GE HealthCare

R3

Vscan Air™ with Vscan Air CL probe

See more. Treat faster.

Contents

Vscan Air with Vscan Air CL probe

Vscan Air is a battery-operated, general-purpose diagnostic ultrasound imaging system for use by qualified and trained healthcare professionals or practitioners. It enables ultrasound imaging guidance as well as visualization and measurement of anatomical structures and fluid.

Vscan Air CL consists of a dual-headed probe model with a curved transducer on one end and linear array transducer on the other. It comes with an app which can be installed on Android™ or iOS® mobile devices.

Its pocket-sized portability and simplified user interface enable integration into training sessions and examinations in professional healthcare facilities (ex. hospital, clinic, medical office), home environments, road/air ambulance, and other environments described in the product 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 assessments for adult, pediatric, and neonatal patients. Vscan Air can also be useful for interventional guidance.

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

General characteristics

- 128 physical channel beamforming
- Harmonic imaging for increased signal-to-noise ratio and reduced artifacts from side lobes, grating lobes, and reverberations, resulting in superior tissue definition and reduced speckle artifacts. With the greater penetration of lower ultrasound frequencies, high-quality harmonic imaging at greater depth can be performed.
- Total scan time of 50 minutes with fully charged battery (with 80% black and white, 20% color imaging)
- Recharge battery from 10% to 90% capacity in 75 minutes
- Start scanning faster with smart connect pairing, which keeps your probe connected to your display device while charging
- Dimension: 131 x 64 x 31 mm
- Weight: 205 +/- 3 grams
- IP67-rated
- Drop robustness: MIL-STD-810G, Method 516.7, Table 516.7-VII

Curved array transducer for deep scanning

- Specific clinical applications and exam types including: abdominal, fetal/obstetric, gynecological, urological, thoracic/lung, cardiac (adult and pediatric, 40 kg and above), vascular/peripheral vascular, musculoskeletal (conventional), pediatric, interventional guidance (includes free-hand needle/catheter placement, fluid drainage, nerve block, and biopsy)
- Broad-bandwidth curved array:
  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

- Specific clinical applications and exam types including: vascular/peripheral vascular, musculoskeletal (conventional and superficial), small organs, thoracic/lung, ophthalmic, pediatric, neonatal cephalic, interventional guidance (includes free-hand needle/catheter placement, fluid drainage, nerve block, vascular access, and biopsy)
- Broad-bandwidth linear array:
  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

Modes

B-mode

Black/white imaging

- Black-and-white mode for displaying anatomy in two dimensions in real time

Color Doppler

Color flow

- Color-coded overlay for real-time blood flow imaging

PW

Pulsed wave spectral Doppler

- Displays speed and direction of blood flow allowing velocity measurements

M-mode

Motion mode

- Displays tissue motion over time (along one direction as indicated by M-mode cursor)

User interface

Helps enhance ultrasound imaging with a minimized number of keys and intuitive, thumb-controllable, touchscreen user interface. The Vscan Air app supports portrait as well as landscape mode to optimize image size and ergonomics for different use scenarios.

- Single key/gesture to control freeze/unfreeze, store, gain, and depth control
- Two steps to change preset with appropriate transducer
- Two steps to start reviewing images from an exam
- Presets with optimized settings for imaging different organs. User-selectable default preset for immediate use after starting the app.
- Measurements: Distance, circumference, angle, velocity, slope, heart rate, bladder volume and obstetric measurements (BPD, HC, AC, FL, CRL, AFI, DVP and AOP)
- Annotations: Arrow and free text
- Transducer element check
- Selectable centerline marker
- Selectable TGC control with 6 depth-dependent gain controls
- Device configuration and management tools are easily reachable by swiping in the menu
  - Enablement of TGC controls, preview mode, storage of binary images
  - Settings for auto-freeze, video duration
  - Configuration of probe button function (freeze or store)
  - Download user manual in selectable language to Vscan Air app
  - Diagnostics in Vscan Air app with ability to upload log files to GE HealthCare server
  - Direct access to customer support information
  - Link to cloud-based educational materials
  - Information about software status of probe and app with ability to un- and re-register

Data storage

Patient data identification

- Manual data entry of patient information for an exam
- Select from DICOM® Modality Worklist on request. Such worklist supports consistent labeling of images, video clips, and exams before export to DICOM PACS.
- Query DICOM Modality Worklist for a particular Patient ID

Exam data on device

- Data for up to 500 exams can be stored on mobile device
- Data is stored in generic formats: jpg for still frames, mpg for videos
- Complementing storage of binary image data can be selected. Such data could be useful for further image analytics in collaboration with GE HealthCare.
- Data is organized as individual examinations with a collection of images and can be linked with patient identification
- All stored data can be recalled for review

Data export

- Anonymized images and videos can be shared with other apps available on smart devices
- Images, video clips, or exams with or without patient information can be wirelessly exported in generic formats (jpg, mp4) to shared network folders
- Images, video clips, or exams with patient information can be wirelessly exported in DICOM format to DICOM PACS
- Images, video clips, or exams with patient information can be wirelessly exported in DICOMweb™ format using TLS protocol to MyImageCloud[1] (option) or other compatible third-party cloud storage (STOW-RS)
- MPPS

Supported DICOM services

- Verify
- Modality Worklist
- Store
- Storage Commitment
- Secure DICOM (TLS)
- Secure DICOMweb – STOW-RS (TLS)

Data security

Secured data at rest

- Vscan Air app starts only after confirmation of mobile device protection with user authentication
- Additional security provision via unique user accounts and password protection for the app
- Multiple users utilizing a shared mobile device can create and use their own account

Data security (con't)

Secured data at rest

- Account sign-in credentials support the integration of enterprise identity providers (IdP)[1] for Enterprise Single sign-on (SSO) user authentication
- Images and other patient information data are stored in a private, on-device space with no access from other apps on the mobile device
- Images are stored on-device without embedded patient identification and linked with encrypted patient database
- FIPS 140-2 compliant database encryption (AES-256-bit encryption)
- User-selectable, additional PIN or biometric (Face ID or fingerprint) protected access to patient data on Vscan Air app
- Exam data is wiped off the device after 10 attempts with incorrect PIN

Secured data on the move

- Images are anonymized before being shared with other apps on the mobile device
- Support of enterprise-grade wireless encryption standards including EAP and WPA2 (PSK)
- TLS encryption with optional peer authentication to support secure DICOM transfer
- Configurable time period for image removal on the device after confirmed storage from DICOM Storage Commitment server
- MyRemoteShare[i] calls are encrypted end to end (over TLS) (option)
- Image/Exam export to MyImageCloud[1] is via secure DICOMweb transfer (STOW-RS over TLS) (option)

Secure Authentication Options

- Complex password authentication with automatic sign-out options or Federated identity Enterprise Single sign-on (SSO)

SSO prerequisites:

- Public IP Addresses: Federation servers should be accessible via a public IP address over the internet
  - Firewall Configuration: Open specific ports to allow federation traffic (e.g., ports 443 for HTTPS)
  - Internet Connection: A stable and reliable internet connection with sufficient bandwidth to handle the anticipated traffic

Software:

- Install necessary software (e.g., ADFS, Azure AD Connect) to support federation
- Data Encryption: Ensure all data in transit is encrypted using TLS/SSL

Supported protocols:

- SAMLv2 (Strongly preferred)
- Open ID Connect (OIDC)/OAuth2.0 (Strongly preferred)
- Read-only Lightweight Active Directory Protocol (LDAPS) over a secure channel

Digital Tools & AI features

Digital Tools and AI features for Vscan Air are optional and may be sold separately from the device, either individually or as part of an offering bundle.

MyRemoteShare[2]

- Enables a Vscan Air user to engage in an audio conversation with a remote person while using the device to share the scan screen (video from the user's mobile device camera may also be shared)
- Remote participants can join a MyRemoteShare session via any standard web browser on a computer or mobile devices via a unique link
- MyRemoteShare is powered by Zoom's secure healthcare application

MyImageCloud

- A cloud based secure data storage and management solution for DICOM images and exams exported from a Vscan Air app
- Accessed by sign-in to myvscan.gehealthcare.com using the same credentials used for the Vscan Air app
- Review uploaded exams/images or share them with named peers or colleagues

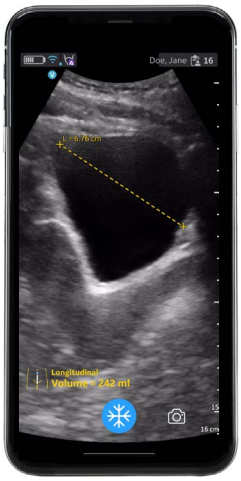
MyDeviceHub

- A device management solution for enterprises to manage their fleet of Vscan Air devices
- Accessed by the organization's named administrators via myvscan.gehealthcare.com
- Ability to register Vscan Air probes, manage access to named users, and centrally configure DICOM servers

Auto Bladder Volume[1]

Vscan Air CL with Auto Bladder Volume provides rapid and easy urinary bladder volume measurements to help prevent the unnecessary use of catheters. Auto Bladder Volume is built with an AI powered algorithm that detects the borders of the bladder and automatically places the measurements. With Vscan Air users get image quality that allows for clear visualization of the bladder and then control over the final measurements for when adjustments are needed. Auto bladder volume then automatically calculates the volume.

Experience a different kind of bladder scanner. Empowering users to make the best clinical decisions with the confidence that comes with visual confirmation and clear information.



Display devices and operating system options[5]

Operating system options
Android phones and tablets with OS version 12, 13, 14 or newer. Devices with 0x64 ARM based CPU architecture and 64-bit Kernel, minimum 4 GB RAM, Android open GL ES 3.0, and compatibility with Google Play™ store
iPhone devices with iOS 15, 16, 17 or newer
iPad devices with iPad OS 15, 16, 17 or newer

Screen requirements
Size: 5 to 20 inches
960 x 640 (or 640 x 960) pixel or more

Internal memory requirement
8 GB storage space

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

We highly recommend using a display device and OS that are verified/validated by GE HealthCare for compatibility with Vscan Air. The list of verified/validated devices can be found in Vscan Support Center.

Standard configuration

The following items are included in the standard Vscan Air offering

- Vscan Air CL probe
- Vscan Air app (Vscan Air for iOS and Vscan Air for Android)[3]
- Protective carrying case
- Wireless charger including USB cable
- Country-specific AC adapter[4]
- Quick Start Guide
- Electronic user manual

Available accessories

- User manual in different languages
- Additional protective carrying case
- Additional wireless charger including USB cable
- trophon® Wireless Ultrasound Probe Holder[1]
- AC Adapter Multiplug[1]
- Vscan Air Roll Stand[1]

The list of the verified and validated mobile devices can found on Vscan Support Center.

User support tools

Vscan Family web portal

- Enhances the Vscan Air experience by providing online resources from product information to clinical and service support
- Additional educational resources will be posted on the Vscan Family web portal, including webinars, thought leadership, further online programs, and training opportunities

Ultrasound education solutions

To help users get familiar with common point of care applications and improve ultrasound skills and knowledge, two digital education solutions are available via our partners.

Point of Care Ultrasound FocusClass by 123sonography[1]

This course includes access to five hours of high-quality video content, easy-to-follow and hands-on demos, practical clinical examples, and proven didactic principles to help increase competence and confidence. This program is designed for primary care covering a variety of ultrasound exam types including cardiac, OB, abdominal, lung, joints, carotid artery, and eFAST.

OB/GYN Ultrasound FocusClass by 123sonography[1]

This is an online, clinical training course tailored for obstetrics and gynecology application users. The individual lectures contain a general introduction to the topic, image acquisition theory and demonstration, and normal findings and pathology presented in real cases. The training comprises of 6 online modules and is focused on different, common indications: Fetal well-being/decreased or absent fetal movements, evaluation of cervical insufficiency, use of HHUS/POCUS during labor and delivery, evaluation of abdominal pain with missed periods and bleeding, evaluation of bleeding and pain in late second or third trimester, evaluation of menorrhagia, and post-menopausal bleeding or irregular cycles.

Safety conformance

Safety classifications

Vscan Air CL probe is classified as internally powered medical electrical equipment with type BF applied parts according to IEC 60601-1.[6]

Vscan Air CL C1 and Vscan Air CL G1 probes are CE-marked according to the European medical device directive (93/42/ECC), RED (2014/53/EU), RoHS (2015/863/EU), and is compliant to 2012/19/EU (WEEE).

Vscan Air R3 for Android and Vscan Air R3 for iOS are CE-marked according to MDR (2017/745/EU).

Vscan Air CL probe is NRTL Certified to CAN/CSA-C22.2 No. 60601-1 and ANSI/AAMI ES60601-1.

Wireless charger pad of Vscan Air is certified according to IEC/EN62368-1.

Vscan Air conforms to applicable clauses of the following safety standards:	
IEC 60601-1[7]	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2[7]	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests (Group One, Class B per CISPR 11 / EN 55011)
IEC 60601-2-37	Medical electrical equipment — Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 60601-1-11	Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 60601-1-12	Medical electrical equipment — Part 1-12: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
EN 13718-1	Medical vehicles and their equipment — Air ambulances Part 1: Requirements for medical devices used in air ambulances
EN 1789	Medical vehicles and their equipment — Road ambulances
ISO 10993-1[8]	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
IEC62304	Medical device software – Software life cycle processes
IEC62366-1	Medical devices – Part 1: Application of usability engineering to medical devices

About GE HealthCare

GE HealthCare is a leading global medical technology, pharmaceutical diagnostics, and digital solutions innovator, dedicated to providing integrated solutions, services, and data analytics to make hospitals more efficient, clinicians more effective, therapies more precise, and patients healthier and happier. Serving patients and providers for more than 100 years, GE HealthCare is advancing personalized, connected, and compassionate care, while simplifying the patient's journey across the care pathway. Together our Imaging, Ultrasound, Patient Care Solutions, and Pharmaceutical Diagnostics businesses help improve patient care from prevention and screening, to diagnosis, treatment, therapy, and monitoring. We are an $18 billion business with 51,000 employees working to create a world where healthcare has no limits.

Follow us on Facebook, LinkedIn, Twitter, Instagram, and Insights for the latest news, or visit our website gehealthcare.com for more information.

References:

1. Not available in every country
2. The quality of the ultrasound image visible to the remote participant is dependent on the network connection and display device used by the participant, thus cannot be validated. MyRemoteShare is therefore not intended for diagnostic purposes.
3. The Vscan Air app can be downloaded via App Store or Google Play, accordingly. It converts after confirmed by e-mail registration into a medical device. Before converting, it can be used for preview purposes as a non-medical device.
4. In accordance to IEC classification for power plugs, one AC adapter with either an A, C, G, or I connector will be part of standard configuration.
5. 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 in all devices. A recommended step in testing a particular device compatibility is the download, installation and first use of the Vscan Air app in preview mode.
6. When not charging using the wireless charger.
7. Including national deviations.
8. Includes compliance to relevant sub-parts of ISO 10993 as per the intended use of Vscan Air.

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