

Vscan Extend

Datasheet



Vscan Extend

Vscan Extend™ is a general purpose diagnostic ultrasound imaging system that can enable qualified and trained healthcare professionals to visualize and measure anatomical structures and fluid.

Its pocket-sized portability and simplified user interface enable integration into examination and training sessions. The information can be used for basic or focused assessments. It can also be used along with other medical data for clinical diagnostic purposes during routine periodic monitoring and triage assessments for adult and pediatric patients. Vscan Extend can also be used for procedural guidance. It meets requirements of use in the home healthcare environment.

Vscan Extend is available in two probe configurations – either with sector probe¹ or with a dual-headed probe that integrates both sector and linear transducers.

Vscan Extend is offered in three connectivity configurations²:

- USB configuration allows the transfer of images or videos via USB cable connection to a PC
- Wi-Fi access configuration includes USB features and adds the ability to export images wirelessly to shared Windows® network folders, along with wireless access to the GE Marketplace for download and installation of Vscan Extend apps
- The DICOM® configuration includes USB and Wi-Fi access features and adds the ability to wirelessly communicate with DICOM servers

Vscan Extend customers have access to the Vscan™ web portal, including online access to product and clinical reference materials.

General Specification

Dimensions and Weight

Display unit: 168 x 76 x 22 mm, 321 grams (including battery)

Display: 12.7 cm, 720 x 1280 pixels resolution

Sector probe: 129 x 32 x 25 mm, 85 grams

Dual probe: 129 x 39 x 28 mm, 120 grams

Imaging

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

Color-coded overlay for real-time blood flow imaging

Total scan time of 60 minutes with new fully charged battery (with 80% black-and-white/20% color imaging)

Universal power supply with 100 – 240 V, 50/60 Hz. Global plugs enable recharge of battery in 75 minutes for 90% battery capacity

Probe Characteristics

Vscan Extend is Available in Two Probe Configurations:

Sector probe allowing deep scanning

Dual probe integrating both sector and linear transducers, allowing deep and shallow scanning

Sector Transducer Holding a Phased Array for Deep Scanning (Available with Sector and with Dual Probe)

Broad-bandwidth phased array: 1.7 – 3.8 MHz

Field-of-view for black-and-white imaging: up to 70 degrees with maximum depth of 24 cm

Color flow sector represents blood flow within an angle of up to 40 degrees

Specific clinical applications and exam types include: cardiac, abdominal, renal, obstetrics and gynecology, urology, fetal, evaluation of presence of fluid, imaging guidance for needle/catheter placement (e.g. paracentesis, pericardiocentesis, thoracentesis, amniocentesis), peripheral vascular imaging (e.g. arteries and veins), thoracic/lung (e.g. pleural motion/sliding, line artifacts), adult cephalic, and pediatrics

Linear Array Transducer for Shallow Scanning (Available with Dual Probe)

Broad-bandwidth linear array: 3.3 – 8.0 MHz

Field-of-view for black-and-white imaging: aperture width of 2.9 cm with maximum depth of 8 cm

Color flow sector represents blood flow over image with full aperture and entire depth

Linear Array Transducer for Shallow Scanning (Available with Dual Probe) (cont.)

With the addition of the linear array transducer on the dual-headed probe solution, the specific clinical applications and exam types are expanded to include: peripheral vascular imaging (e.g. lower extremity, carotid), procedure guidance for arterial or venous vessels (e.g. central lines, upper extremity), small organs including thyroid, musculoskeletal (long bone, hip, shoulder, elbow and knee joints), evaluation of presence of fluid; thoracic/lung (e.g. pleural motion/sliding, line artifacts), ophthalmic,³ and pediatrics

User Interface

Basic ultrasound imaging with minimized number of keys and intuitive thumb-controllable user interface for right- and left-hand users (without reconfiguration)

Swiping menu to enable easy reach of advanced functions to manage exams and data

Presets to help simplify optimized settings for imaging different organs. Three presets can be set as favorites for quick access

Protocols to guide through series of steps during the ultrasound examination with automated labeling of stored images

AutoCycle (cardiac preset) to automatically detect full heart cycle for easy and fast review or storage or review

Duration of clip stored (non-cardiac presets) configurable to one, three or four seconds

Measurements

Distance measurement on-board device

A urinary bladder volume measurement tool is available as Vscan Extend app through GE Marketplace (optionally available with Wi-Fi access or DICOM configuration)

Data Storage

Data Security

GE process to design for privacy and security

- Privacy Impact Assessment covers data flows where data leaves the trusted boundary of the device. Potential risks are identified and mitigated as part of product design
- Security Risk Assessment to identify security risk to confidentiality and integrity of patient data, and to mitigate risks as part of product design

Secured data at rest

- Images anonymized
- FIPS 197 compliant database encryption (SQL Cipher with PBKDF2-based key generation and AES-256 bit encryption)
- Password protected access to patient data on Vscan Extend device

Secured data on the move

- Inter-application data flow is encrypted
- Support of enterprise-grade wireless encryption standards including EAP and WPA2 (PSK)
- Restricted administrative access to critical settings like Wi-Fi encryption or MDM (Mobile Device Management) client installation
- Validated MobileIron® and Airwatch® MDM client support

Wi-Fi Specification

IEEE 802.11 b/g/n supported⁴

Data Labeling

Exams can be manually labeled with patient information

Device synchronizes on-board DICOM Modality Worklist on request (option available with DICOM configuration). Such worklist supports consistent labeling of images, videos and exams before export to DICOM PACS

On-Board of Device

Data is stored in device memory and can be backed up on MicroSD or MicroSDHC card

Data is stored in generic formats: jpg for still frames, mp4 for videos

Data is stored in examination folders that can be linked with patient identification

All data can be recalled for review

Data encryption is provided

Image Export

Selected images, videos or exams can be exported to PC when the device is connected via USB cable. The anonymized data will be seen as on a memory stick

Selected images, videos, or exams can be wirelessly exported in generic formats (jpg, mp4) to Windows® shared network folders (option available with Wi-Fi access or DICOM configuration)

Selected images, videos, or exams can be wirelessly exported in DICOM format to DICOM PACS (option available with DICOM configuration)

Vscan Extend Uplink apps support easy export of selected images, videos, or exams to cloud-based image management solutions to support ultrasound case communication and collaboration (options available with DICOM configuration)

Supported DICOM Functionalities (Option Available with DICOM Configuration)

Verify

Modality Worklist

Store

GE Marketplace (Option Available with Wi-Fi Access or DICOM Configuration)

Enabling the update of Vscan Extend firmware, GE Marketplace, GE Kiosk and the basic scanner application through the internet. New versions of these software applications can be automatically detected when connected to the GE Marketplace. Updates can then be manually downloaded and installed

Host of Vscan Extend apps available over the Internet

Access to available apps with screenshots and additional information

Notification of newly available apps or app updates by e-mail to the customer account. App updates can be initiated from the device itself

Vscan Web Portal

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

Specific application references and product education, including an interactive basic ultrasound anatomy section, probe placement tips and reminders, and example images

Additional education resources to be posted on the Vscan web portal, including webinars, further online programs, and training opportunities

Standard Configuration

The following items are included in the standard Vscan Extend

- Vscan Extend device with either sector probe or dual probe
- Global AC adapter with interchangeable region-specific plugs
- One rechargeable battery
- USB cable
- Two MicroSD memory cards⁵
- Soft case
- User manual⁶
- Hardcopy quick card
- Gel (60 g bottle)⁷

Selectable Accessories

Additional soft case

Robust case to carry complete Vscan Extend set

Robust case to carry only scanner, gel, and potential extra battery

External battery charger

Additional battery

Additional AC adapter

Hardcopy user manual

Safety Conformance

Safety Classification

Classified as internally powered medical electrical equipment when not connected to the AC adapter with a type BF applied part medical electrical equipment, according to IEC 60601-1

CE marked to European Medical Devices Directive (MDD) 93/42/EEC

Certified to CAN/CSA C22.2 No.601.1

Conforms to the applicable clauses of the following safety standards

- IEC 60601-1⁸
- IEC 60601-1-2⁸
- IEC 60601-1-4⁸
- IEC 60601-1-6⁸
- IEC 60601-2-37⁸
- IEC 60601-1-11
- IEC 60601-1-12
- NEMA UD3
- ISO 10993-1
- EN 300 328
- IEC 62304⁸
- IEC 62366⁸
- EMC emissions group one class B requirements per CISPR 11/EN 55011

AC adapter classified as class II medical electrical equipment according to IEC 60601-1

Vscan Extend is Available in Three Connectivity Configurations:	USB Configuration	Wi-Fi Access Configuration	DICOM Configuration
Generic image format (jpg, mp4) for data stored on device or exported to PC	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Image transfer to PC via USB cable	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Manual labeling of exam data with patient ID	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>
FIPS-compliant data encryption	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Data backup capability on MicroSD card	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Wireless image transfer to shared network folders	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Enterprise-grade wireless encryption standards including EAP and WPA2 (PSK)	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Mobile Device Management client support	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Access to GE Marketplace to selectively download and install Vscan Extend apps	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Wireless reading of DICOM Modality Worklist	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Wireless image export in DICOM format	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Access to reference materials on Vscan web portal	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>

Vscan Extend Apps

Apps give you the option to customize your Vscan Extend to efficiently fit the care areas you already serve, and to manage more clinical care scenarios⁹ Apps are selectively downloadable from the GE Marketplace over the internet for installation on the device.

Auto Optimize

Enables automated TGC (Time Gain Compensation) with a single key stroke during live scanning. Gain will be automatically adjusted for all depths. (Auto Optimize is not available for ophthalmic scanning).

Bladder Volume

Protocol-enabled measurements enable calculation of urinary bladder volume. Edge-detection algorithm suggests automatically placed measurement calipers for sagittal and transverse views. Measurements can be accepted to manually adjusted before bladder volume is calculated.

Comprehensive Label

Wirelessly exported .jpg files and .mpg clips can be complemented by patient identifier and scan information, as recommended by ultrasound documentation standards such as AIUM and DEGUM. Linked patient name, patient ID, date of birth, exam date, exam number, transducer name, chosen preset, transmit frequency, MI and TI, transmit focus point, and facility name will be part of exported image or clip.

Enterprise Archive Uplink

The Enterprise Archive Uplink app⁷ provides the interface to GE's Centricity Enterprise Archive™, a vendor neutral archive solution for both DICOM and non-DICOM content. The Enterprise Archive Uplink app enables a secure export of Vscan Extend ultrasound DICOM images to Centricity Enterprise Archive via the DICOMweb® standard STOW-RS. (Centricity Enterprise Archive needs to be purchased separately).

Lung M-Mode

The Lung M-Mode app provides the M-Mode capability specifically to support the assessment of lung and documentation of signs like seashore.

After entering this lung M-Mode tool, a centered vertical M-Mode cursor line will be applied to generate the anatomical M-Mode display. Such tool will be enabled for linear transducer with lung preset and sector transducer with cardiac preset (the recommended preset for lung assessment with the sector transducer).

Lung Protocol

The protocol systematically guides the user to acquire and evaluate thoracic ultrasound images. A simple report summarizes findings. Temporary hints help users understand the functions of soft keys and can be deactivated if not needed. The protocol can be configured by number of thoracic areas and by choice between qualitative assessment and scoring.

LVivo EF

The LVivo EF app enables an automated edge detection of left myocardial wall and calculates end-systolic, end-diastolic left ventricular volumes and ejection fraction using apical 4-chamber views. This app has been developed by and licensed from DiA Imaging Analysis Ltd. (App is available for purchase).

NOBORI® Uplink

The NOBORI Uplink app⁷ includes the interface to NOBORI, a cloud-based PACS solution, which is separately provided by TechMatrix Corporation, Japan. NOBORI enables safe storage, utilization and sharing of medical information such as Vscan Extend ultrasound images.

Protocol Creator

Create a customized exam script that will help ensure exam consistency by guiding you through an ultrasound image acquisition protocol. These protocols can help increase consistency with exams by providing a list of scan planes and context-sensitive help. Automated presets for all steps and automated annotations for saved images are provided to help enhance productivity. Users can also customize protocols to include ultrasound images that can be used as reference during the exam.

Vscan Extend Apps *(cont.)*

Scan Coach FATE

The Scan Coach module for Focused Assessment Transthoracic Echo (FATE) provides a protocol of standard ultrasound imaging views and context-based reference materials to perform a systematic FATE exam.

During the exam, users will have access to a reference ultrasound image of normal anatomy and examples of common pathologies for each scan plane.

It provides 3D animations to help remind the user the relationship of probe positioning with resulting ultrasound images and annotated schematics for anatomical landmarks help acquire desired views.

The steps overview page provides a checklist of views defined by the protocol to track completion during the exam.

User instructions at the beginning of every step provide information related to the specific view and can be deactivated if not needed.

Scan Coach FCU

Scan Coach module for Focused Cardiac Ultrasound (FCU) evaluation provides a protocol of standard ultrasound imaging views and context-based reference materials to perform a systematic evaluation of the heart.

During the exam, users will have access to a reference ultrasound image of normal anatomy and examples of common pathologies for each scan plane.

It provides 3D animations to help remind the user the relationship of probe positioning with resulting ultrasound images and annotated schematics for anatomical landmarks help acquire desired views.

The steps overview page provides a checklist of views defined by the protocol to track completion during the exam.

User instructions at the beginning of each step provide information related to the specific view and can be deactivated if not needed.

Scan Coach RHD

Scan Coach module for Rheumatic Heart Disease (RHD) evaluation provides a protocol of standard ultrasound imaging views and context-based reference materials to perform a systematic evaluation for presence of RHD.

During the exam, users will have access to a reference ultrasound image of normal anatomy and examples of common pathologies for each scan plane.

It provides 3D animations to help remind the user the relationship of probe positioning with resulting ultrasound images and annotated schematics for anatomical landmarks help acquire desired views.

The steps overview page provides a checklist of views defined by the protocol to track completion during the exam.

User instructions at the beginning of each step provide information related to the specific view and can be deactivated if not needed.

Screen Mirror

Mirror the display of the Vscan Extend onto a wireless display via Miracast.¹⁰ You will have the ability to share and collaborate with other healthcare providers and patients.

Tricefy™ Uplink

Tricefy Uplink app^{7,11} supports easy export of selected images, videos or exams to Tricefy to support ultrasound case communication and collaboration over the cloud. Tricefy is an integrated cloud-based solution from Trice Imaging.

1. Used as synonym to phased.
2. All configurations may not be available in every country. Table comparing features for these three configurations is provided in "Standard Configuration" section.
3. Ophthalmic preset is not available in the U.S.A., China and Japan.
4. Only 2.4 GHz supported (5 GHz are not supported).
5. For potential service needs only (one empty card for temporary files, one with software in case of re-installation needs).
6. Electronic CD or paper copy in selected countries.
7. Not available in all countries.
8. Including national deviations.
9. All apps may not be available in every country.
10. Screen Mirror app can connect displays which are Miracast-certified. For displays that do not have a built-in Miracast support, adapters (dongles) that plug into the HDMI ports can be purchased separately. There is no need for an internet connection, as the Miracast employs peer-to-peer Wi-Fi Direct® standard.
11. The Vscan Extend app includes the interface to Tricefy, a cloud-based case exchange solution which is separately provided by Trice Imaging. Customers may elect to try Tricefy via trial period by entering into an agreement with Trice Imaging. Trice Imaging bears sole responsibility for the Tricefy Uplink app and Tricefy cloud solution.

Imagination at work

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August 2018
DOC1839644

