GE Healthcare

Vscan Air™

Data Sheet



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, 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 that can be installed on Android™ or iOS® mobile devices.

Its 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 in 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.

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

Probe Characteristics

128 physical channel beamforming

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

Color-coded overlay for real-time blood flow imaging

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.

Selectable centerline marker

Selectable focal zone marker

Selectable TGC control with 6 depth-dependent gain controls

Total scan time of 50 minutes with fully charged battery (with 80% black and white, 20% color imaging)

Any Qi-compliant wireless charger can be used to charge probe

Recharge battery in 75 minutes from 10% to 90% battery capacity

Dimensions: 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 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)

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

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)

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

User Interface

The Vscan Air offers 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, color on/off, gain and depth control

2 steps to change preset with appropriate transducer

2 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, ellipse

Device configuration and management tools in easy reach through swiping in menu:

- Enablement of TGC controls, preview mode, storage of binary images
- Setting Auto Freeze Time, 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 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.

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.
Data is organized as individual examinations with 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 device
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

Supported DICOM services
Verify
Modality Worklist
Store
Storage Commitment
Secure DICOM (TLS)

Data security

Secured data at rest:

- Vscan Air app starts only after confirmation of mobile device protection with user authentication
- Images and other patient information data are stored in private space of device with no access from other apps on 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 protected access to patient data on Vscan Air app
- Wiping off exam data 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 export to a DICOM PACS server

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)[i]
Protective carrying case
Hardcopy Quick Start Guide
Electronic Instruction Use Guide
Wireless charger pad including micro USB cable
Country-specific AC adapter[ii]

Available Accessories

Hardcopy user manual in different languages

Additional protective carrying case

Additional wireless charger pad

International AC adapters[ii]

Supported Mobile Platforms[iii]

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 requirements

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

Verified/ Validated mobile devices

The list of the verified and validated mobile devices can found on Vscan family web portal.

User Support Tools

Vscan family web portal

Online services to enhance the Vscan Air experience by providing resources, from product information to clinical and service support

Additional educational resources will be posted on the Vscan web portal, including webinars, thought leadership, further online programs and training opportunities

Ultrasound education solutions[iv]

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 123 Sonography

- This course includes access to five hours of high-quality video content, easy-to-follow hands-on demos, practical clinical examples and proven didactive 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 and joints

SonoSim® 365 for GE Healthcare

- SonoSim 365 for GE Healthcare provides convenient ultrasound education through integrated didactic instruction, hands-on training, and knowledge assessment. A portable, virtual ultrasound training experience utilizing real patient cases with a broad spectrum of normal and pathologic conditions. This offering includes a SonoSim probe, SonoSim drive, and your choice of five modules immediately accessible online – choose from a wide selection of modules including anatomy, physiology, and clinical procedures.

Safety Conformance

Safety classification
Vscan Air CL probe is classified as internally powered medical electrical equipment with type BF applied parts according to IEC 60601-1[v]
Vscan Air CL probe is CE-marked according to MDD (93/43/EEC), RED (2014/53/EU), RoHS (2011/65/EU), and is compliant to 2012/19/EU (WEEE)
Vscan Air for Android and Vscan Air for iOS are CE-marked according to MDD (93/42/EEC)
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 and/or IEC/UL/cUL60950-1

Vscan Air conforms to applicable clauses of the following safety standards:

IEC 60601-1[vi]	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2[iv]	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[vii]	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

[i] 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 non-medical device.

[ii] 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.

[iii] 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.

[iv] Not available in every country

[v] When not charging using the wireless charger.

[vi] Including national deviations.

[vii] Includes compliance to relevant sub-parts of ISO 10993 as per the intended use of Vscan Air.

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GE Medical Systems, Inc., doing business as GE Healthcare.

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