Vscan Extend

Data Sheet

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 probe[1] or with a dual-headed probe that integrates both sector and linear transducers.

Vscan Extend is offered in three connectivity configurations[2]:

- 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
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)

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

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

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

Swiping menu to enable easy reach of advanced functions to manage exams and data	• Synchronizing with DICOM Modality Worklist • Linking of images with patient identification • Access to exam-assisting protocols • Device configuration including administrator settings to integrate with network

Lung protocol to assist systematic thoracic assessment with annotation, assessment scores and simple reports (Vscan Extend app available through GE Marketplace)

Measurements

Distance measurement on-board device

Assisted bladder volume measurement (Vscan Extend app available through GE Marketplace)

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

Data Security *(cont.)*

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 802.11b/g/n supported[4]

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

Data storage (cont.)

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)

Tricefy® Uplink (Vscan Extend app developed by Trice® Imaging and available through GE Marketplace) supports easy export of selected images, videos, or exams to Tricefy to support ultrasound case communication and collaboration over the cloud[5, 6]

Supported DICOM Functionalities (Option Available with DICOM Configuration)

Verify

Modality Worklist

Store

GE Marketplace (option available with Wi-Fi Access or DICOM configuration)

Host of Vscan Extend apps available over the internet

Access to available apps with screenshots and additional information before download

Apps selectively downloadable over the internet for installation on the device

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

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 or manually adjusted before bladder volume is calculated

Lung Protocol

Template systematically acquires and evaluate thoracic ultrasound images

Simple report summarizes findings

Temporary hints help users understand the functions of soft keys and can be deactivated if not needed

Template can be configured by number of thoracic areas and by choice between qualitative assessment and scoring

Tricefy Uplink

Interface supports image export from Vscan Extend to Tricefy, a separate cloud-based case-exchange solution provided by Trice Imaging

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 cards[7] • Soft case • User manual[8] • Hardcopy Quick Card • Gel (60 g bottle)[5]

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	◉	◉	◉
Image transfer to PC via USB cable	◉	◉	◉
Manual labeling of exam data with patient ID	◉	◉	◉
FIPS-compliant data encryption	◉	◉	◉
Data backup capability on MicroSD card	◉	◉	◉
Wireless image transfer to shared network folders	○	◉	◉
Enterprise-grade wireless encryption standards including EAP and WPA2 (PSK)	○	◉	◉
Mobile Device Management client support	○	◉	◉
Access to GE Marketplace to selectively download and install Vscan Extend apps	○	◉	◉
• Bladder Volume	○	◉	◉
• Lung Protocol	○	◉	◉
• Tricefy Uplink	○	◉	◉
Wireless reading of DICOM Modality Worklist	○	○	◉
Wireless image export in DICOM format	○	○	◉
Access to reference materials on Vscan web portal	◉	◉	◉

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 60601-1[9] • IEC 60601-1-2[9] • IEC 60601-1-4[9] • IEC 60601-1-6[9] • IEC 60601-2-37[9] • IEC 60601-1-11 • IEC 60601-1-12 • NEMA UD3 • ISO 10993-1 • EN 300 328 • IEC 62304[9] • IEC 62366[9] • 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	

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 U.S.A., China and Japan.

4. Only 2.4 GHz supported (5 GHz are not supported).

5. Not available in all countries.

6. 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.

7. For potential service needs only (one empty card for temporary files, one with software in case of re-installation needs).

8. Electronic CD or paper copy in selected countries.

9. Including national deviations.

Imagination at work