selected preset is highlighted in blue.

To set a preset as default

Press and hold the preset which needs to be set as default.

A small blue bar displays on the bottom of the preset indicating that it is set as default.



1. Blue Bar

Figure 5-6. Preset as default

Resolution and Penetration setting

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

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

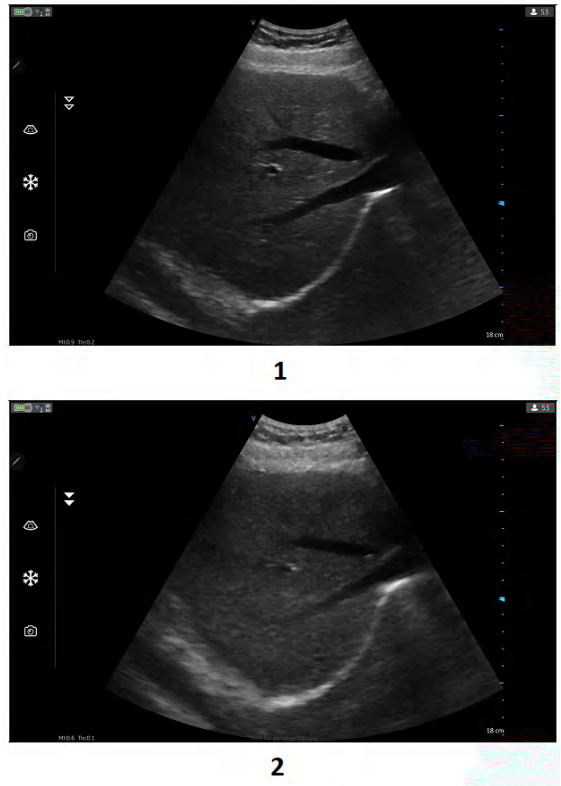
Penetration setting is useful for imaging at greater depths by optimizing visualization of structures in the far-field in larger than average or difficult to scan patients. An increase in penetration is obtained at the expense of decreased resolution.

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

Curved array	Linear array
Abdominal	Vascular
Cardiac	

Resolution and Penetration setting (continued)

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



1. Resolution setting (default)
2. Penetration setting

Figure 5-7. Resolution and Penetration setting

Black/white imaging (B-mode)

NOTE: Scanning does not start if the Vscan Air CL is not connected to a Vscan Air App.

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

Black and white imaging is the default scanning mode.

Figure 5-8. Black/ white (B-mode) scan screen

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

Black and white imaging adjustments

Gain

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

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

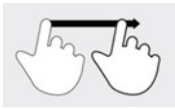


Figure 5-9. Drag

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

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

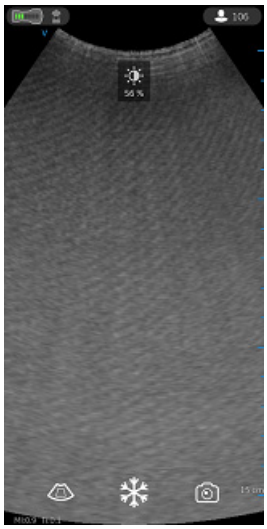


Figure 5-10. Gain

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

Time Gain Compensation (TGC)

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

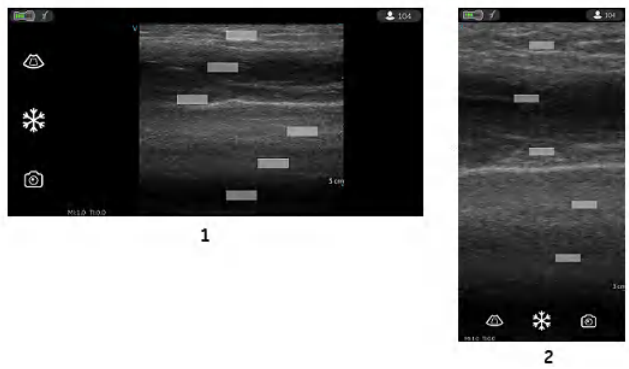
TGC sliders are spaced proportionately to the depth. The area each slider amplifies varies as well.

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

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

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

The TGC sliders will disappear from screen after a timeout period.



1. Landscape mode
2. Portrait mode

Figure 5-11. TGC

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

Depth

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

1. Swipe your finger up/down on the screen at least half a centimeter to initiate depth

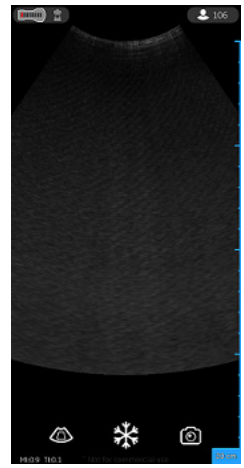


Figure 5-12. Depth adjustment

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

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

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

   OR

   Change depth per 0.5 cm from 2-5 cm.

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

Zoom an image

Pinch on the image with two fingers to zoom.

Figure 5-13. Pinch

NOTE: You can zoom images only before saving.

Color flow (Color doppler)

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

1. Press the **Color** icon.

   A color flow area displays on top of the black and white image.

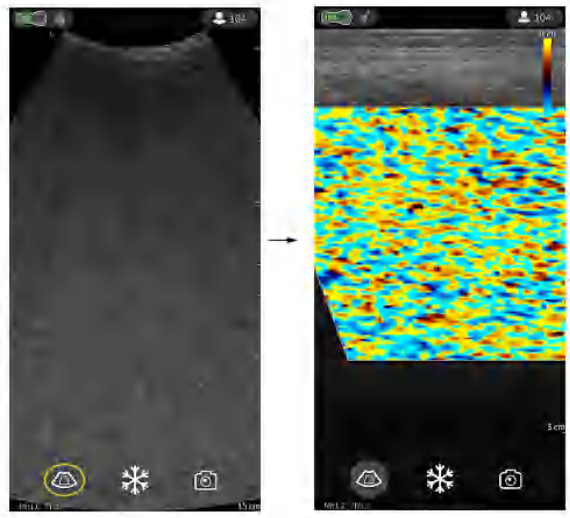


Figure 5-14. Color icon

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

Color imaging Scanning Adjustments

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

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

Color Gain

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

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

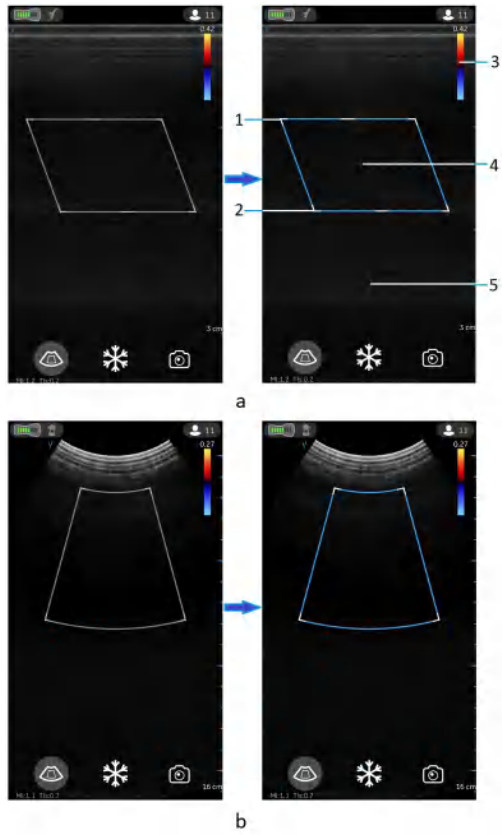
NOTE: Small movements will be ignored to avoid unintentional activation of the color gain control.

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

Position and resize ROI

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

Drag your finger inside the ROI to move and position. The box turns blue indicating that the controls for adjusting the ROI are activated. Use the controls on the corners to adjust size.



a. Flat linear array, Color Flow
b. Curved Linear Array, Color Flow

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

Figure 5-15. Position and resize ROI

Color steer

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

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

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

Color Aliasing

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

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

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

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

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

Pulse repetition frequency - Fast and slow flow (High and low velocity scale)

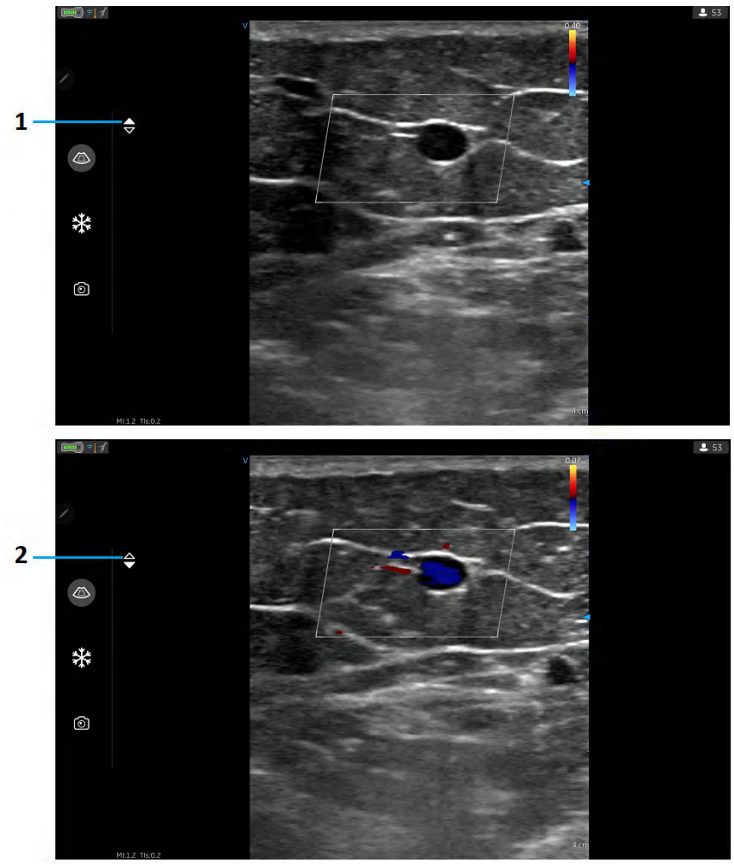
For a few presets, there is a control available in the color flow mode for alternating between high and low velocity scales. A higher velocity scale is needed to avoid aliasing while imaging of faster (arterial) flow. A lower velocity scale optimizes the imaging of slow low (venous).

The presets that support selection between high and low velocity scale are following:

Curved array	Linear array
Abdominal	Vascular
OB-Gyn	MSK
Vascular	Small Parts
MSK	

Pulse repetition frequency - Fast and slow flow (High and low velocity scale) (continued)

To change the velocity scale, tap on the  to alternate between the velocity scales. The  indicates that the higher velocity scale is selected and  indicating the lower scale. The velocity setting corresponding to both scales can be seen at the top of the velocity bar  .



1. High velocity scale (default)
2. Low velocity scale

Figure 5-16. PRF- Fast and slow flow

Freeze

To freeze an image:

1. Press the Freeze button or tap anywhere on the image area on the scan screen.

Figure 5-17. Tap or press

When in freeze mode, you can store an image or review frames in the available video buffer.

To reactivate the image:

1. Press **Freeze** icon again.

   OR

   Tap anywhere on the image.

Video buffer

Video buffer displays with an ability to scroll, play and pause the frames in the video buffer..

The indicator is placed on the last frame.

To jump frames:

1. Tap on the video buffer bar to view any frame.
2. Scroll to jump multiple frames

Auto freeze

If Vscan Air CL is idle for a period of time, the device enters freeze mode to minimize risk of overheating and battery drainage. Press the display to unfreeze the image and continue scanning.

Storing an image

Press **Store** button on the scan screen when the image is frozen to store a still image.

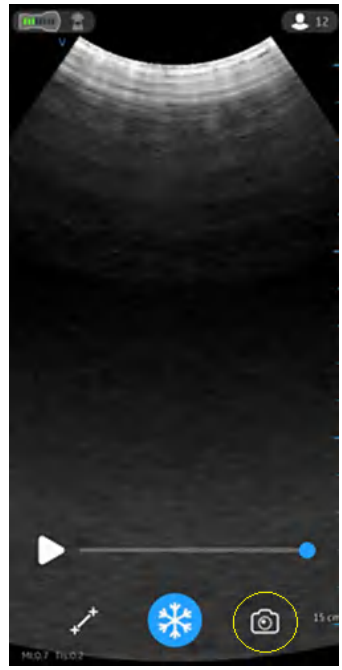


Figure 5-18. Store still image

Storing a video

To store a video:

1. Press the '**Store**' button on the scan screen when the image is live.

   OR

2. Play the video buffer by using the '**Play**' button on the video scroll bar and then press **Store**.

Press **Store** button on the scan screen to store a video.

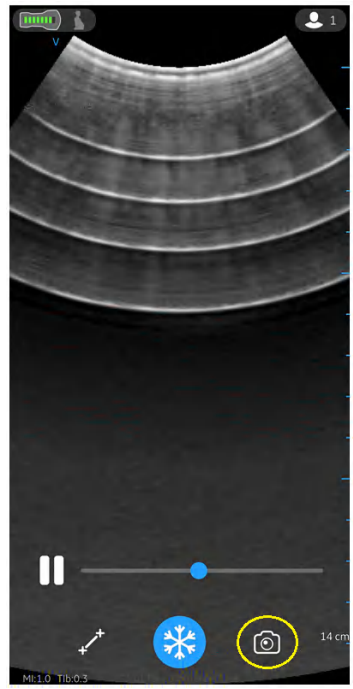


Figure 5-19. Store video

Protected Health Information

Protected Health Information is the data that helps in identifying a patient. It is possible to either manually enter patient details/ patient data in the Vscan Air application or assign patient/Study information from a scheduled exam retrieved from the Modality Worklist Server.

Assign Patient data manually to the current exam

To assign patient details manually to the current exam in Vscan Air application, follow the procedure below.

1. Swipe from right to left.

   or

   Press Patient icon on the top right corner.

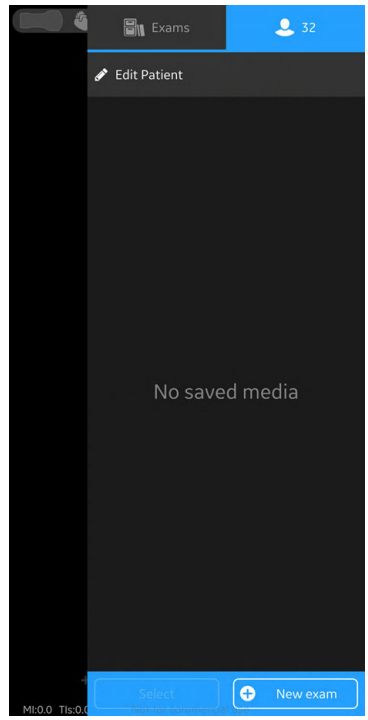


Figure 5-20. Patient Icon

NOTE: Patient data can be assigned to an individual exam only. You can not assign Patient data to more than one exam simultaneously.

Assign Patient data manually to the current exam (continued)

2. Press “**Edit Patient**” and enter the required information in the respective fields under “New Patient” screen.

   Press "**Add**" button to assign Patient data to the current exam. After successful assignment of Patient data, application takes you to the scan screen.

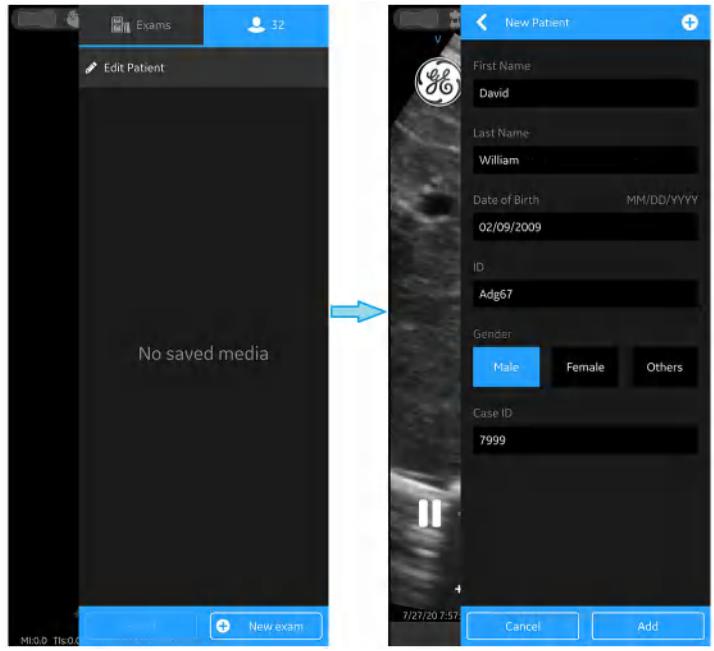


Figure 5-21. Edit Patient

NOTE: Once the Patient data is assigned to an exam, you can not re-assign or alter the patient details in that exam.

Assign Patient data manually to the current exam (continued)

3. Patient's Last Name, First Name and ID are shown on the top of the scan screen.

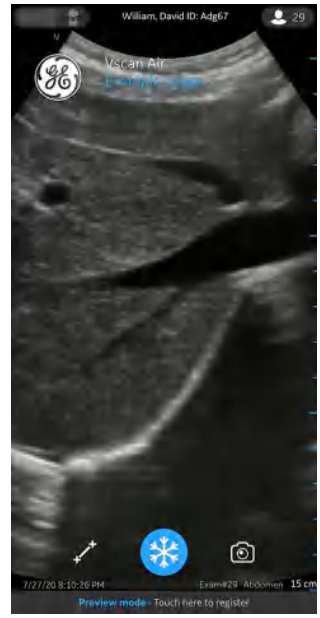


Figure 5-22. Scan Screen with Patient data

4. Press **Patient** icon to view the images/videos under current exam.

Assign Patient data manually to an existing Exam

To assign patient details manually to an existing exam in Vscan Air application, follow the procedure below.

1. Swipe from right to left.

   or

   Press **Patient** icon on the top right corner.

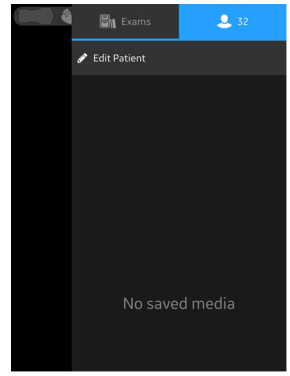


Figure 5-23. Patient Icon

2. Press **Exams** tab.

   Press the desired Exam ID for which you wish to assign Patient data.

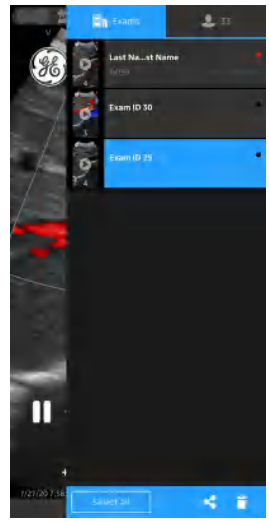


Figure 5-24. Exam Tab

NOTE: *Patient data can be assigned to an individual exam only. You can not assign Patient data to more than one exam simultaneously.*

Assign Patient data manually to an existing Exam (continued)

3. Press “**Edit Patient**” button at top right corner and enter the required information in the respective fields under “New Patient” screen.

   Press "**Add**" button to assign Patient data to the existing exam. After successful assignment of Patient data, application takes you to the scan screen.

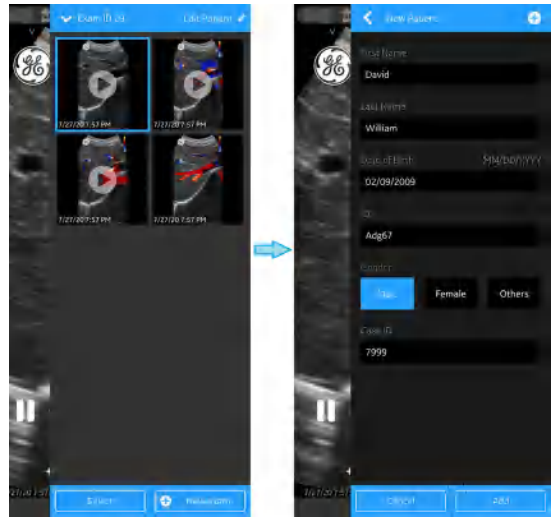


Figure 5-25. Edit Exam

NOTE: Once the Patient data is assigned to an exam, you can not re-assign or alter the patient details in that exam.

Assign Patient data manually to an existing Exam (continued)

4. Patient's Last Name, First Name and ID are shown on the top of the scan screen.

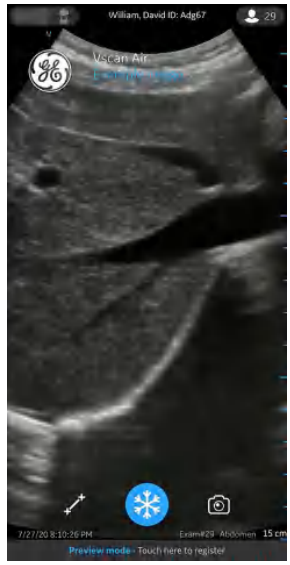


Figure 5-26. Scan Screen with Patient data

5. Press **Patient** icon to view the images/videos under the existing exam.

Assign Patient data from Modality Worklist Server to the current exam

Protected Health Information is added under each patient name in the Modality Worklist Server.

To assign Patient data from Modality worklist Server to the current exam in the Vscan Air application, follow the procedure below.

1. Swipe from right to left.

   or

   Press **Patient** icon on the top right corner.

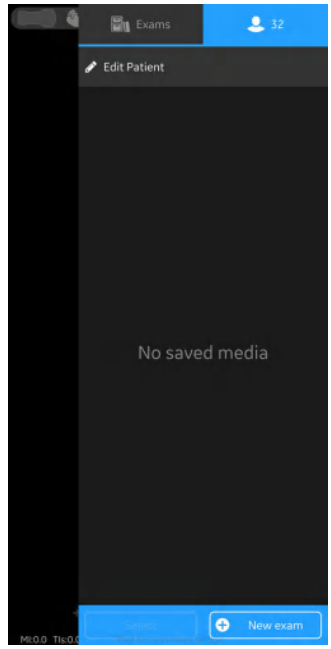


Figure 5-27. Patient Icon

NOTE: Patient data can be assigned to an individual exam only. You can not assign Patient data to more than one exam simultaneously.

Assign Patient data from Modality Worklist Server to the current exam (continued)

2. Press “**Edit Patient**” and then Press the  symbol at top right corner of “New Patient” screen.

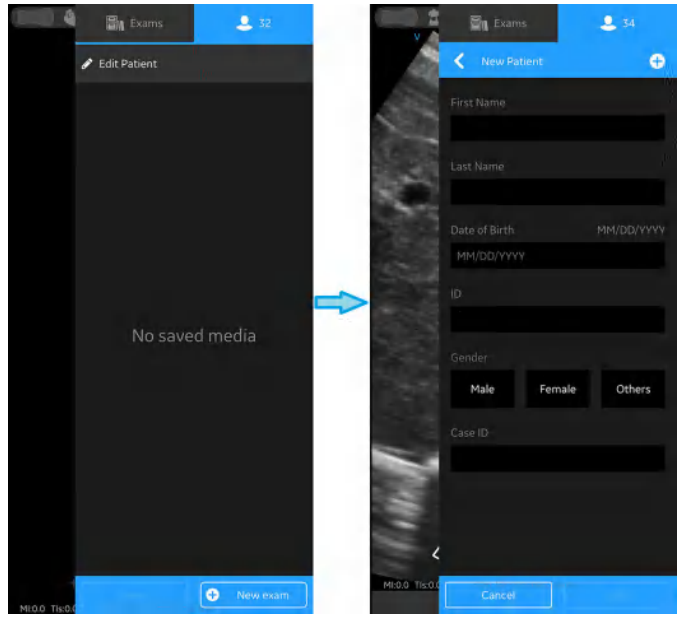


Figure 5-28. Edit Patient

Assign Patient data from Modality Worklist Server to the current exam (continued)

3. Press the refresh button on the “Worklist” screen to import the list of patients from Modality Worklist Server.

   Tap on the desired Patient Name/Patient ID.

   OR

   Enter Patient Name or Patient ID in the search field to find the details of particular patient.

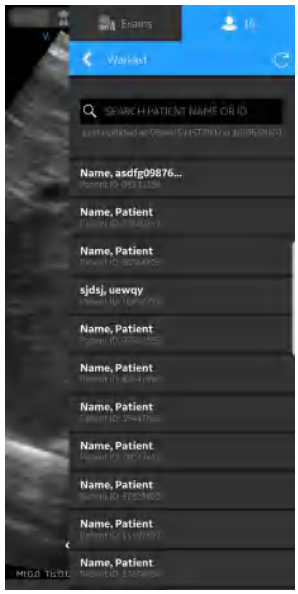


Figure 5-29. Search Patient

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

NOTE: When you refresh the patient details in “worklist” screen, the connection between Vscan Air Probe and display device may be temporarily interrupted.

NOTE: For any patient, if details are missing in Modality Worklist server, import of those patient records will be rejected in the application and it will be displayed in the paitient list as “Rejected”.

Assign Patient data from Modality Worklist Server to the current exam (continued)

4. Press "**Add**" button to assign Patient data to the current exam. After successful assignment of Patient data, application takes you to the scan screen.

   Patient's Last Name, First Name and ID are shown on the top of the scan screen.

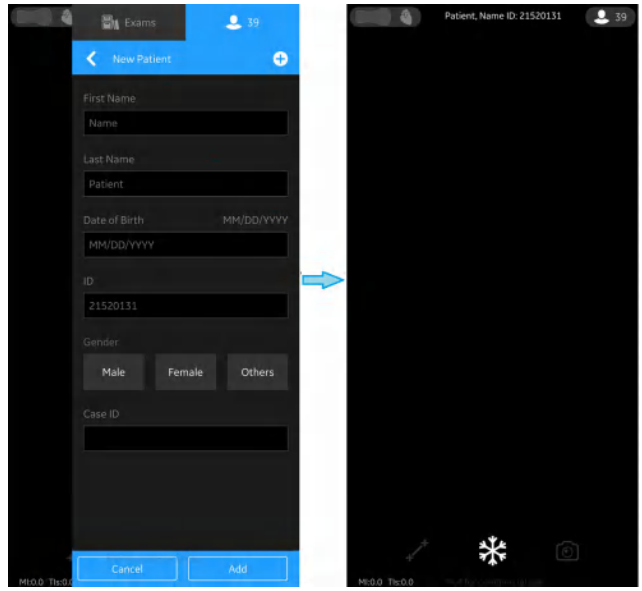


Figure 5-30.

NOTE: Once the Patient data is assigned to an exam, you can not re-assign or alter the patient details in that exam.

5. Press **Patient** icon to view the images/videos under current exam.

Assign Patient data from Modality Worklist Server to an existing exam

Protected Health Information is added under each patient name in the Modality Worklist Server.

To assign Patient data from Modality worklist Server to an existing exam in the Vscan Air application, follow t.he procedure below.

1. Swipe from right to left.

   or

   Press **Patient** icon on the top right corner.

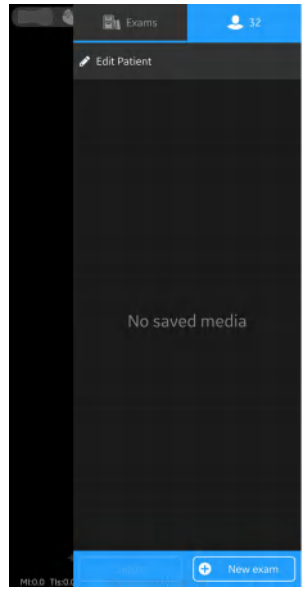


Figure 5-31. Patient Icon

NOTE: Patient data can be assigned to an individual exam only. You can not assign Patient data to more than one exam simultaneously.

Assign Patient data from Modality Worklist Server to an existing exam (continued)

2. Press **Exams** tab.

   Press the desired Exam ID for which you wish to assigh Patient data.

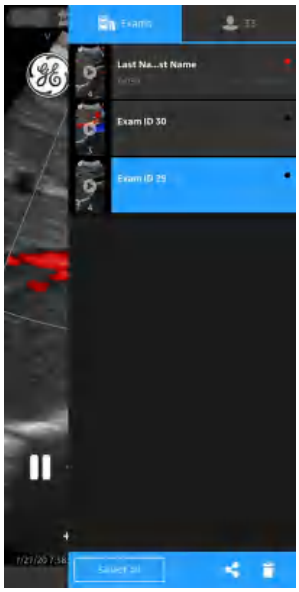


Figure 5-32. Exam Tab

Assign Patient data from Modality Worklist Server to an existing exam (continued)

3. Press "**Edit Patient**" button at top right corner.
   Press the ⊕ symbol on "New Patient" screen.

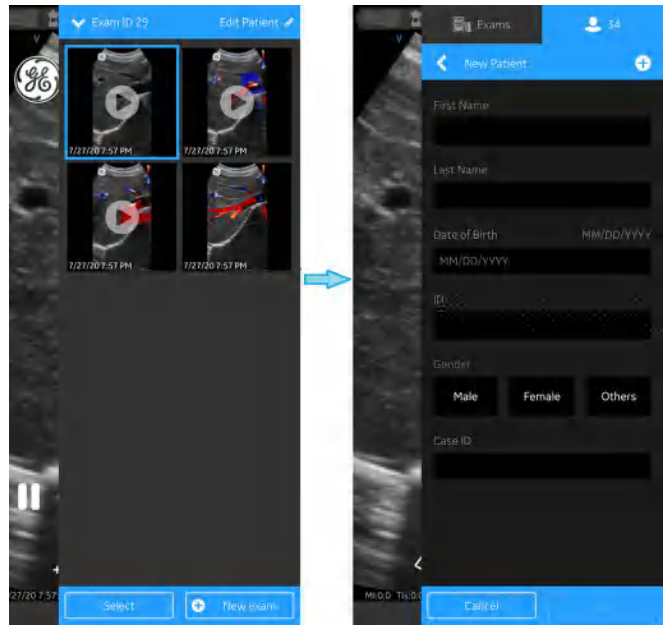


Figure 5-33. Edit Exam

Assign Patient data from Modality Worklist Server to an existing exam (continued)

4. Press the refresh button on the “Worklist” screen to import the list of patients from Modality Worklist Server.

   Tap on the desired Patient Name/Patient ID.

   OR

   Enter Patient Name or Patient ID in the search field to find the details of particular patient.

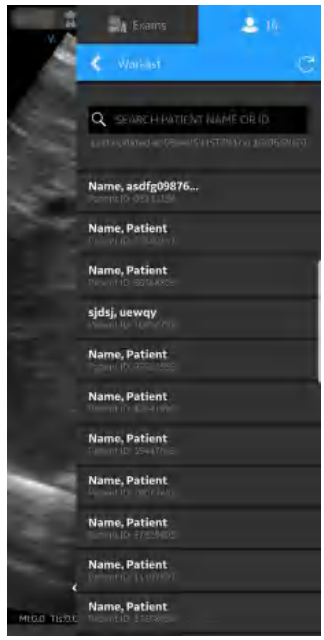


Figure 5-34. Search Patient

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

NOTE: When you refresh the patient details in “worklist” screen, the connection between Vscan Air Probe and display device may be temporarily interrupted.

NOTE: For any patient, if details are missing in Modality Worklist server, import of those patient records will be rejected in the application and it will be displayed in the paitient list as “Rejected”.

Assign Patient data from Modality Worklist Server to an existing exam (continued)

5. Press "**Add**" button to assign Patient data to the existing exam. After successful assignment of Patient data, application takes you to the scan screen.

   Patient's Last Name, First Name and ID are shown on the top of the scan screen.

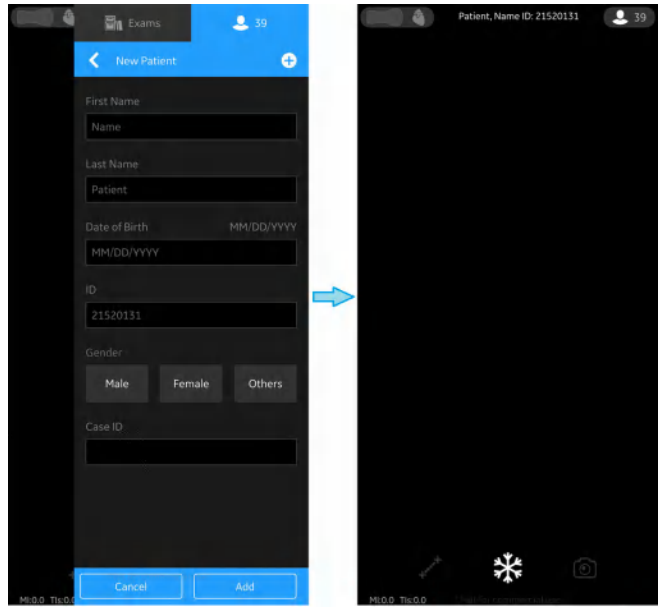


Figure 5-35. Add Patient

NOTE: Once the Patient data is assigned to an exam, you can not re-assign or alter the patient details in that exam.

6. Press **Patient** icon to view the images/videos under the existing exam.

Measurements

Taking measurements

Vscan Air app enables two types of measurements with the Vscan Air CL probe - distance and ellipse, on frozen images in both black and white and color imaging. Up to four distance measurements can be performed on an image. Measurements can be done during image review or on recalled stored images.

To perform a distance measurement:

1. On a frozen image, press **Measure**.

   The measurement calipers displays. '**Distance**' and '**Ellipse**' measurements options are displayed with the distance calipers being activated by default.

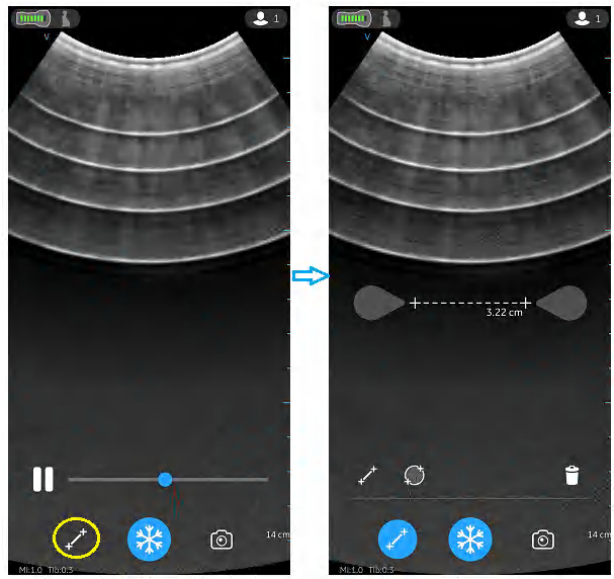


Figure 5-36. Select measurement

2. Drag to position the calipers to obtain the desired measurement.
3. To store the image with a measurement, press **store**.

Taking measurements (continued)

To make additional measurements:

1. Press the distance measurement icon again to make additional measurements on the displayed image.

   Up to 4 distance measurements can be made on a single image.

To delete a distance measurement:

1. Select the measurement you wish to delete.
2. Press '**Bin**' icon to delete the selected measurement.

To perform an ellipse measurement:

1. On a frozen image, press the '**Measure**' button. Select the ellipse icon to change the measurement type from '**Distance**' to '**Ellipse**.

   The measurement calipers displays.

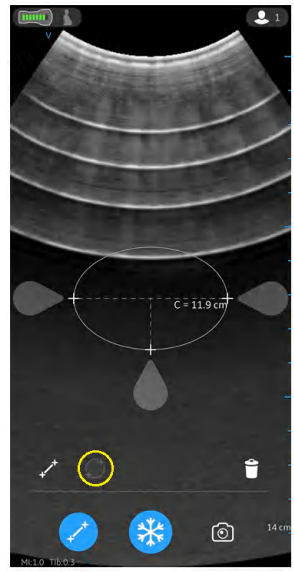


Figure 5-37. Select Ellipse measurement

2. Drag to position the calipers to obtain the desired measurement.
3. To store the image with a measurement, press **store**.

NOTE: Only a single ellipse measurement can be performed on the displayed image.

Taking measurements (continued)

To delete an ellipse measurement:

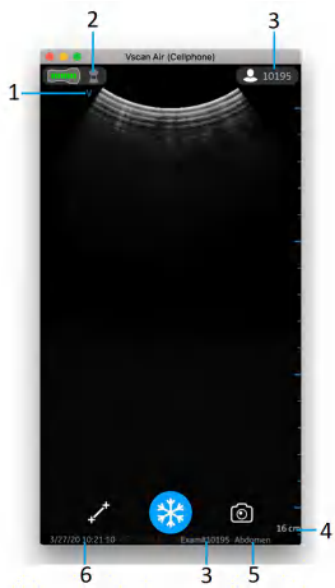
1. Select the measurement.
2. Press the ‘**Bin’** icon to delete the selected measurement.

To exit the **Measure** mode select the '**Measure**‘ icon or press ‘**Freeze**’ icon or switch frame with Video buffer slider.

Review and recall of stored data

Review Current Exam

1. Swipe from right to left.
   OR
   Tap on **Patient** icon on the top right corner.
   Images and video loops captured in current exam is shown.
2. Select to activate and review stored images.



1. Image orientation marker
2. Recalled image preset icon
3. Recalled image exam number
4. Recalled image depth
5. Recalled image preset
6. Recalled image date and time

Figure 5-38. Recalled stored image

Review Saved Exams

1. Swipe from right to left.

   OR

   Tap on **Patient** icon on the top right corner.
2. Tap Exams on top tab.

   Saved exams will show in a list. Most recent exams are shown on top.

NOTE: *When accessing Exam list, select the desired image to go to the viewer. The Viewer opens with selected image and the Exam list closes. The freeze button becomes active. You can unfreeze to continue scanning using the current exam. The Exam list then closes.*

Delete images/videos

You can delete images or videos individually or from an exam list.

Delete images/videos from an exam list

The steps describe deleting entire exams from the list.

1. Open **Exam** List.

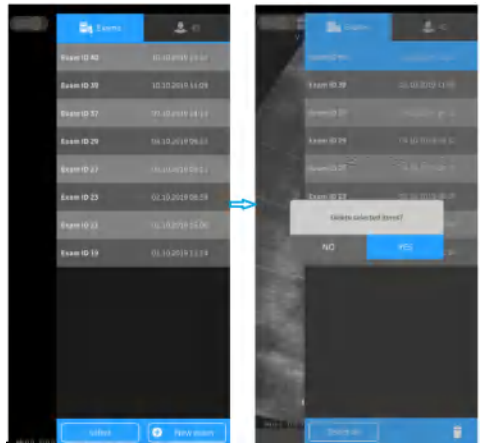


Figure 5-39. Delete image or video

2. Select the desired exam ID you wish to delete.
3. Press **Select** or Press and hold.
4. Press the '**Bin**' icon to delete.

Delete individual images/videos

1. Press **Select**.
2. Tap Select box on the image/video.
3. Press the '**Bin**' icon to delete.

Clear selection

1. Press **Select All**.
2. Press **Clear all** to clear the selection if you do not wish to delete.

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

Share data

Use the share functionality to share important data to a selected storage destination if needing to secure data storage.

Share individual images /videos

1. Swipe from right to left.

   OR

   Press **Patient** icon button on the top left corner.

   A list of stored images or videos for the current exam display.
2. Select the desired exam or video you wish to share.
3. Press **Share** icon.
4. Choose the Share function on your display device to share the images.

Share all images /videos from an exam

1. Press **Exams** tab on the right panel.
2. Select the desired exam ID from which you wish share images/videos.
3. Press **Select**.
4. Press **Select All**.

   OR

   Press **Clear all** to clear the selection.
5. Press **Share** icon.
6. Choose the Share function on your display device to share the images.

To exit review mode

In portrait mode, tap on scan screen or swipe out panel.

In landscape mode, swipe out panel.

Export data

The Vscan Air CL is regarded an imaging acquisition device and not an image storage device or image archive.

Make sure to share images, videos (loops) or exams via the share function on the Vscan Air app.

Disclaimer: When sharing data from the Vscan Air app, data can be shared to other apps including anonymized images and movies/loops.

Preparing for a guided procedure with Vscan Air

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

If a temporary, unexpected disruption to real time imaging is determined to have a severely negative adverse effect on the patient's health outweighing the benefits of using an ergonomic wireless probe at the point of care, it is recommended to consider using a wired ultrasound device for the specific procedure guidance.

Assessing Display Device Wi-Fi Performance with Vscan Air probe

Prior to setting up for a guided procedure, it is recommended to check if the display device being planned for use during the procedure supports a stable connection with the Vscan Air probe, by following the below steps.

Step	Step name	Description
1	Configure app settings	Set the Video duration to 1 second from Menu -> Configuration. This will help to visualize discontinuities in loop playback which indicate lost frames.
2	Connect probe and app	Connect the probe with the app
3	Select preset with color	Select Small Parts from the Shallow (Linear) presets menu. Enter color flow mode by pressing the ROI button. Adjust the color gain to 100% to visualize noise inside the color ROI.
4	Confirm/Verify	Observe the noise pattern inside the color ROI. The randomness of the pattern should not appear to pause occasionally.
5	Review cine	Press freeze. Then press the Play button to the left of the scroll bar.
6	Confirm/Verify	Observe the blue cine position indicator as it moves from left to right along the position indicator. It should move in a consistent fashion from left to right (the distance it moves with each increment appears equal).

If the display device does not pass the above criteria successfully, using an alternate display device is recommended for supporting guided procedures.

General considerations

- There may be differences in the physical characteristics of a wireless probe (shape, design, weight etc.) and the way it might be handled during a scan or a procedure when compared to a probe attached to a console. Hence, it is recommended for users to get comfortable with handling the Vscan Air device prior to performing a procedure to minimize accidental dropping or slipping of the probe during the procedure.
- Wherever possible, prior use of the probe and preferred display device in the network environment where the procedure is expected to be performed will help uncover any unexpected challenges with a stable connection between the probe and app before the actual procedure.
- Make sure to follow the disinfection protocol to prepare the probe and display device for the procedure being performed. More information on cleaning and disinfection methods and approved agents can be found in the ‘Cleaning and Disinfection’ section of the user manual. Use probe sheaths for procedures where a sterile field needs to be maintained or infection is a concern.
- In order to make the interventional part of the procedure more efficient, and if this is not an emergency procedure, you may want to perform a preliminary scan to familiarize yourself with anatomical landmarks around the target and procedural planning like the anticipated entry point, needle path and tracking method. It might be helpful to mark transducer location, anticipated needle entry point and trajectory, whenever possible and appropriate.

Setting up device for procedure

Please read and follow the below instructions to prepare the device before performing a dynamic ultrasound guided procedure with Vscan Air.

Step	Step name	Description
1	Configure app settings	• If working with a display device for the first time, use an example image to adjust the brightness level for optimal visualization of the image based on the ambient environment where the procedure is expected to be performed. Consider dimming ambient lights for better image visualization, wherever possible. • Adjust/maximize the Auto-freeze time to avoid image freeze during the procedure due to no user interface interactions. Note that this setting minimizes device heating and battery drainage when device is not being used by freezing the image. • Centreline marker can be turned on from the Menu -> Configuration, if desired. Please note that Vscan Air supports only free hand biopsy and needle procedures so the centreline marking should not be confused with biopsy guidelines indicating needle path on the image. • The probe button can be configured for additional functionality (Store or Freeze) that could be helpful during procedure to minimize interaction with the display device. It can be configured from the Menu -> Configuration. Accidental long press (5 secs or more) of this button during scanning can lead to unintentional shut down of the probe. • The video duration should be set to save cine clips of a length appropriate for documentation requirements.
2	Use a cool probe	Make sure the probe is sufficiently cooled down after any previous scanning. Disruption may occur due to the probe getting warm if a lengthy procedure is anticipated. Leaving the probe on a desk (outside the pocket or the case) after it off will help cooling down faster. It should take about 30-60 minutes to get to a reasonably cool state depending on how warm it was from the previous scan and the ambient temperature. If accelerated cooling of the probe is required, place the probe, while turned off, in front of a fan, run under cold water, or apply cooling pack.

Step	Step name	Description
3	Minimize lost connection between probe and mobile device during scan	The probe without a cable can be very helpful to support sterile procedures. At the same time its use depends on bandwidth and stability of the wireless connection between probe and mobile device. Following are the recommendations for minimizing loss of real time images due to connection instability: a. The probe and mobile device should be within 1 m to each other during pairing, and less than 1.5 meters while in use. b. Avoid congested Wi-Fi network environments, if possible. c. In cases where multiple Vscan Air probes and display devices with the app are available, make sure - the app is closed on all other devices except the one to be used and - all other probes are turned off and moved away from the vicinity of the device.
4	Check battery levels of probe and display device	Ensure that the probe and display device have enough charge before starting a procedure. Charge levels of 50% and above are recommended before starting, and above 30% during procedure. Battery levels of the probe can be checked on the top left corner of imaging screen after connecting with the app. Please refer to the user manual for the detailed description of the battery level indicator bars.
5	Select appropriate preset	Choose the correct preset based on the anatomy being visualized and the planned procedure. Details of the presets and the optimized anatomy are available in the user manual.
6	Position display device	Position the display device in such way that it is comfortable to visualize the image during the procedure (for e.g. Imaging features such as orientation marker is clearly visible, ambient lighting is optimal, display device is in the line of sight and no straining is required). Consider using a cart or stand to mount the display.

Export data

Use the share functionality to share important data to a selected storage destination if needing to secure data storage.

Share individual images/videos

1. Swipe from right to left.

   OR

   Press Patient icon button on the top right corner.

   A list of stored images or videos for the current exam display.
2. Select the desired exam or video you wish to share.
3. Press Share icon.
4. Choose the Share function on your display device to share the images/videos.

Share all images/videos from an exam

1. Press Exams tab on the right panel.
2. Select the desired exam ID from which you wish to share images/videos.
3. Press Select.
4. Press Select All.

   OR

   Press Clear all if you wish to clear the selection.
5. Press Share icon.
6. Choose the Share function on your display device to share the images/videos.

Share Exams

1. Press Exams tab on the right panel.
2. Select the desired single/multiple exam IDs from Exams list.
3. Press Share icon.
4. Choose the Share function on your display device to share the entire single/multiple Exams.

Export data to the Dicom Image Server

To export images/Videos/Exams from Vscan Air application to DICOM Image Server, follow the procedure below.

1. Swipe from right to left.

   OR

   Press Patient icon on the top right corner.

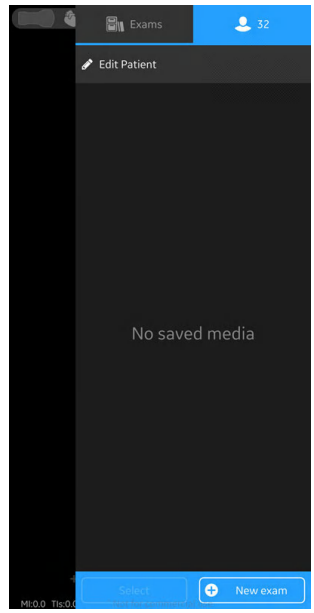


Figure 5-40. Patient Icon

Export data to the Dicom Image Server (continued)

2. Press “Exams” tab and select the desired Exam from which you wish to share images/videos.

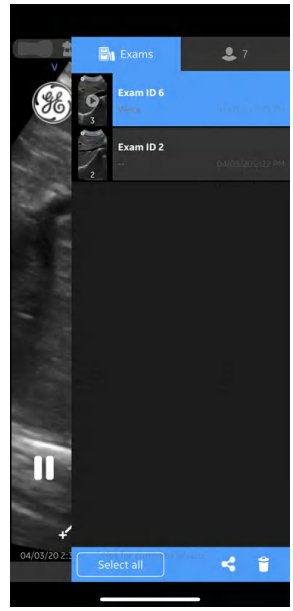


Figure 5-41. Exams Tab

Export data to the Dicom Image Server (continued)

3. Select the desired image or video you wish to export and Press the Share icon. See ‘Share individual images/videos’ on *page 5-55* for more information.

   OR

   Select all images or videos you wish to export and Press the Share icon. See ‘Share all images/videos from an exam’ on *page 5-55* for more information.

   OR

   Select the desired single/multiple exams you wish to export from Exams list and Press the Share icon. See ‘Share Exams’ on *page 5-56* for more information.

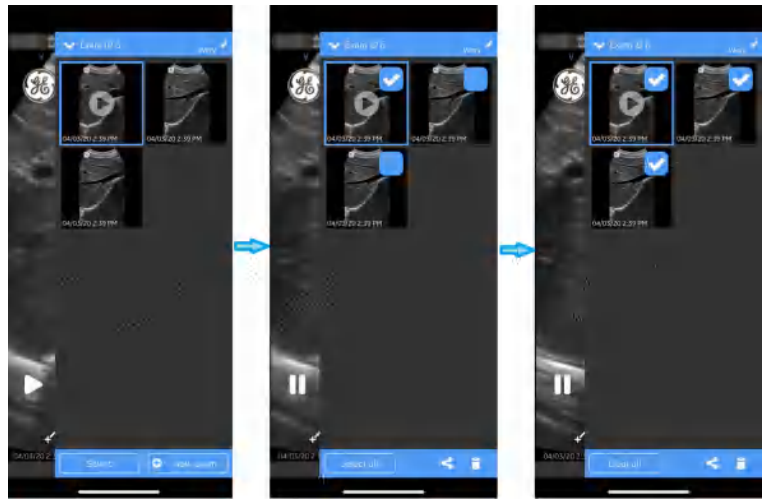


Figure 5-42. Select Images/Videos

Export data to the Dicom Image Server (continued)

4. Select the Dicom Image Server as storage destination and Press OK button to initiate the export.

   If there are more than one Dicom Image servers, select the desired Dicom Image Server as storage destination.

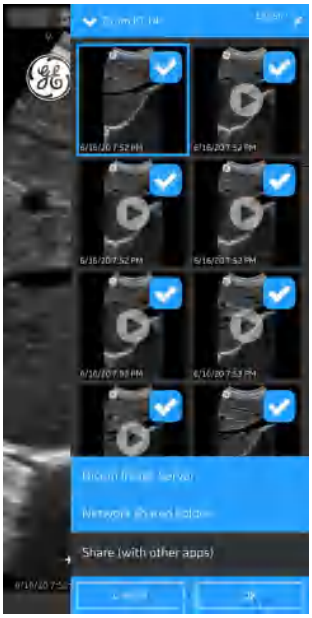


Figure 5-43. Share Images/Videos

NOTE: You can also select all the servers simultaneously, if you wish to share the data with all the servers that supports data exporting.

NOTE: To export Images/videos/Exam to DICOM Image Server, you need to assign Patient information to that particular Exam

Export data to the Dicom Image Server (continued)

5. You will find Image Queue with remaining items in the Queue.

   In addition to image queue you will also find export status of image/Video/Exam, where a green dot on the image/Video/ Exam indiactes it is successfully exported and a red dot indicates the export is failed.

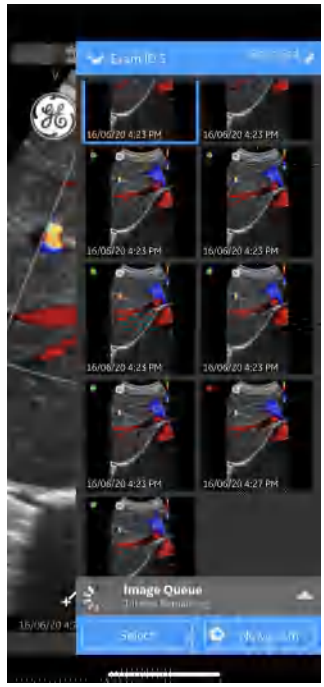


Figure 5-44. Image Queue

Export data to the Dicom Image Server (continued)

In one attempt you can export maximum of 200 images. When you try to export more than 200 images in a single attempt, application throws the following warning message.

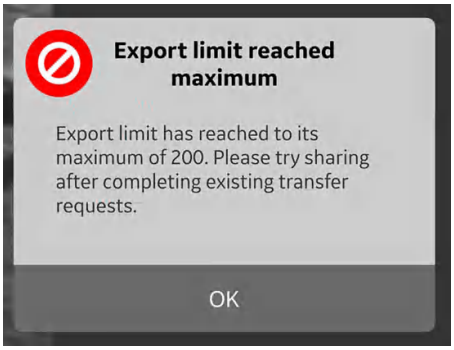


Figure 5-45. Export limit warning message

NOTE: The application initiates an Auto Retry in case of a failed export due to various reasons including network interruption.

NOTE: Once you initiates the export of images/Videos/Exam, the Protected Health Information related to that particular exam becomes read only in the application.

Secure Dicom

Secure Dicom enables a secure connection between the Vscan Air application and a server over the Internet.

Trusted certificates are typically used to make secure connections. You can get a certificate from your system administrator or download it from sites that require authentication.

To enable Secure Dicom in Vscan Air app, follow the procedure below:

1. While configuring Dicom Image Server or Modality Worklist Server, to enable Secure Dicom, select the check box Secure Dicom on “Add New Server” screen.

   See ‘Configure Dicom Image Server’ on *page 4-14* for more information.

   See ‘Configure Modality Worklist Server’ on *page 4-10* for more information.

Secure Dicom (continued)

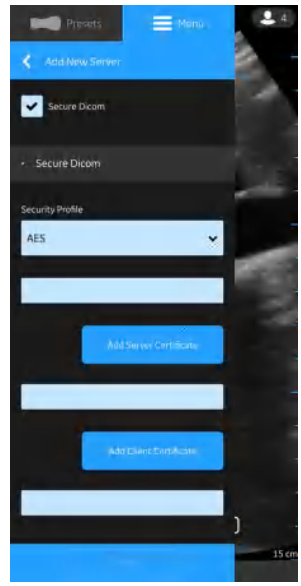


Figure 5-46. Select Secure Dicom

2. Under Secure Dicom select the desired Security Profile.

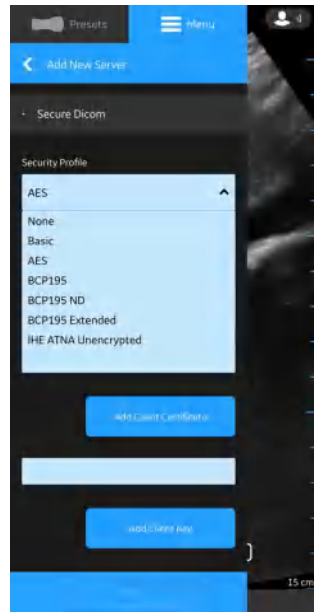


Figure 5-47. Select Security Profile

Secure Dicom (continued)

3. Press the Add Server Certificate button, to upload the server certificate.

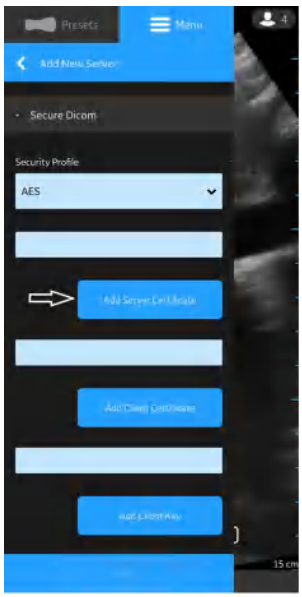


Figure 5-48. Add Server Certificate

4. Press the Add Client Certificate button, to upload the Client certificate.

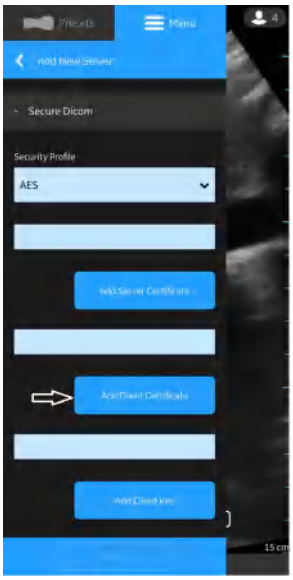


Figure 5-49. Upload Client Certificate

Secure Dicom (continued)

5. Press the Add Client Key button, to upload the Client Key.

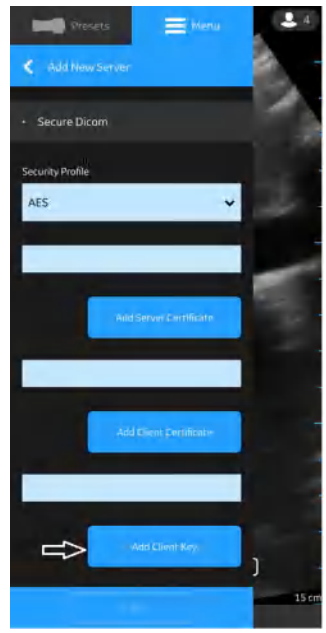


Figure 5-50. Upload Client Key

6. After successful uploading of the certificates, you can verify the server.

Export data to the Network Shared Folder

To export images/Videos/Exams from Vscan Air application to Network Shared Folder, follow the procedure below.

1. Swipe from right to left.

   OR

   Press Patient icon on the top right corner.

Figure 5-51. Patient Icon

2. Press “Exams” tab and select the desired Exam from which you wish to share images/videos.

Figure 5-52. Exams Tab

Export data to the Network Shared Folder (continued)

3. Select the desired image or video you wish to export and Press the Share icon. See ‘Share individual images/videos’ on *page 5-55* for more information.

   OR

   Select all images or videos you wish to export and Press the Share icon. See ‘Share all images/videos from an exam’ on *page 5-55* for more information.

   OR

   Select the desired single/multiple exams you wish to export from Exams list and Press the Share icon. See ‘Share Exams’ on *page 5-56* for more information.

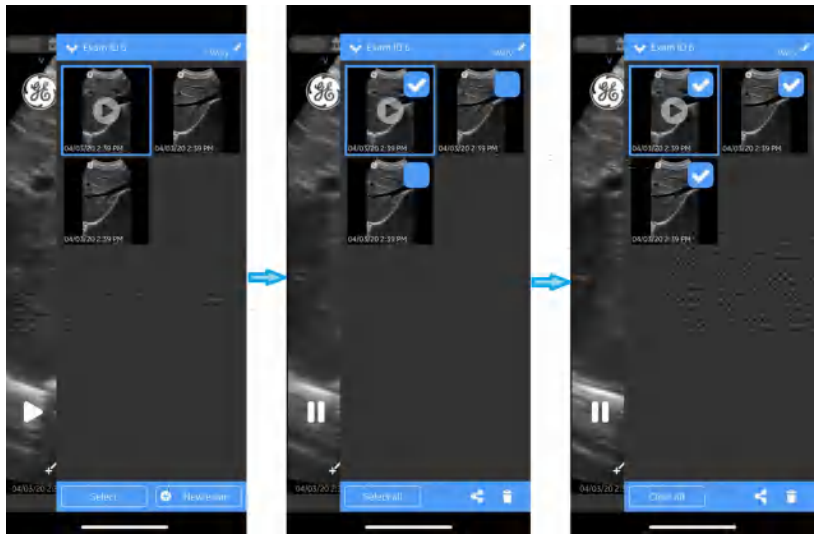


Figure 5-53. Select Images/Videos

Export data to the Network Shared Folder (continued)

4. Select the Network Shared Folder as storage destination and Press OK button to initiate the export.

   If there are more than one Network Shared Folders, select the desired Network Shared Folder as storage destination.

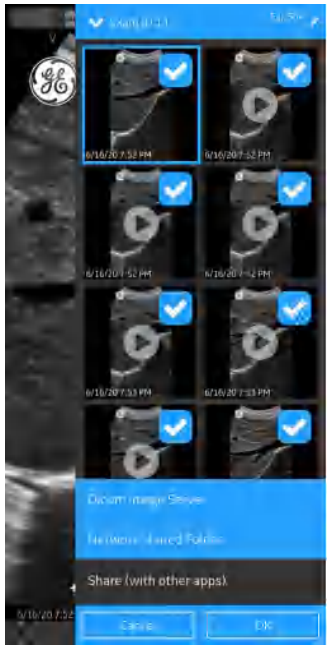


Figure 5-54. Share Images/Videos

NOTE: You can also select all the servers simultaneously, if you wish to share the data with all the servers that supports data exporting.

NOTE: You can export Images/Videos/Exams to Network Shared Folder without assigning the patient details.

5. You will find Image Queue with remaining items in the Queue.

   In addition to image queue you will also find export status of image/Video/Exam, where a green dot on the image/Video/Exam indiactes it is successfully exported and a red dot indicates the export is failed.

Export data to the Network Shared Folder (continued)

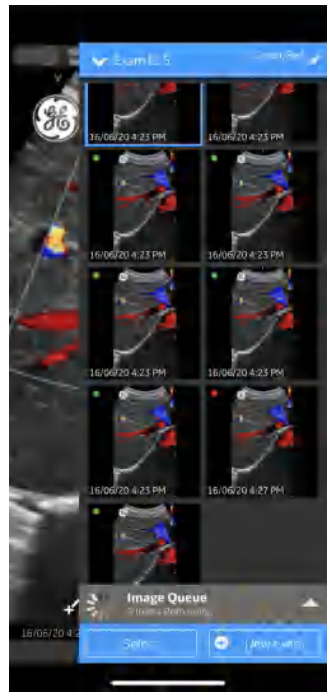


Figure 5-55. Image Queue

In one attempt you can export maximum of 200 images. When you try to export more than 200 images in a single attempt, application throws the following warning message.

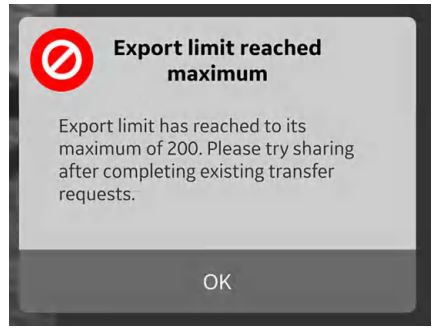


Figure 5-56. Export limit warning message

NOTE: *Once you initiates the export of images/Videos/Exam, the Protected Health Information related to that particular exam becomes read only in the application.*

Comprehensive exam info

While configuring network shared folder, you can optionally configure to export the below mentioned exam data along with media files. See ‘Configure Network Shared Folder’ on *page 4-19* for more information.

The Exam Data that can be exported to Network Shared Folder along with the media files is Exam ID, Patient’s First Name, Patient’s Last Name, Patient ID.

Network Shared Folder Structure

Network Shared Folder structure is as follows in different scenarios:

1. **If only “Patient ID” is assigned to an Exam**

   If only “Patient ID” is assigned to an Exam, the Network Shared Folder structure appears as below after exporting to your PC. The media files are stored in a series of folders.

   Folder: Shared Folder created by customer in PC

   Sub Folder: Patient ID

   Sub-sub Folder: Exam creation date and time(YYYYMMDDHHMMSS)

   Media file: Media creation date and time(YYYYMMDDHHMMSS)

2. **If only “Patient ID” and “First Name” are assigned to an Exam**

   If only “Patient ID” and “First Name” is assigned to an Exam, the Network Shared Folder structure appears as below after exporting to your PC. The media files are stored in a series of folders.

   Folder: Shared Folder created by customer in PC

   Sub Folder: Patient ID_First Name

   Sub-sub Folder: Exam creation date and time(YYYYMMDDHHMMSS)

   Media file: Media creation date and time(YYYYMMDDHHMMSS)

Network Shared Folder Structure (continued)

3. **If only "Patient ID" and "Last Name" are assigned to an Exam**

   If only "Patient ID" and "Last Name" is assigned to an Exam, the Network Shared Folder structure appears as below after exporting to your PC. The media files are stored in a series of folders.

   Folder: Shared Folder created by customer in PC

   Sub Folder: Patient ID_Last Name

   Sub-sub Folder: Exam creation date and time(YYYYMMDDHHMMSS)

   Media file: Media creation date and time(YYYYMMDDHHMMSS)

4. **If "Patient ID", "First Name" and "Last Name" are assigned to an Exam**

   If "Patient ID","First Name" and "Last Name" are assigned to an Exam, the Network Shared Folder structure appears as below after exporting to your PC. The media files are stored in a seriesof folders.

   Folder: Shared Folder created by customer in PC

   Sub Folder: Patient ID_First Name_Last Name

   Sub-sub Folder: Exam creation date and time(YYYYMMDDHHMMSS)

   Media file: Media creation date and time(YYYYMMDDHHMMSS)

5. **If Patient details are not assigned to an Exam**

   If Patient details are not assigned to an Exam, the Network Shared Folder structure appears as below after exporting to your PC. The media files are stored in a series of folders.

   Folder: Shared Folder created by customer in PC

   Sub Folder: Exam ID

   Sub-sub Folder: Exam creation date and time(YYYYMMDDHHMMSS)

   Media file: Media creation date and time(YYYYMMDDHHMMSS)

Export data to other apps (Social Networking Applications)

To export images/Videos/Exams from Vscan Air application to Social Networking Applications, follow the procedure below.

1. Swipe from right to left.

   OR

   Press Patient icon on the top right corner.

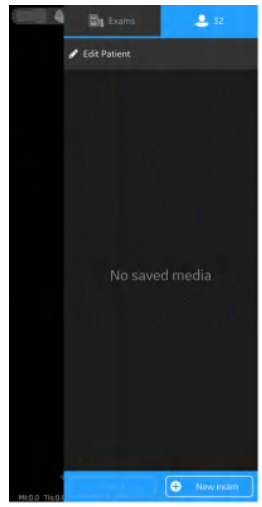


Figure 5-57. Patient Icon

2. Press “**Exams**” tab and select the desired Exam from which you wish to share images/videos.

Figure 5-58. Exams Tab

Export data to other apps (Social Networking Applications) (continued)

3. Select the desired image or video you wish to export and Press the Share icon. See ‘Share individual images/videos’ on *page 5-55* for more information.

   OR

   Select all images or videos you wish to export and Press the Share icon. See ‘Share all images/videos from an exam’ on *page 5-55* for more information.

   OR

   Select the desired single/multiple exams you wish to export from Exams list and Press the Share icon. See ‘Share Exams’ on *page 5-56* for more information.

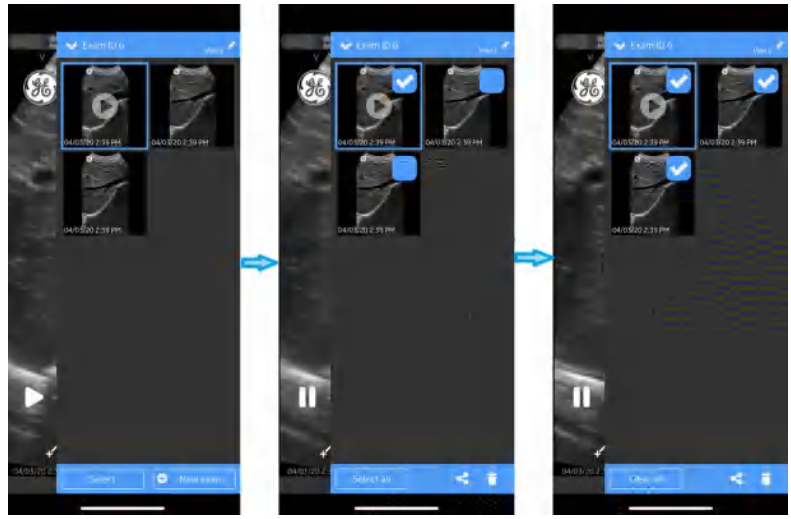


Figure 5-59. Select Images/Videos

Export data to other apps (Social Networking Applications) (continued)

4. Press “**Share** (with other apps)” to share images/videos/ Exams to a social networking application.

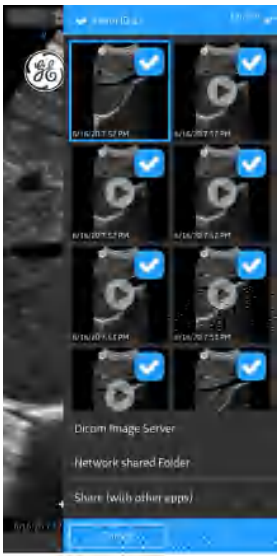


Figure 5-60. Share Images/Videos

5. Tap on the desired social networking application to initiate the export.

Chapter 6

Vscan Air Maintenance

Contents

System care and maintenance

Overview

Only trained persons should perform the safety inspections.

The Vscan Air CL requires regular care and maintenance to function safely and properly.

The expected service life of the Vscan Air CL is 5 years.

To ensure that the Vscan Air constantly operates at maximum efficiency, we recommend that the following procedures be observed as part of the customer's internal routine maintenance program.

Inspection

Inspecting the Vscan Air

If any defects or damages are found on the Vscan Air CL probe, do not use it. Contact GEHC.

Examine the following on a monthly basis (or whenever there is a reason to assume that any issue may have occurred):

- Equipment for cracks, loose or missing hardware.

To avoid electrical shock hazard, do not remove covers from the Vscan Air CL.

Before each use

1. Inspect the lens and the probe housing.
2. Look for damage that might allow liquid into the probe.
3. Test the functionality of the probe.

Cleaning and disinfection

Reprocessing recommendation (Frequency)

After Each Use

1. Inspect the Vscan Air CL (See ‘Inspecting the Vscan Air’ on *page 6-3*).
2. Clean the Vscan Air CL.
3. If required, clean the display device.

NOTE: *The display device should be cleaned and/or disinfected according to the device manufacturer's recommendations. Example: https://support.apple.com/en-us/HT204172. Please be aware that medical grade display devices often supports a wider range of cleaners and disinfectants compared to display devices for the consumer market.*

4. If required, disinfect the Vscan Air CL.

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

If any defects or damages are found on the Vscan Air CL, do not use it. Contact GEHC service.

Risk of Infection. ALWAYS clean and disinfect the probe between patients to the level appropriate for the type of examination.

Cleaning and disinfection

Adequate cleaning and disinfection between patient cases are necessary to prevent disease transmission. All probes must be thoroughly cleaned prior to disinfection. The level of disinfection required is based on patient contact. Use the following guidance to determine the appropriate level of disinfection based on system use.

Use	Method
Contact with non-intact skin	Cleaning followed by High-Level Disinfection
Contact with intact skin	Cleaning followed by Intermediate-Level Disinfection Cleaning followed by Low-Level Disinfection

Vscan Air is not intended for intra-operative use, it is also not intended for intra-cavitary use. It may be used during interventional procedures such as biopsy which based on proximity of the probe to the needle injection site it could get contaminated with blood or bodily fluids during use.

Chemicals Used for Efficacy Validation

The table below lists the products and intended use (cleaning, Intermediate-level disinfection, high-level disinfection) that were validated with the Vscan Air CL probe.

Table 6-1: Chemicals used for Efficacy Validation with Vscan Air CL

Product Type	Trade Name	Manufacturer	Active Ingredients
Cleaning (Wipe)	Sani-Cloth® Bleach	PDI Healthcare	Sodium Hypochlorite
Intermediate-level Disinfection (wipe)	Sani-Cloth® Bleach	PDI Healthcare	Sodium Hypochlorite
Intermediate-level Disinfection (wipe)	Oxivir® Tb Wipes	Diversey	Hydrogen peroxide
High-Level Disinfection (Solution)	Cidex® OPA Solution	Advanced Sterilization Products (J&J)	Ortho-Phthalaldehyde

Special Label Designations, Warnings and Precautions

Never use thinner, benzene, abrasive cleaners, or other strong solvents, as these may cause damage to the Vscan Air CL.

Special accessories

Special accessories are not applicable.

Probe Reprocessing

Vscan Air CL Pre-Treatment at the Point of Use (Required for all Vscan Air CL probes)

The pre-treatment step is for removal of gel and to minimize risk for cross contamination.

1. After each use,

   - remove the protective sheath from the Vscan Air CL if used.

   - gently remove all coupling gel from the Vscan Air CL by wiping with a soft, low lint cloth.

Do not use abrasive paper products when cleaning or wiping a GEHC ultrasound probe. The use of abrasive wipes can damage the soft lens (acoustic window).

To extend the life of the Vscan Air CL lenses, pat dry only.

2. Wipe the Vscan Air CL with one of the wipes (listed in the website https://www.gehealthcare.com/products/ultrasound/ultrasound-transducers) from the lens of one transducer to the other. Dispose off the cloth, wipe and gloves in the clinical trash.
3. After each use, inspect the lenses and housing of the Vscan Air CL. Look for any damage that would allow liquid to enter the Vscan Air CL.

If the Vscan Air CL is damaged, do not place it into any liquid (e.g. for disinfection) and do not use it until it has been inspected and repaired/replaced by a GEHC Service Representative.

Avoid processing procedures and chemicals that may damage the probe, such as: Do not steam autoclave or subject or the probe to Ethylene Oxide (ETO).

Manual cleaning Instructions

Manual cleaning is required to ensure the Vscan Air CL is cleaned to the extent necessary for further processing.

When cleaning select one of the cleaning methods described below, cleaning using wipes or cleaning using a cleaning solution.

Cleaning using Wipes

1. Dispense a cleaning wipe from the wipe canister.
2. Hold the Vscan Air CL with the large lens facing away from your body.
3. Gently wipe the Vscan Air CL with a cleaning wipe along the length of the Vscan Air CL. Gently wipe the Vscan Air CL large lens.
4. Rotate the Vscan Air CL and wipe the surface of the Vscan Air CL. As the wipe becomes visibly soiled, discard the wipe into clinical trash and dispense fresh wipes as needed.
5. Wrap a clean wipe around a soft nylon bristle brush to access crevasses on the surface of the Vscan Air CL. Do not use the brush on the Vscan Air CL lenses.
6. Turn the Vscan Air CL so that the small lens is facing away from your body.
7. Gently wipe the Vscan Air CL with the cleaning wipe along the length of the Vscan Air CL. Gently wipe the Vscan Air CL small lens.
8. Rotate the Vscan Air CL and continue wiping until the entire surface of the Vscan Air CL has been wiped.
9. Visually inspect the Vscan Air CL for any remaining soil and, if necessary, repeat steps 2 through 8 until the Vscan Air CL is visibly clean.

NOTE: Pay special attention to lenses, edges and groves.

Cleaning using a cleaning solution

1. Prepare a basin with enzymatic cleaner per the manufacturer's instructions.
2. Immerse probe in the cleaning solution and ensure no air bubbles are trapped.
3. Use a soft nylon bristle brush to clean the probe. Do Not use the brush on the probe lenses as this can damage the soft acoustic lens.
4. Ensure the probe remains in the cleaning solution for the minimum contact time listed on the enzymatic cleaner label. Make sure to follow manufacturers' recommendations.
5. Visually inspect the probe and probe components for soil. Repeat steps 4 - 6 until all visible soil has been removed from the surface of the probe.
6. Thoroughly rinse the probe to remove traces of the cleaner solution. Follow the cleaner manufacturers' instructions.
7. Visually inspect the device in a well-lit area to ensure all surfaces are free from residual cleaning solution. Repeat Step 7 if visible cleaning solution is observed.
8. Thoroughly pat dry the probe using a clean low-lint soft, dry disposable cloth or wipe. Do not use abrasive paper products.

Low-level/Intermediate level disinfection with wipes

1. Use a clean set of gloves.
2. Hold the Vscan Air CL with the large lens facing away from your body.
3. Wipe the Vscan Air CL from the large lens to the small lens, slightly rotating the Vscan Air CL after each wiping pass.
4. Turn the Vscan Air CL so that the small lens is facing away from your body.
5. Use a new wipe and apply to the small lens. Now, wipe the Vscan Air CL from the small lens to the large lens, slightly rotating the Vscan Air CL after each wiping pass.
6. Wrap a clean wipe around a soft nylon bristle brush to access crevasses on the surface of the Vscan Air CL. Do not use the brush on the Vscan Air CL lenses.
7. Once the Vscan Air CL has been completely wiped, use additional wipes and continue wiping the Vscan Air CL as needed to ensure all surfaces remain wet for the required exposure time listed on the disinfectant manufacturer's label.
8. Dry all surfaces of the Vscan Air CL using a sterile, lint-free, soft wipe or cloth. Blot or pat the lenses dry.
9. After each use, inspect the lenses, and housing of the Vscan Air CL. If the Vscan Air CL is damaged, do not place it into any liquid (e.g. for disinfection) and do not use it until it has been inspected and repaired/replaced by a GEHC Service Representative.

High-level disinfection – Soak

High-Level Disinfection is required for devices that contact non-intact skin.

In order for cleaner to be effective, all visible residue must be removed during the cleaning process. Follow the cleaning instructions as given in ‘Manual cleaning Instructions’ on *page 6-8* to clean the probe before performing disinfection.

Do not soak probes in cleaner for longer than stated by the chemical manufacturers instructions for use. Extended soaking may cause probe damage and early failure of the enclosure, resulting in possible electric shock hazard.

1. Prepare a basin with the high-level disinfectant per the manufacturer’s instructions for use. Be sure to follow all precautions for storage, use and disposal. Observe specifically soak times and dilution rates.
2. Immerse cleaned and dried probe in the disinfectant for the time specified by the chemical manufacturer and ensure no air bubbles are trapped.
3. Thoroughly rinse the probe to remove traces of the disinfectant. Follow the disinfectant manufacturers instructions.
4. Thoroughly dry all surfaces of the device using a sterile, lint-free wipe or cloth, changing wipes/ cloths when necessary to ensure the device is completely dry.

NOTE: *High-level disinfectants may be available as powder products. Follow the manufacturer’s instructions for use for preparing the disinfecting solution from the powder product.*

WARNING

DO NOT soak probes in cleaner for longer than is stated by the chemical instructions for use. Extended soaking may cause probe damage and early failure of the enclosure, resulting in possible electric shock hazard.

Choosing a Disinfectant

When choosing a disinfectant, determine the required level of disinfection. If the possibility of cross-contamination or exposure to unhealthy or non-intact skin exists, then high level disinfection should be performed. Good hand hygiene practice is highly recommended to help further reduce the risk of cross-contamination.

NOTE: For additional information about cleaning and disinfection, refer to the recommendations of the Association for Professionals in Infection Control (APIC), the U.S. Food and Drug Administration (FDA), and the U.S. Centers for Disease Control (CDC). For country-specific disinfection regulations, check with your local regulatory infection control authorities.

NOTE: A validated, high-level disinfection process, combined with the use of a sterile gel and a probe cover/sheath is an accepted method of infection control for Ultrasound probes. Adequate records or a log book detailing the time, date, disinfection method, and verification of disinfectant effectiveness or test results is recommended. For more information about establishing an evidence based disinfection protocol for your practice, refer to the FDA, CDC, HICPAC, APIC, or the Joint Commission websites.

Covering the Vscan Air CL using a Sterile, Protective Sheath

CAUTION

Vscan Air CL probe sheaths should be used in any clinical situation where infection is a concern.

1. Place an appropriate amount of gel inside the protective sheath and/or on the transducer face.

NOTE: Failure to use imaging gel may result in poor image quality.

2. Insert Vscan Air CL into sheath, making sure to use proper sterile technique. Pull cover tightly over Vscan Air CL face to remove wrinkles and air bubbles, taking care to avoid puncturing the sheath.

1. Protective sheath
2. Vscan Air CL with the Protective sheath

Figure 6-1. Applying the Sheath

3. Secure the sheath in place.
4. Inspect the sheath to ensure there are no holes or tears. If the sheath becomes compromised, stop the procedure and replace immediately.

Cleaning the protective case

The protective case is compatible with the set of cleaners and disinfectants listed for the Vscan Air CL probe. When cleaning the protective case pay special attention to its edges and grooves. Requirements for the protective case cleanliness will be defined by the way the protective case is implemented in the workflow for storing the Vscan Air CL probe. Cleaning of the protective case will be required if the Vscan Air CL was not properly cleaned of disinfected before it was storage in the protective case.

Figure 6-2. Protective case

GEHC ultrasound transducers web site

The GEHC Ultrasound transducers web site contains a list of chemicals that have been tested for compatibility with GEHC ultrasound probes. Verify probe compatibility via the GEHC ultrasound transducers web site. The reprocessing instructions provided in this document have been validated with the chemicals specified in ‘Chemicals used for Efficacy Validation with Vscan Air CL’ on *page 6-5*.

GEHC ultrasound transducers web site
https://www.gehealthcare.com/products/ultrasound/ultrasound-transducers

WARNING

Creutzfeldt-Jakob disease

This device is not indicated for neurological use. Neurological contact on patients with this disease MUST BE avoided. If the Vscan Air CL becomes contaminated, there is no adequate means to disinfect it. In this case, the contaminated device/ probe MUST BE discarded in accordance with local biological waste hazard procedures.

Chemicals compatible with Vscan Air CL

The table below lists the chemicals that were tested for compatibility with the probes.

The chemicals listed below are compatible with Vscan Air CL and will not cause degradation, but have not been proven to effectively clean or disinfect the probe. If you are interested in using an alternate chemical from the compatibility tables, please contact your GEHC representative. Alternate chemicals require validation by GEHC prior to use to ensure efficacy.

Table 6-2: Chemicals compatible with the Vscan Air CL probe

Trade Name	Manufacturer	Active Ingredients
Cidezyme/ Enzol	Advanced Sterilization Products (J&J)	Subtilisins (proteolytic enzymes)
Alcohol 70% Ethanol on a wipe	All manufacturer	Ethyl Alcohol
Alcohol 70% Isopropanol on a wipe	All manufacturer	Isopropyl Alcohol
CaviWipes 1	Metrex	Isopropanol
Oxivir® Tb Wipes	Diversey	Hydrogen peroxide
Sani-Cloth® AF3	PDI Healthcare	Quaternary ammonium compounds
Sani-Cloth Bleach Germicidal Disposable Wipe	PDI Healthcare	Sodium Hypochlorite
Sani-Cloth HB Germicidal Disposable Wipe	PDI Healthcare	Quaternary Ammonium Compounds
Super Sani-Cloth Germicidal Disposable Wipe	PDI Healthcare	Quaternary Ammonium Compounds
Cidex® OPA	Advanced Sterilization Products (J&J)	Ortho-Phthalaldehyde
Rely+On™ PeraSafe™	Antec International Limited	• Disodium carbonate, compound with hydrogen peroxide (2:3) • Citric acid • Sodium carbonate
Sekusept™ Aktiv	Ecolab	• Sodium Percarbonate • Citric acid • Sodium Carbonate(soda) • Solvents /additives

Upgrades

Upgrade software

Download App software upgrades when available from either Google Play store or Apple Store.

Vscan Air CL probe software

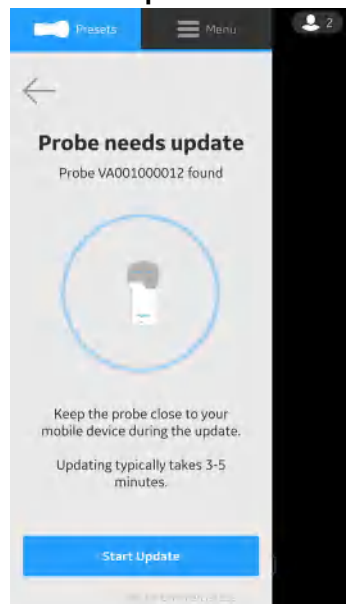
After downloading an App software upgrade the Vscan Air CL probe software might need to be upgraded.

Follow the on-screen instructions when connecting the probe to the App to upgrade probe software.

NOTE: The system reverts to the previous active installation, if a power cycle happens before the probe software upgrade is completed.

Vscan Air CL probe software upgrade

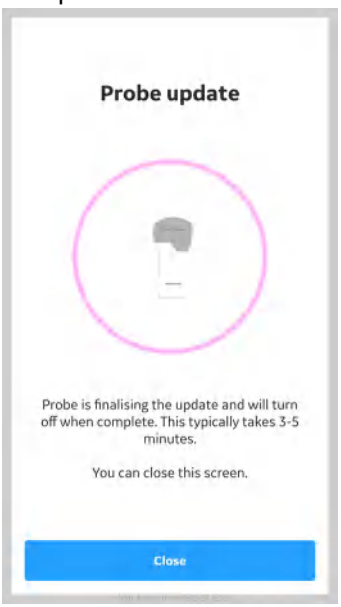
1. Pair the Vscan Air CL probe to the app. If the probe software need to be updated it prompts for an upgrade '**probe needs update**'. Click on '**start update'**.



2. The probe update is in progress.

Vscan Air CL probe software upgrade (continued)

3. The probe update process takes around 3 to 5 mins.



4. When the probe update is complete the probe turns off. The user will need to start the probe whenver probe needs to be used again.

Troubleshooting

Troubleshooting

Table 6-3: Troubleshooting

Problem	Possible cause	Solution
Vscan Air CL has no power.	When battery is discharged.	Charge the Vscan Air CL probe for at least 10 minutes and then power on.
Battery defect or end of life.	.	Contact GEHC Service (see ‘Contact Information’ on *page 1-13*)
Vscan Air CL is not charging.	Defective battery or probe hardware issue	Contact GEHC Service (see ‘Contact Information’ on *page 1-13*)
	Defective AC adapter.	Contact GEHC Service (see ‘Contact Information’ on *page 1-13*)
	Defective wireless charger pad.	Contact GEHC Service (see ‘Contact Information’ on *page 1-13*)
	Defective USB cable.	Contact GEHC Service (see ‘Contact Information’ on *page 1-13*)
	Mains power is down.	
	Temperature is outside the specified limits.	Ensure the ambient temperature is within the specified limits (see ‘Contact Information’ on *page 1-13*)
Display screen is blank when the device is powered on.	Connection broken during software loading.	Contact GEHC Service (see ‘Contact Information’ on *page 1-13*)
Parts of the image is missing when scanning.	Channels are missing.	Contact GEHC Service (see ‘Contact Information’ on *page 1-13*)
No image displayed when scanning.	Defective probe.	Contact GEHC Service (see ‘Contact Information’ on *page 1-13*)
Scan screen is not displayed.	Battery may not have sufficient charge.	Charge the Vscan Air CL probe for at least 60 minutes.

Diagnostics

Diagnostics Test

1. Slide the left panel.
2. Press **Diagnostics** from the Menu.

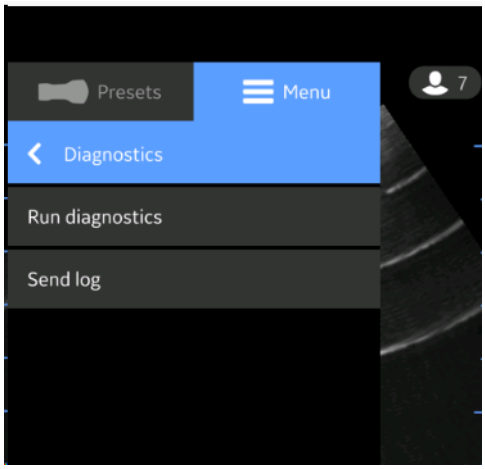


Figure 6-3. Diagnostics Menu

3. Press the **Run Diagnostic** button to start the test.

Diagnostics Test (continued)

4. Press the '**Start**' button to start the diagnostics test. The progress will be shown at the bottom of the screen.

NOTE: The display device must be connected to a probe to be able to start the diagnostics.

1. Diagnostic screen
2. Diagnostic progress bar

Figure 6-4. Diagnostics in Progress

Diagnostics Test (continued)

Figure 6-5. Diagnostics Process

5. If the Diagnostics test passes the below screen displays:

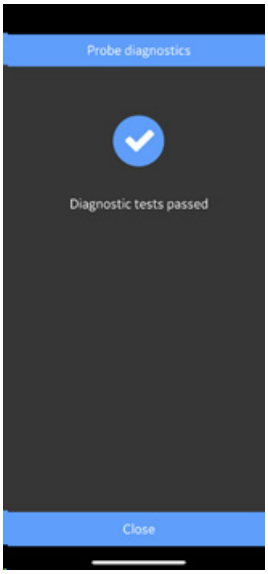


Figure 6-6. Diagnostics Passed

OR

If the Diagnostics test fails, contact GEHC Service via the hotline number:

Diagnostics Test (continued)

You can share device logs with GEHC for instance, if diagnostic test fails.

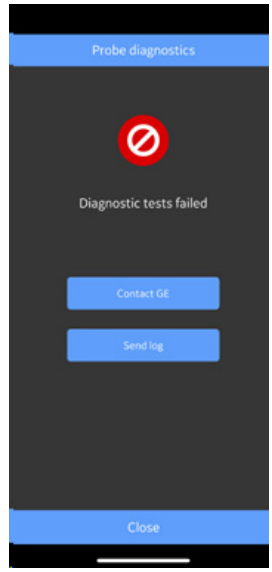


Figure 6-7. Diagnostics Failed

6. GEHC service guides the customer through the procedure to upload the system log file.

NOTE: System logs exported from the device will be stored for GEHC service access 1 year before being deleted from the server.

7. GEHC service runs checklist.
8. GEHC service places the order for the replacment Vscan Air CL and provides shipment details.

Transducer Element test

The transducer element test transmits/receives on each element to determine if the element working as intended. If the Element test fails, the failing element(s) are reported in the system logfile.

The transducer element test is part of the probe diagnostics test which is found via the app Menu -> Diagnostics -> Run Diagnostics.

The element test is then executed as part of a predefined test list of diagnostic tests.

NOTE: If diagnostics fails, GEHC service will have to look through the logfile to determine which test failed. If the transducer element test failed, service will then be able to identify the failing transducer element(s) and guide on further actions needed.

Probe warning messages

Probe errors

Probe overheats

Probe is overheating and the system will shut down. If the problem persists, contact GEHC.

Battery low

Battery critically low. Connect charger immediately.

Probe voltage critical

Probe voltage is at critical level and will shut down. If the problem persists, contact GEHC.

Connectivity error

Unable to connect. Check your internet connection and try again.

Handling a defective Vscan Air CL probe or battery

If the Vscan Air CL is damaged and needs a replacement, make sure you clean and disinfect the Vscan Air CL, pack it in the packing box, before shipping or returning to GEHC.

If the battery does not charge, or if it is damaged. Contact GEHC for battery replacement.

Automatic deactivation of the Vscan Air app

Deactivation soft limit

The Vscan Air App will on a daily basis try to contact the Vscan Air Product Registration server. If the Vscan Air app is inactive and/or not connected to internet for more than 70 days you will see the following message when you try to use the app.

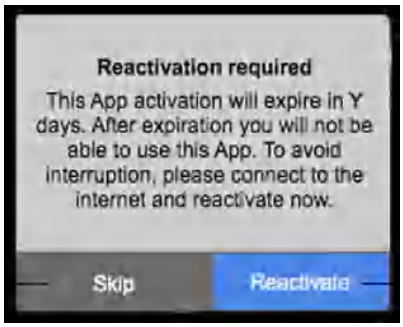


Figure 6-8. Reactivate warning message

Deactivation hard limit

The Vscan Air App will on a daily basis try to contact the Vscan Air Product Registration server. If the Vscan Air app is inactive and/or not connected to internet for more than 110 days the Vscan Air app is deactivated and you will see the following message when you try to use the app.

Figure 6-9. Auto Deactivated message

NOTE: To avoid the Auto Deactivation of Vscan Air app, make sure you use the app before it reaches the hard limit of inactive duration.

Chapter 7

Appendix

Contents:

Specifications

Dimension and weight (maximum)

- Dimension: 131 x 64 x 31 mm (length, width, height)
- Weight: 205 +/- 3g

Curved array transducer for deep scanning

- Broad-bandwidth curved array: from 2 - 5 MHz with center frequency of 3.3 MHz
- Number of elements: 128
- Footprint: 64 mm x 16 mm (lens)
- Viewing angle: 60°
- Depth: up to 24 cm

Linear array transducer for shallow scanning

- Broad-bandwidth linear array: from 3 - 12 MHz with center frequency of 7.7 MHz
- Number of elements: 192
- Footprint: 40 mm x 7 mm (lens)
- Depth: up to 8 cm

Acoustic Output

The real-time display of acoustic output indices

The Vscan Air software have real-time display features according to IEC62359 Ed.2. A thermal (TI) and a mechanical (MI) index is displayed. These two indices are intended to estimate the potential for thermal and mechanical bioeffects induced by ultrasound. Both TI and MI are displayed with increments of 0.1. The displayed (estimated) TI and MI are nominal values.

Thermal Index

TI is defined as: $TI = \frac{W_0}{W_{deg}}$

where: W0 is the time-averaged acoustic power and Wdeg is the estimated power necessary to raise the target tissue 1°C.

The displayed TI is an estimate of temperature increase of soft tissue or bone, presented to make it easier for the operator to implement the ALARA (As Low As Reasonably Achievable) principle. There are three thermal index categories:

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

The correct category is chosen based on display standard, mode of operation and chosen application, and the relevant TI category presented to the operator. It is therefore important that the operator chooses the right application. The system also provides the ability to select the display of any of the TI categories regardless of the current application.

Vscan Air will for each scan setup calculate and limit TI for the chosen index category to 3.0.

Mechanical Index

MI is the estimated likelihood of tissue damage due to cavitation.

MI is defined as:

$$MI = \frac{p_{r,a}(z_{MI})\, f_{awf}^{-1/2}}{C_{MI}}$$

equivalent to Track3 MI when the depth ZMI=Zsp.

The MI will not exceed a value of 1.9 according to Track 3 in the FDA 510(k) guidance of September 9, 2008.

The depth for $p_{r,a}$ *(z)* is not limited by the Break-Point Depth.

The MI according to IEC62359 Ed2 will not exceed 1.9.

Controls Affecting Acoustic Output

The initial means by which the user can affect acoustic output are by 1) selecting a probe, 2) selecting an application (exam category) and then 3) selecting the imaging mode or imaging characteristics (depth, color ROI center position). This is achieved through an acoustic output control scheme in which all parameters that directly or indirectly affect acoustic output are fed to the control algorithm. The algorithm estimates all relevant parameters and compares them to the FDA limits.

Output levels remain below the limits with a 95% confidence margin. The absolute maximum allowable output for all applications is:

- ISPTA less than or equal to 720 mW/cm2
- MI less than or equal to 1.9
- TI less than or equal to 6

The Acoustic Output Control Scheme

Input Parameters		Control Algorithm		Output Parameters
Transmit frequency	---->			
Transmit apodization	---->			
Focal depth	---->			
Steering angle	---->	Output control never to exceed limit minus toleranes	---->	Transmit voltage control to Beamformer
Sector size	---->			
Pulse repitition frequency	---->			
Pulse length	---->			
Mode combination	---->	I_{SPTA}	---->	Thermal/mechanical Indices to Output Display
Application	---->	TIS/TIB/TIC		
Acoustic ouput control	---->	MI		
Probe sensitivity	---->			

FDA Limits @ 95% confidence tolerance

Probe surface temperature safety mechanisms

The system has an Probe Surface Temperature Control Algorithm to ensure that each probe is set up and run within temperature limits given by the harmonized safety standard IEC60601-2-37. The Control Algorithm is implemented in the software and calibrated by laboratory measurements of surface temperature on each probe type. A Control Algorithm Input Parameter check is performed during setup of each new scan, and any detected error in the input, and/or malfunction are protected by software error handling that aborts setup and prevents start of scanning. The system has monitoring of voltage and power used by the ultrasound transmits circuitry and probe. If transmit voltage or power exceeds expected values, the transmit voltage will be set to zero and scanning will stop. This mechanism will protect against illegal setup and/or probe defects.

These safety mechanisms are designed to ensure that the lens surface temperature of the two transducers, is kept within values listed in the table ‘Maximum Vscan Air CL temperature’ on *page 2-23* section in this user manual. The Vscan Air probe is equipped with internal temperature sensors and mechanisms to monitor and limit the probe temperature so that the lens surface temperature is kept <43°C.

No particular user actions are required for the proper functioning of the described safety mechanisms.

Acoustic Parameters as Measured in Water

Definitions, symbols and abbreviations

The following definitions, symbols and abbreviations are used in the acoustic output reporting tables in this chapter::

IEC	Meaning—IEC/EN62359 Ed.2
MI	Mechanical Index
TIS	Soft Tissue Thermal Index
TISas	Soft Tissue Index at-surface, scanning or non-scanning
TISbs	Soft Tissue Index below-surface, scanning or non-scanning
TIB	Bone Thermal Index
TIBas	Bone Thermal Index at surface, scanning or non-scanning
TIBbs	Bone Thermal Index below-surface, scanning or non-scanning
TIC	Cranial-bone Thermal Index
$p_{r,\alpha}$	Attenuated peak-rare-factional acoustic pressure
C_{MI}	Normalizing Coefficient 1MPa*MHz-1/2
P	Output power
P_{1x1}	Bounded square output power
z_s	Depth for TIS below surface
z_b	Depth for TIB below surface
z_{MI}	Depth for MI
$Z_{pii,\ \alpha}$	Depth for $I_{pa,\ ,\alpha}$ and $I_{spta,\ ,\alpha}$
fawf	Acoustic working frequency
prr	Pulse repetition rate
srr	Scan repetition rate
n_{pps}	Number of pulses per scan line
$I_{pa,\ ,\alpha}$	Attenuated pulse average intensity
$I_{spta,\ ,\alpha}$	Attenuated speatial-peak temporal-average intensity
I_{spta}	Spatial-peak temporal-average intensity
pr	Peak-rare-factional acoustic pressure

Operating Conditions

All table entries are with the operating conditions specified at the end of the table.

Acoustic Output Reporting Tables for Track 3/EN/IEC 60601-2-37

NOTE: These acoustic output reporting tables are produced according to IEC 62359 Ed.2.

NOTE: The Acoustic Output tables are in English only.

Transducer Model: Curved array transducer

Operating Mode: black and white (including harmonic)

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			1,58	0,32		0,31		#
Index component value				0,32	0,32	0,31	0,31	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2,45					
	P	(mW)		143,2		141,9		-
	P_{1x1}	(mW)		27,5		27,2		
	z_s	(cm)			3,3			
	z_b	(cm)					5,1	
	z_{MI}	(cm)	4,6					
	$z_{pii,\alpha}$	(cm)	4,6					
	f_{awf}	(MHz)	2,43	2,42		2,4		-
Other Information	prr	(Hz)	1830					
	srr	(Hz)	4,7					
	n_{pps}		3					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	209,5					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	7,4					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm^2)	16,0					
	p_r at z_{pii}	(MPa)	3,54					
Operating Conditions	Depth (cm)		9,4	18,4		18,4		-
	Width (°)		68	68		68		-
	Application		Vascular	Vascular		Ob		-

Figure 7-1. Curved array transducer - black/white (including harmonic)

NOTE: This transducer does not have a preset optimized for Transcranial/Neonatal cephalic use.

Transducer Model: Curved array transducer

Operating Mode: black and white (including harmonic) and color

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			1,59	0,81		0,90		#
Index component value				0,81	0,81	0,90	0,90	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2,47					
	P	(mW)		147,4		174,5		-
	P_{1x1}	(mW)		82,3		81,0		
	z_s	(cm)			2,2			
	z_b	(cm)					4,2-4,6	
	z_{MI}	(cm)	4,9					
	$z_{pii,\alpha}$	(cm)	4,9					
	f_{awf}	(MHz)	2,42	1,9/2,0		2,3-2,42		-
Other Information	prr	(Hz)	1238					
	srr	(Hz)	3,1					
	n_{pps}		3					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	206					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	5,4					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm^2)	12,2					
	p_r at z_{pii}	(MPa)	3,65					
Operating Conditions	Depth (cm)		10,4	8,4		8,4		-
	Width(°) black and white		68	60		68		-
	ROI center(cm)		5	5		6		-
	ROI span(cm)		5	7		5		-
	Width(°) color		20	30		20		-
	Application		Ob	Cardiac		Ob		-

Figure 7-2. Curved array transducer - black/white (including harmonic) and color

NOTE: This transducer does not have a preset optimized for Transcranial/Neonatal cephalic use.

Transducer Model: Linear array transducer

Operating Mode: black and white (including harmonic)

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			1,14	0,03		#		0,04
Index component value				0,03	0,03	-	-	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2,96					
	P	(mW)		2,13		-		0,90
	P_{1x1}	(mW)		0,79		-		
	z_s	(cm)			0,7			
	z_b	(cm)					-	
	z_{MI}	(cm)	1,5					
	$z_{pii,\alpha}$	(cm)	1,5					
	f_{awf}	(MHz)	6,69	6,69		-		8,50
Other Information	prr	(Hz)	1515					
	srr	(Hz)	13					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	390,1					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm²)	2,9					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm²)	5,7					
	p_r at z_{pii}	(MPa)	4,01					
Operating Conditions	Depth (cm)		4,1	4,1		-		6,1
	Width (-)		2	2		-		2
	Application		SmallParts	SmallParts		-		Neo Head

Figure 7-3. Linear array transducer - black/white (including harmonic)

NOTE: This transducer does not have a preset optimized for Obstetric/ Fetal use.

Transducer Model: Linear array transducer

Operating Mode: black and white (including harmonic) and color

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			1,35	0,69		#		1,34
Index component value				0,69	0,69	-	-	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	3,15					
	P	(mW)		27,5		-		27,2
	P_{1x1}	(mW)		26,7		-		
	z_s	(cm)			0,7-0,8			
	z_b	(cm)					-	
	z_{MI}	(cm)	1,6					
	$z_{pii,\alpha}$	(cm)	1,6					
	f_{awf}	(MHz)	5,43	8,74 / 5,43		-		5,4-8,8
Other Information	prr	(Hz)	184					
	srr	(Hz)	14,1					
	n_{pps}		1					
	$I_{ps.\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	601,8					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm²)	103,3					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm²)	188,2					
	p_r at z_{pii}	(MPa)	4,25					
Operating Conditions	Depth (cm)		3,1	3,1		-		2,5
	Width(-) black and white		2	2		-		2
	ROI center(cm)		2	2		-		2
	ROI span(cm)		1	1				1
	Width(-) color		1	1		-		1
	Application		Nerves	Muscular		-		Neo Head

Figure 7-4. Linear array transducer - black/white (including harmonic) and color

NOTE: This transducer does not have a preset optimized for Obstetric/ Fetal use.

Transducer Model: Linear array transducer

Operating Mode: black and white, Ophthalmic

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			0,19	0,0015		#		#
Index component value				0,0015	0,0015	-	-	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	0,58					
	P	(mW)		0,09		-		-
	P_{1x1}	(mW)		0,04		-		
	z_s	(cm)			0,9			
	z_b	(cm)					-	
	z_{MI}	(cm)	2,0					
	$z_{pii,\alpha}$	(cm)	2,0					
	f_{awf}	(MHz)	9,15	9,03		-		-
Other Information	prr	(Hz)	1440					
	srr	(Hz)	15					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	19,1					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm²)	0,1					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm²)	0,3					
	p_r at z_{pii}	(MPa)	1,07					
Operating Conditions	Depth (cm)		3,5	4,5		-		-
	Width (-)		2	2		-		-
	Application		Ophthalmic	Ophthalmic		-		-

Figure 7-5. Linear array transducer - black/white, Ophthalmic

NOTE: The Linear array Ophthalmic preset is not optimized for Obstetric/Fetal or Transcranial/Neonatal cephalic use.

Transducer Model: Linear array transducer

Operating Mode: black and white and color, Ophthalmic

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			0,20	0,006		#		#
Index component value				0,006	0,006	-	-	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	0,49					
	P	(mW)		0,36		-		-
	P_{1x1}	(mW)		0,23		-		
	z_s	(cm)			0,7-0,8			
	z_b	(cm)					-	
	z_{MI}	(cm)	1,5					
	$z_{pii,\alpha}$	(cm)	1,5					
	f_{awf}	(MHz)	5,61	9,19 / 5,61		-		-
Other Information	prr	(Hz)	4964					
	srr	(Hz)	155					
	n_{pps}		1					
	$I_{ps.\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	9,0					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm²)	0,9					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm²)	1,6					
	p_r at z_{pii}	(MPa)	0,64					
Operating Conditions	Depth (cm)		3,1	3,1		-		-
	Width (-) black and white		1	2		-		-
	ROI center (cm)		1,75	1,75		-		-
	ROI span(cm)		1	1				-
	Width (-) color		1	1		-		-
	Application		Ophthalmic	Ophthalmic		-		-

Figure 7-6. Linear array transducer - black/white and color, Ophthalmic

NOTE: The Linear array Ophthalmic preset is not optimized for Obstetric/Fetal or Transcranial/Neonatal cephalic use.

Appendices

Statements on the safety of ultrasound

October 1982, revised March 1983 and October 1983.

Diagnostic ultrasound has been in use for over 35 years. Given its known benefits and recognized efficacy for medical diagnosis, including use during human pregnancy, the American Institute of Ultrasound In medicine herein addresses the clinical safety of such use.

No confirmed biological effects on patients or instrument operators caused by exposure at intensities typical of present diagnostic ultrasound instruments have ever been reported. Although the possibility exists that such biological effects may be identified in the future, current data indicate that the benefits to patients of the prudent use of diagnostic ultrasound outweigh the risks, if any, that may be present.

Measurement accuracy

Measurement accuracy

The following information is intended to provide guidance to the user in determining the amount of variation or measurement error that should be considered when performing clinical measurements with this equipment. Error can be contributed by equipment limitations and improper user technique. Be sure to follow all measurement instructions and develop uniform measurement techniques among all users to minimize the potential operator error. Also, in order to detect possible equipment malfunctions that could affect measurement accuracy, a quality assurance (QA) plan should be established for the equipment that includes routine accuracy checks with tissue mimicking phantoms.

Please be advised that all distance related measurements through tissue are dependent upon the propagation velocity of sound within the tissue. The propagation velocity usually varies with the type of tissue, but an average velocity for soft tissue is assumed. This equipment is designed for, and the accuracy statements listed on are based on, an assumed average velocity of 1540 m/s..

Table 7-1: Measurement accuracy - Curved array (deep scanning) transducer

Measurement	Unit	Useful range	Accuracy
Distance			
Axial	cm or mm	2mm-200mm	±1mm or ±3% whichever is greater
Lateral	cm or mm	4mm-100mm	±2mm or ±5% whichever is greater
Circumference (ellipse)	cm or mm	10mm-300mm	±5% or ±2mm whichever is greater

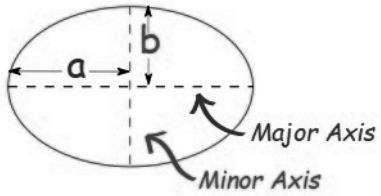
Measurement accuracy (continued)

Table 7-2: Measurement accuracy - Linear array (shallow scanning) transducer

Measurement	Unit	Useful range	Accuracy
Distance			
Axial	cm or mm	1mm-60mm	±0.5mm or ±3% whichever is greater
Lateral	cm or mm	2mm-40mm	±1mm or ±5% whichever is greater
Circumference (ellipse)	cm or mm	5mm-150mm	±5% or ±1mm whichever is greater

The ellipse circumference is calculated via the below formula from §16 in Ramanujan, Srinivasa (1914), "Modular Equations and Approximations to π". Quart. J. Pure App. Math. 45: 350–372. ISBN 9780821820766.

$$\pi \left[3(a+b) - \sqrt{(3a+b)(a+3b)} \right]$$



Speed of Sound in Tissue

The average value 1540 meters / second is used for all calculations. Depending on the tissue structures, this generalization may give errors from 2% (typical) to 5% (much fatty tissue layers present).

Indications Reference Guide

Disclaimer

The information in this section is meant to be reference for examples of anatomies and examinations that can be evaluated by this product. The list may not be all inclusive.

Curved Array (Deep scanning) Transducer

The curved array transducer on Vscan Air CL supports Black/ white (B-mode), Color (Color doppler) and Harmonic imaging modes. Vscan Air is indicated for ultrasound imaging, measurement, and analysis of the human body in clinical applications that include:

Table 7-3: Curved Array Transducer

Clinical Application	Anatomy	Evaluation
Abdominal (Adult/ Pediatrics)	• Gall bladder, biliary tree, common bile duct • Liver • Pancreas • Spleen • Bowel including Appendix, small bowel loops • Abdominal aorta • Kidneys	• Gall stones • Gall bladder inflammation ((wall thickening, surrounding fluid) • Biliary obstruction (duct dilatation) • Hepatomegaly • Fatty liver • Splenomegaly • Intestinal obstruction • Appendicitis • Peritoneal fluid • Mass/cyst/ Abscess • Abdominal aortic aneurysm • Kidney stones
Urology (Adult/ Pediatrics)	• Kidneys • Ureter • Urinary Bladder • Uretero-vesicular junction • Prostate	• Kidney, ureteral, bladder stones • Kidney length • Hydronephrosis • Bladder dysfunction • Pre-post Bladder volume • Bladder inflammation (wall and mucosal changes, calcifications) • Prostate size and volume • Mass/ cyst • Ureteral jets with color

Table 7-3: Curved Array Transducer

Clinical Application	Anatomy	Evaluation
OB-Gyn	• Uterus and endometrium • Ovaries • Cervix • Pouch of Douglas (POD) • Gestational Sac (GS) • Placenta • Amniotic fluid • Fetus(es)	• GS location (Intra-uterine/ extra-uterine) • Fetal viability/ heart motion • Placenta position- (including low-lying and previa) • Fetal position and presentation • Amniotic fluid assessment • Cervical length measurement/ cervical insufficiency • Fetal well-being assessment: Biophysical profile (breathing, movements, tone, amniotic fluid) • Confirmation of fetal death • Intrauterine device position • Endometrial thickness measurement • Uterine/ adnexal mass/ cyst (fibroids, cysts) • Free fluid in Pouch of Douglas

Lung/Thoracic (Adult/ Pediatrics)	• A-lines, B-lines, E-lines
	• Pleura
	• Lung tissue
	• Lung sliding
	• Lung point
		• Pneumothorax and hemothorax
		• Pleural Effusion
		• Lung consolidation
		  • Pneumonia/ pneumonitis
		  • Pulmonary fibrosis
		• Pulmonary interstitial and inflammatory disorders (Ex. ILD, COPD)
		• Acute respiratory distress syndrome

Cardiac and hemodynamic assessment (Adult/ Pediatrics*)
 	
**Pediatric population for Cardiac application defined as minimum body weight 40 Kg and above.*
	• Heart (atria, ventricles, valves) including pericardium
	  • Subcostal view
	• Inter-atrial and interventricular septum
	• Pulmonary arteries/ veins
	• IVC
		• Pericardial fluid
		• LV and RV size and function
		• Valvular regurgitations/ stenosis
		• Volume status and responsiveness
		  • IVC size
		  • Respiratory variation

Musculoskeletal (Conventional) (Adult/ Pediatrics)	• Hip/knee/ Shoulder joints • Femur • Humerus/elbow • Tibia/fibula • Radius/ulna • Muscles • Ligaments • Tendons • Nerves	• Fluid • Cyst/ Mass • Long bone fractures • Ligament and joint integrity • Tendon injuries (tendonitis, rupture/ tear) • Muscle tears • Peripheral nerve blocks

Table 7-3: Curved Array Transducer

Clinical Application	Anatomy	Evaluation
Procedure guidance (Adult/ Pediatrics)	• Heart • Lung • Uterus • Abdomen • Thorax • Bladder • Nerve plexus • Hip/Knee/ Shoulder joints	• Fluid detection: Pericardial, Pleural, Peritoneal, Amniotic, Joints • Procedures: Thoracentesis, Paracentesis, Pericardiocentesis, Amniocentesis, Arthrocentesis • Foreign body visualization/ localization • Bladder catheterization • Nerve blocks • Biopsy • Placement and monitor position of tubes and catheters
Protocols	• Heart • IVC • Lungs • Abdomen	• FAST • eFAST • BLUE • FASH • FASE

Linear Array (Shallow scanning) Transducer

The linear array transducer on Vscan Air CL supports Black/ white (B-mode), Color (Color doppler) and Harmonic imaging modes. Vscan Air is indicated for ultrasound imaging, measurement, and analysis of the human body in clinical applications that include:

Table 7-4: Linear Array Transducer

Clinical Application	Anatomy	Evaluation
Peripheral Vascular (Adult and Pediatrics)	• Arteries including Carotid, vertebral, subclavian, axillary, brachial, iliac, saphenous, popliteal, femoral • Veins including Jugular, subclavian, cephalic, basilic, saphenous, femoral, popliteal, tibial	• Deep vein thrombosis • Atherosclerosis- Intima media thickness, plaques, vessel occlusion/ stenosis • Subclavian Steel syndrome

Lung/ Thoracic (Adult / Pediatric)	• A-lines, B-lines, E-lines
	• Pleura
	• Lung tissue
	• Lung sliding
	• Lung point
		• Pneumothorax and hemothorax
		• Pleural Effusion
		• Lung consolidation
		  • Pneumonia/ pneumonitis
		  • Pulmonary fibrosis
		• Pulmonary interstitial and inflammatory disorders (Ex. ILD, COPD)
		• Acute respiratory distress syndrome

Table 7-4: Linear Array Transducer

Clinical Application	Anatomy	Evaluation
Small organs (Adult/ Pediatric)	• Testes • Scrotum • Thyroid • Breast • Bowel • Abdominal wall • Skin • Subcutaneous tissue • Fascia • Lymph nodes	• Testicular torsion (size, echo-texture and vascularity) • Epididymo-orchitis • Fluid collection in scrotal sac • Hematomas, hernias • Breast nodules, mass, cyst • Abdominal wall masses, hernias • Thyroid nodules/cyst/mass/ diffuse enlargement • Bowel pathology (ex. appendicitis, diverticulitis, intestinal obstruction) • Pyloric stenosis/ Intussusception for pediatric patients • Soft tissue infection (cellulitis, abscess, bed sore) • Foreign body visualization/ localization • Cutaneous mass
Musculoskeletal – (Superficial and conventional) (Adult/ Pediatrics)	• Tendons • Muscles • Ligaments • Nerves • Long bones (ex. Humerus, Radius, Ulna, Femur, Tibia, Fibula) • Joints (Ankle, Shoulder, Knee, Elbow, Wrist) • Joint space/ bursa	• Tendon injuries (tendonitis, rupture/ tear) • Muscle tears • Long bone fractures • Carpal Tunnel syndrome • Fluid collection in joint space, muscles, bursae • Joint and ligaments integrity • Cyst/ Mass • Hip joint evaluation for neonates and infants
Nerves (Adult/ Pediatrics)	• Peripheral nerves including examples as Interscalene, supraclavicular, infraclavicular, axillary plexus, Median N, Radial N, Ulnar, Femoral, Popliteal, Tibial, Peroneal, Saphenous N	• Peripheral nerve blocks
Neck and airway (Adult / Pediatric)	• Cervical Lymph nodes • Trachea • Epiglottis, cricoid cartilage, cricothyroid membrane • Esophagus • Vocal folds	• Neck masses • Airway assessment • Vocal cord dysfunction

Table 7-4: Linear Array Transducer

Clinical Application	Anatomy	Evaluation
Procedural guidance (Adult/ Pediatrics)	• Thorax • Veins (including Jugular/ Subclavian/ Axillary/ Femoral / Brachial/ Basilic/ Cephalic) • Arteries (including femoral, radial, brachial, axillary, dorsalis pedis) • Peripheral nerves • Joints • Vertebral spaces • Skin and subcutaneous tissue • Trachea and surrounding structures	• Fluid detection and removal support: thoracentesis • Peripheral venous access • Central venous catheterization • Arterial access • Assessment and support of dialysis access • Nerve blocks • Joint aspiration and injections • Cyst aspiration • Biopsy • Abscess drainage • Foreign body visualization/ localization • Lumbar Puncture • Endotracheal tubes placement and confirmation • Support placement and monitor position of tubes and catheters
Ophthalmic	• Optic nerve sheath • Retina • Globe • Lens	• Retinal detachment • Vitreous hemorrhage • Intra-ocular foreign body visualization • Globe rupture • Optic Nerve sheath diameter • Lens dislocation
Cephalic (Neonatal)	• Fontanelle • Superficial and mid-superficial cranial structures	• Gyral-sulcal anatomy • Superior sagittal sinus thrombosis • Cerebral edema • Extra-axial fluid collections
Protocols	• Lungs	• eFAST • BLUE

Disclaimer: Ophthalmic is not available in Japan.

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