Technical Publications

Vscan Extend™

Version 1.0

CE 0123

User Manual

5721203-100 — English

Rev. D

Operating Documentation

Regulatory requirement

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 Vscan Extend. It applies to all versions of the 1.0 software for the Vscan Extend ultrasound system.

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

Revision History

Reason for Change

REV	DATE (YYYY/MM/DD)	REASON FOR CHANGE
Rev. A	2016/04/05	Initial draft
Rev. B	2016/05/19	Included External Battery charger label Included Power button under device labels Included revised rating label Included sections in Privacy and Security chapter
Rev. C	2016/06/01	Removed breast and testes from indication of use statement Included the revised rating label, battery label and external charger label Included the scope for all the standards in Table i-1
Rev. D	2016/08/18	Included IP33, Ophthalmic and Aorta presets, IEC 60601-11 and 12 standards, Tricefy App

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 GE 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 system must be approved by the manufacturer: GE Medical Systems. 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) 2007/47/EC (MDD amendment) Directive 2011/65/EU RoHS 2002/96/EC WEEE 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.
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* 60601-1-4	Medical Electrical Equipment - part 1-4. Collateral standard: Programmable electrical medical systems
IEC* 60601-1-6	Medical Electrical Equipment - part 1-6. Collateral standard: Usability.
NEMA/AIUM UD-3	Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment.

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	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
* including national deviations	

Certifications

- GE Vingmed Ultrasound 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:

- Vscan Extend has an internal battery which allows the operation during AC power absence.
- The AC adapter is Class II.
- Vscan Extend has type BF Applied Part.

Vscan Extend main unit is rated IP33:

- 3: Protected against solid foreign objects of 2,5 mm Ø and greater.
- 3: Protected against spraying water.

Vscan Extend probe (immersible portion) is IPX7.

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 mode	Single fault condition
Patient leakage current	<100 microA	<500 microA

Original Documentation

- The original document was written in English.

Country Specific Approval

- USA AND TERRITORIES

The following optional feature IS NOT available in the USA and its territories:

– Ophthalmalic

- JAPAN

The following optional feature IS NOT available in JAPAN:

– Ophthalmalic

- CHINA

The following optional feature IS NOT available in CHINA:

– Ophthalmalic

Importer Information

Turkey

İTHALATÇI
PENTA ELEKTRONİK MEDİKAL
SİSTEMLER SAN. VE TİC. A. Ş.
HOŞDERE CAD. FUAR SOK. 5 / 3
Y. AYRANCI / ANKARA

Table of Contents

Chapter 1

Introduction

Contents:

Overview

Attention

This manual covers the following two configurations of the Vscan Extend. Refer to the relevant section based on the configuration purchased.

- Vscan Extend™ configured with a sector probe allowing deep scanning (holding the phased array transducer G3S)
- Vscan Extend™ configured with a Dual Probe allowing deep and shallow scanning (holding the phased array transducer G3S and the linear array transducer G8L)

Vscan Extend is a trademark of General Electric Company.

General description

Vscan Extend is a pocket-sized, battery powered general purpose diagnostic ultrasound system. The system consists of a handheld unit with a 5 inch touch screen display and a permanently attached probe.

The battery can be charged either in the system or alone. The system is capable of transferring images wirelessly to a DICOM server or via Windows Share. Data can also be exported to a standard PC using a wired USB export.

Capabilities also include access to GE Marketplace, which allows the user to download Bladder Volume, Lung Protocol, Barcode Reader and Interface to Case Exchange Software Apps.

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 image monitor.

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. Keep the manual with the equipment at all time. Periodically review the procedures for operation and safety precautions.

Intended use

Vscan Extend is a general purpose diagnostic ultrasound imaging system for use by qualified and trained healthcare professionals enabling visualization and measurement of anatomical structures and fluid.

Indications for use (for all countries except USA, China and Japan)

Vscan Extend is a general purpose diagnostic ultrasound imaging system for use by qualified and trained healthcare professionals enabling visualization and measurement of anatomical structures and fluid. It's pocket-sized portability and simplified user interface enables integration into examination and training sessions indoors and in other environments 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 monitoring, and triage.

With the phased array transducer on the sector probe, the specific clinical applications and exam types include: Cardiac; Abdominal; Renal; OB/GYN; 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.

With the addition of the linear array transducer on the single 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 (e.g. 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*; and Pediatrics.

*Ophthalmic use is provided as an option. Ophthalmic scanning MUST only be used with the linear functionality of the Dual Probe.

If the Vscan Extend purchased does NOT have the Ophthalmic preset option, DO NOT use for ophthalmic use or any use causing the acoustic beam to pass through the eye.

Indications for use (for USA, China and Japan)

Vscan Extend is a general purpose diagnostic ultrasound imaging system for use by qualified and trained healthcare professionals enabling visualization and measurement of anatomical structures and fluid. It's pocket-sized portability and simplified user interface enables integration into examination and training sessions indoors and in other environments 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 monitoring, and triage.

With the phased array transducer on the sector probe, the specific clinical applications and exam types include: Cardiac; Abdominal; Renal; OB/GYN; 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.

With the addition of the linear array transducer on the single 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 (e.g. thyroid); Musculoskeletal (Long Bone; Hip, shoulder, elbow and Knee Joints); Evaluation of Presence of Fluid; Thoracic/Lung (e.g. pleural motion/sliding, line artifacts); and Pediatrics.

Contraindication for use (for USA, China and Japan)

The Vscan Extend ultrasound device is not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye.

Intended users

Vscan Extend is intended to be used by qualified and trained healthcare professionals that are legally authorized by law in the country, state or other local municipality in which he practices to use the device. The list of the potential users includes but is not limited to (based on title/geographical location): primary care physicians, point-of-care users, sonographers, medical healthcare technicians, nurses, midwives, paramedics, nurse practitioner, physician assistants, medical students.

The users may or may not be working under supervision or authority of a physician.

Prescription Device

For USA only:

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Operator profile

Qualified and trained healthcare professionals with at least a basic level of general ultrasound training that includes limited image acquisition techniques and interpretation (i.e. position the probe correctly on the patient and determine at least normal vs. abnormal anatomy views during scanning).

The operator must read and understand the user manual.

Contact GE sales representative for product training assistance and visit the Vscan web portal for reference materials.

Warnings

Important Safety Considerations

To prevent damage of the equipment or injury to yourself or others, read the following safety warnings before using Vscan Extend.

- Vscan Extend is a precision instrument. Handle Vscan Extend and its accessories with care. Do not subject Vscan Extend to mechanical shock or impact.
- Do not attempt to disassemble or alter any part of the unit including the probe, the battery, the AC/DC 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 the casing is damaged, including the probe. Failure to do so may result in electrical shock.
- Do not use the device if the gorilla glass is broken.
- Do not use the AC/DC adapter if showing visible damages.
- Use only the designated power accessories (battery and charger). Failure to do so may result in electrical shock or fire.
- Do not place the battery near a heat source or expose it to direct flame. Such exposure may lead to corrosive liquid leakage, electrical shock or fire.
- To reduce risk for electrical shock, do not plug or unplug the AC/DC adapter from mains socket with wet hands.
- Avoid dropping or subjecting the unit, including the probe, the battery and accessories to severe impacts. This could result in electrical shock, corrosive liquid leakage and injury.
- Keep good hand contact with Vscan Extend during scanning to avoid heating up of the unit and termination of scan due to built-in temperature limits.
- At times, user may be required to enter PIN to save patient data. It is extremely important to remember this PIN in order to avoid loss of patient data in case of entering wrong PIN multiple times or if the user forgets the PIN.

Important Safety Considerations (continued)


WARNING

- Do not short-circuit the battery terminal with metallic objects. This may result in overheating and burns.
- Do not store or carry a battery loosely with metallic devices.
- Disconnect the battery charger when not in use to avoid fire hazard.
- Keep the charger dry. Failure to observe this precaution may result in fire and electric shock
- Keep this unit out of reach of children. Strangulation resulting from baby or child entanglement in probe cable may occur.

Before charging or using a battery it is important that you read and understand the battery safety and environment information.


WARNING

- Do not damage the rechargeable battery. A damaged battery can cause an explosion or fire, and can result in personal injury and/or property damage. To prevent injury or damaged do not use or charge the battery if it appears to be damaged. Signs of damage include, but are not limited to, discoloration, warping, and leaking battery fluid. Do not expose the battery to fire, high temperature, or direct sunlight. Do not immerse or expose the battery to water. Do not use or store the battery inside a vehicle during hot weather. Do not drop or puncture the battery. Do not open the battery or short-circuit its contacts.


WARNING

Avoid contact with the rechargeable battery if it appears to be leaking. Battery fluid is corrosive, and contact with it can result in personal injury and/or property damage.

To prevent injury or damage:

- If the battery leaks, avoid contact with the battery fluid. If any liquid from the battery should come in contact with the eye, immediately wash the eye with plenty of water and seek medical advice as soon as possible. Do not rub your eyes!
- If battery fluid gets onto your skin or clothing, immediately use clean water to wash off the battery fluid.

Important Safety Considerations (continued)

WARNING

Charge and use the rechargeable battery only in strict accordance with the instructions. Charging or using the battery in unauthorized equipment can cause an explosion or fire, and can result in personal injury and/or equipment damage.

To prevent injury or damage:

- Do not charge or use the battery if it appears to be damaged or leaking.
- Charge the battery only in a Vscan Extend device or in the Vscan Extend battery charger. Be sure to follow all instructions that are provided with the battery charger.
- Discontinue charging a battery that gives off extreme heat or a burning odor.
- Use the battery only in the Vscan Extend.
- Use the battery only for its intended use and according to the instructions in the product documentation.

CAUTION

- Ensure to backup data regularly and to erase the data before sending the Vscan Extend for service.
- To access or add patient information, a device pin is required. Ensure not to lose the pin.

CAUTION

Vscan Extend cannot be sterilized. Apply a sterile sheath if the device is going to be used in an application where a higher degree of cleanliness is required. The sheath should cover the probe and any part of the probe cable that might come in contact with the area requiring higher cleanliness.

Contact Information

Contacting GE Ultrasound

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

Internet

https://vscan.gehealthcare.com

http://www.gehealthcare.com

USA

TEL: (1) 800-437-1171

Ultrasound Service Engineering

9900 Innovation Drive

Wauwatosa, WI 53226

Clinical Questions

Please contact your local Applications or Sales Representative.

Service Questions

For service contact your local Service Representative.

Accessories Catalog Requests

To request the latest GE Accessories catalog or equipment brochures in the United States, call the Response Center

TEL: (1) 800-643-6439

In other locations, contact your local Applications, Sales or Service Representative.

Placing an order

To place an order, order supplies or ask an accessory-related question in the United States, call the GE Access Center

TEL: (1) 800-472-3666

In other locations, contact your local Applications, Sales or Service Representative.

Global ultrasound support center phone numbers

For countries not listed in the tables below, please contact the local distributor.

When contacting Support you will have to provide your system ID. If the system ID is unknown, please give the Temporary System ID “Vscan Extend” to be properly routed for support.

Americas

Table 1-1: Americas

Region	Telephone
United States[1]	800-437-1171
Canada	800-668-0732
Mexico	0800 9043400
Puerto Rico	0800 4371171
Brazil	0800 122345
Argentina	0800 3331984
Chile	0800 367000

[1] 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 Extend” to be properly routed for support.

Europe, Middle East and Africa

Table 1-2: Europe, Middle East and Africa

Region	Telephone
Algeria	+21321484612
Andorra	902 400 246
Austria	0800244260
Belgium Dutch	+32 262 638 38
Belgium French	+32 262 638 39
Bulgarian	+35929712040
Denmark	80404944
Egypt	+202 19434 [hot line]
Finland	0981710182
France	0800139140
G. D. Luxembourg	080022973
Germany	08004373784
Greece	302109690660
Holy See	800 827168
Hungary	+36-23-410-510
Ireland	1800992557
Israel	Contact local distributor
Italy Central	800 827168
Italy North-East	800 827166
Italy North-West	800 827164
Italy South	800 827170
Liechtenstein	0041 44 809 9293
Monaco	0800139140
Netherlands	8000994442
Northern Ireland	08000720248
Norway	80062043
Portugal	800 834 004
Russia	+7 495 739 69 75
San Marino	800 827168

Table 1-2: Europe, Middle East and Africa (Continued)

Region	Telephone
Saudi Arabia	800 1243002
South Africa	800 111 671
Spain	902 400 246
Sweden	0201201436
Switzerland	0800556958
Turkey	Contact local distributor
UAE	800 3646
UK	0845 8503392
Ukraine	+38 044 391 37 56 (57)

Asia and Pacific

Table 1-3: Asia and Pacific

Region	Telephone
China	8008108188
Hong Kong	(852) 21006288
Taiwan	0800-021-770
India	(91) 1800-425-8025
Singapore	(65) 62773444
Australia	1-800-659-465
New Zealand	0800 65 94 65
Japan	0120-055-919
Korea	(82) 2-1544-6119
Bangladesh	(880) 29135488
Sri Lanka	(94) 114891178
Bhutan	Contact GE India
Maldives	Contact GE India
Nepal	Contact local distributor
Malaysia	1800 88 3911
Thailand	(66) 26248400
Vietnam	Contact local distributor
Philippines	Contact local distributor
Indonesia	Contact local distributor
Laos	Contact local distributor
Brunei Darussalam	Contact local distributor
Cambodia	Contact local distributor

Manufacturer

GE VINGMED ULTRASOUND A/S
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 Extend. Procedures for simple care and maintenance of the Vscan Extend 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:


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.


WARNING

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

- Severe personal injury
- Substantial property damage.


CAUTION

Indicates that a potential hazard may exist which through inappropriate conditions or actions will or can cause:

- Minor injury
- Property damage.

Owner responsibility

Overview

It is the responsibility of the owner to ensure that anyone operating Vscan Extend 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 GE. See ‘Contact Information’ on *page 1-10 for more information.*

The owner of Vscan Extend 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 Extend does not respond to the commands described in this manual, the operator should contact the nearest field GE 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.

Overview (continued)

The owner of Vscan Extend MUST be aware of the data protection policies while configuring the DICOM and Windows Share servers. GE is not responsible for data sharing. Before configuring the servers, the owner of the Vscan Extend MUST abide by the applicable privacy acts specific to their region or country.

CAUTION

For USA only:

Federal law restricts this device to sale by or on the order of a physician.

CAUTION

Vscan Extend 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 GE qualified person.

Software upgrade following GE 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 Extend, 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.

Patient Safety

Patient identification


WARNING

The concerns listed in this section can seriously affect the safety of the patient undergoing a diagnostic ultrasound examination.

Always include proper identification with all patient data. Identification errors could result in an incorrect diagnosis.

If the Vscan Extend needs to be sent for repair, ensure that the patient information is backed up and confirm backup was successful. The patient information MUST be erased from internal memory (See ‘Backup’ on *page 5-42 for more information.*) before shipping.


CAUTION

To access or add patient information, a device pin is required. Retain the 4-digit pin in a safe location to prevent loss of the pin. Avoid sharing the PIN. See ‘Administrator Access’ on *page 4-15 for more information.*

Diagnostic information

The images and calculations provided by the system, including bladder volume and lung protocol, 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 system.

The user should be aware of the product specifications and of the system accuracy and stability limitations. These limitations must be considered before making any decision based on quantitative values. If in doubt, the nearest GE 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 Extend 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.

General precautionary advice for the use of diagnostic ultrasound in combination with ultrasound contrast agents

CAUTION

The Vscan Extend is not intended to be used with a contrast agent. Cardiac rhythm disturbances during cardiac studies using gas ultrasound contrast agents have been observed in the diagnostic range of Mechanical Index (MI) values. See the specific package insert for the contrast agent being used for further details.

Mechanical hazards

A damaged probe may result in injury or increased risk of contamination. Inspect the probe frequently for sharp, pointed or rough surface damage that could cause injury or tear protective barriers (gloves and sheaths).

Electrical hazard

A damaged probe may increase the risk of electric shock if conductive solutions come in contact with internal electronics. Inspect the probe often for cracks or openings in the housing and holes in and around the acoustic lens, or other damage that could allow moisture to enter. Become familiar with the probe's care precautions outlined in ‘Inspecting the Vscan Extend’ on *page 6-3*.

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. Malfunctions in the Vscan Extend, or sparks, 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 system.
- If flammable substances are detected after the system has been turned on, do not attempt to turn off the Vscan Extend, or to unplug it.
- If flammable substances are detected, evacuate and ventilate the area before turning off Vscan Extend.

Electrical hazard


WARNING

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

NOTE: Any rest energy within our scanners or their components will be below 60 V DC or 2 mJ.

To avoid injury

- Do not remove the Vscan Extend's protective covers. No user-serviceable parts are inside. If servicing is required, contact GE service.
- Conductive fluids seeping into the active circuit components may cause short circuiting, which could result in an electrical fire.

Pacemaker hazard

The possibility of the system interfering with pacemakers is minimal. However, as this system generates high frequency electrical signals, the operator should be aware of the potential hazard this could cause.

Electrical Safety

Device classifications

Vscan Extend is an internally powered device, type BF.

The AC/DC adapter is Class II.

External Connection

CAUTION

Connection to a PC can be done when the PC is in compliance with the EN/IEC 60950 (Data processing equipment).

The computer connected to Vscan Extend must be kept outside the patient environment (refer to local regulation and EN/ES/IEC 60601-1).

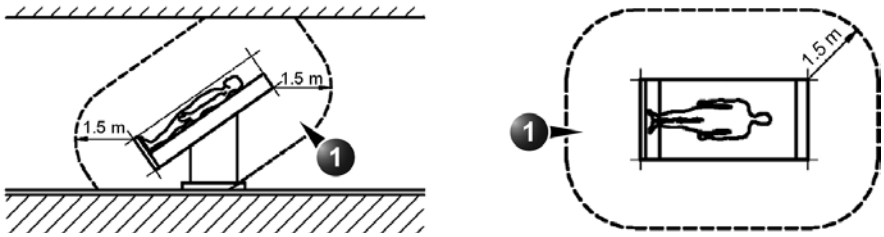


Figure 2-1. Patient environment

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, incubation 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*.

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.

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.

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 2-8*).

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.

The manufacturer is not responsible for any interference or responses caused by the use of interconnecting cables other than those recommended, or by unauthorized changes or modifications to this unit. 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.

Electromagnetic Compatibility (EMC) (continued)

Devices which intrinsically transmit radio waves such as cellular phones, radio transceivers, mobile radio transmitters, radio-controlled toys, and so on, should preferably not be operated near the unit. See ‘Electromagnetic Compatibility (EMC)’ on *page 2-10* about the recommended minimum separation distances between portable and mobile RF communications equipment and the ultrasound unit.

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.

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

FCC compliance statements

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including Interference that may cause undesired operation.

FCC Caution!!!

- Any changes or modifications not expressly approved by the party Responsible for compliance could void the user's authority to operate this Equipment
- This equipment should be installed and operated with minimum distance 20 cm between the radiator & your body.

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.*

FCC compliance statements (continued)

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 for Canada (French translation)

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux.

deux conditions suivantes:

1. l'appareil ne doit pas produire de brouillage, et
2. l'utilisateur de l'appareil doit accepter tout brouillage adioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

FCC compliance statements for Canada (French translation) (continued)

This equipment complies with radio frequency exposure limits set forth by Industry Canada for an uncontrolled Environment. This equipment should be installed and operated with minimum distance 20 cm between the device and the user or bystanders.Cet équipement est conforme aux limites d'exposition aux radiofréquences

définies par Industrie Canada pourun environnement non contrôlé. Cet équipement doit être installé et utilisé avec un minimum de 20 cm de distance entre le dispositif et l'utilisateur ou des tiers.

un appareil numérique, en vertu de l’article 15 de la réglementation de la FCC. Ces limites ont été instaurées pour fournir une protection raisonnable contre toute interférence nuisible dans une installation résidentielle. Cet équipement génère, utilise et peut émettre de l’énergie radiofréquence. S’il n’est pas installé et utilisé conformément aux instructions, il peut provoquer des interférences sur les communications radio. Cependant, il n’est pas garanti que des interférences ne se produiront pas dans certaines installations. Si cet équipement cause des interférences à la réception radio ou télévisée (ce qui peut être vérifi é en éteignant l’appareil puis en le remettant sous tension), l’utilisateur peut tenter de les résoudre en suivant une ou plusieurs des mesures ci-après:

- Réorienter ou déplacer l’antenne réceptrice. Augmenter l’espace entre
- l’appareil et le récepteur. Brancher l’appareil à une prise de courant différente de celle sur laquelle le récepteur est branché.

Pour obtenir de l’aide, contacter le vendeur ou un technician radio/télévision expérimenté.

REMARQUE : Toute modifi cation non autorisée expressément par le fabricant responsable de la conformité peut annuler le droit de l’utilisateur à faire fonctionner le produit.

Electromagnetic emissions

Table 2-1: Electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emission EN55011	Group 1 Class B	The Vscan Extend 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	Group 1 Class B	The Vscan Extend 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 61000-3-2	Complies	
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 Extend is intended for use in the electromagnetic environment below. The customer or the user of the Vscan Extend should assure that it is used in such an environment.			
Immunity test	**EN 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) EN 61000-4-2	±6 kV contact ±8 kV air	±6 kV ±8 kV	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 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 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 Extend is intended for use in the electromagnetic environment below. The customer or the user of the Vscan Extend should assure that it is used in such an environment.			
Immunity test	**EN 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	5% U_T (>95% dip in U_T) for 0,5 cycle 40% UT (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 s	5% U_T (>95% dip in U_T) for 0,5 cycle 40% UT (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 s	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 ultrasound unit is powered from an uninterruptible power supply or a battery.
Power frequency (50/ 60 Hz) magnetic field EN/IEC 61000-4-8	3 A/m	3 A/m	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.			

Electromagnetic immunity (continued)

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 Extend is intended for use in the electromagnetic environment below. The customer or the user of the Vscan Extend should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance[c]**
Conducted RF EN 61000-4-6 Radiated RF EN 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 Mhz to 2,5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ultrasound unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol 
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.			

Table 2-3: Electromagnetic immunity (Part 2) (Continued)

Guidance and manufacturer's declaration – electromagnetic immunity – for all medical electrical equipment and medical electrical systems that not life-supporting			
The Vscan Extend is intended for use in the electromagnetic environment below. The customer or the user of the Vscan Extend should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance[c]**
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ultrasound unit is used exceeds the applicable RF compliance level above, the ultrasound unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ultrasound unit. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Separation distances

Table 2-4: Separation distances

Recommended separation distances between portable and mobile RF communications equipment and the ultrasound unit			
The ultrasound unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ultrasound unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ultrasound unit as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output of transmitter W	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for 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 Extend 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 indexes as aid for safe use of the Vscan Extend.

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:

- NEMA Standards Publication UD 3: “Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment”, Revision 2
- EN/IEC 60601-2-37. Medical electrical equipment. Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment

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 September 9, 2008 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 September 9, 2008 for diagnostic ultrasound systems and transducers.

Acoustic output and display on Vscan Extend

MI and TI values are displayed on the scanning screen.

The maximum possible MI and Ispta on the Vscan Extend is within the limits set in Track 3 in the FDA guidance of September 9, 2008 for diagnostic ultrasound systems and transducers, MI <1.9 and Ispta <720 mW/cm^2.

Display Accuracy and Acoustic Measurement Uncertainties

The display accuracy and measurement precision of the output display are summarized in the table below. Accuracy of the output display (TI, MI) parameters depends on the measurement system precision, the acoustic model used to calculate the parameters and variation in the acoustic output of probes and systems. The measurement precision and overall accuracy of the measurements have been assessed by determining both the random and the systematic uncertainties and given in percent at 95% confidence level.

Table 2-5: Display accuracy

Parameter	Estimated accuracy[a]	Measurement precision
		black and white/color
Pressure, MI	±25%	±15%
Power, TI	±50%	±40%

a. Accuracy = (Measured value - displayed value)/displayed value * 100%

System controls affecting acoustic output

The operator controls that directly affect the acoustic output are discussed in the Acoustic Output Data Tables (See 'Acoustic Output Reporting Tables' on *page 7-3 for more information.*). 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 much lower output. It is important to note the following:

- The duration of an ultrasound examination is as important as the acoustic output, since patient exposure to output is directly related to the exposure time.
- Controls can help to reduce patient exposure, even though it may not directly affect acoustic output.

The British Medical Ultrasound Society has suggested some maximum scanning times relative to displayed TI as follows:

Table 2-6: Maximum scanning times

Obstetric scanning		**General Abdominal, *Peripheral Vascular, Adult cephalic, Musculoskeletal, cardiac and other scanning**		
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			

*Peripheral vascular is applicable for only dual probe

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.

Application selection

Selecting the application appropriate to a particular ultrasound examination automatically provides acoustic output limits within FDA guidances for that application. Other parameters which optimize performance for the selected application are also set automatically, and should assist in 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 (see ‘Acoustic Output Reporting Tables’ on *page 7-3* for TI and MI values in black and white or color imaging).

ALARA

Ultrasound procedures should be performed using output levels and exposure times **A**s **L**ow **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) provided on the Documentation CD. 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.

ALARA (continued)

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, the sections ‘Acoustic output and display on Vscan Extend’ on *page 2-20* and ‘System controls affecting acoustic output’ on *page 2-21* 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 of 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

The table below indicates the maximum probe temperature.

Table 2-7: Maximum probe temperature

Probe	Max Temp in deg C (Simulated use)	Max Temp in deg C (Still air)
Vscan Extend – configured with Sector probe: Phased array transducer (G3S) for Deep scanning	39.7	43.1
Vscan Extend – configured with Dual probe: Phased array transducer (G3S) for Deep scanning	41	42.6
Vscan Extend – configured with Dual probe: Linear array transducer (G8L) allowing shallow scanning	39.1	42.3

NOTE: Measurement uncertainty and probe variation: 2 °C.

NOTE: Lens temperature measured under following conditions per EN/IEC 60601-2-37:

- Thermocouple was placed at the geometric center of the lens.
- Thermal phantom at 33 °C (or 23 °C) for external probes. (Temperature rise is measured and added to 33 °C if the phantom is at 23 °C).

NOTE: Thermal phantom made with tissue-mimicking material as referenced in EN/IEC 60601-2-37.

- Probe placed upright in contact with above thermal phantom.
- Auto-freeze capability is disabled.
- Lens temperature is monitored for 30 minutes.

Device labels and symbols

Vscan Extend Labels (Example)

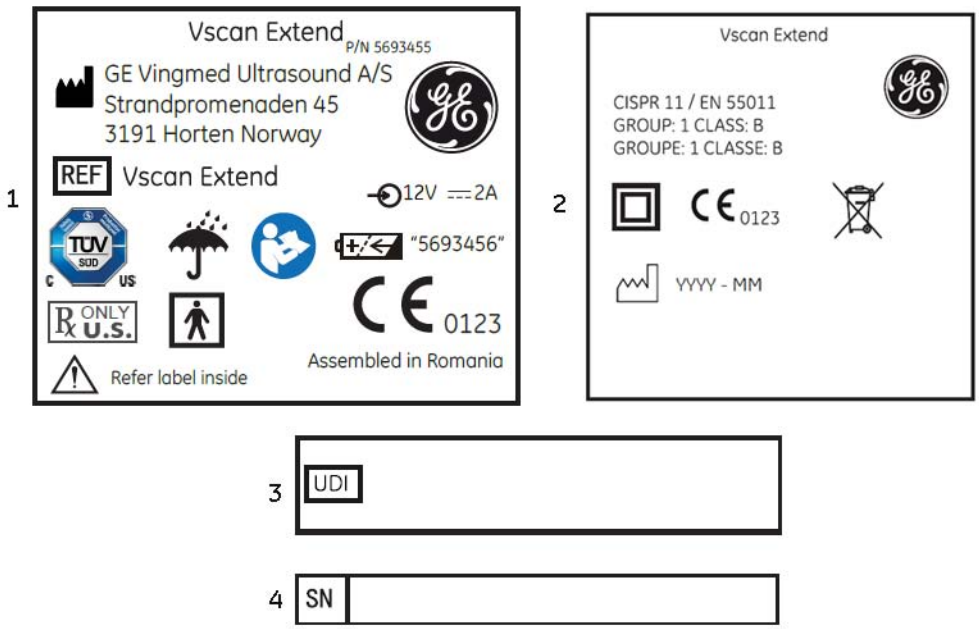


Figure 2-2. Vscan Extend rating label

1. Rating label
2. Inner label
3. UDI label - contains UDI information
4. Serial number label - contains device serial number

NOTE: The label shown in Figure 2-2 is a sample. The label varies country to country based on country requirements.

Vscan Extend Labels (Example) (continued)

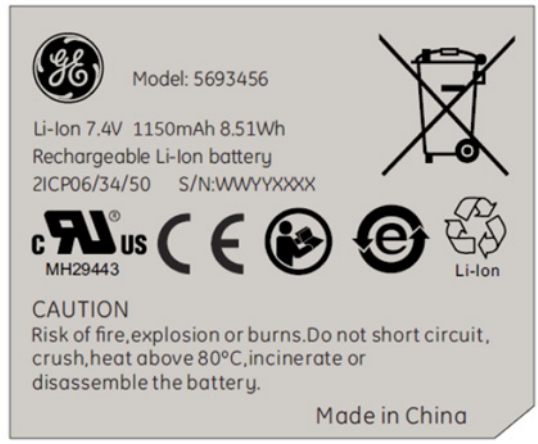


Figure 2-3. Vscan Extend battery label

Figure 2-4. Vscan Extend AC/DC adapter label

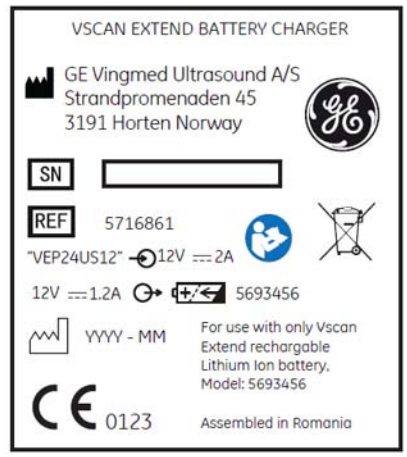


Figure 2-5. Vscan Extend external battery charger label

Vscan Extend Labels (Example) (continued)

The following table describes the purpose of safety labels and other important information provided on the equipment.

Table 2-8: Label Icons

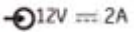
Label	Purpose	Location
	CE mark	• Vscan Extend system • Vscan Extend External Battery charger
	This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact the manufacturer or other authorized disposal company to decommission your equipment.	• Vscan Extend system • Vscan Extend battery • Vscan Extend External battery charger
	Follow instructions for use. Read and understand all instructions in the User's Manual before attempting to use the ultrasound unit.	• Vscan Extend system • Vscan Extend External Battery charger
	TÜV mark	Vscan Extend system
	Prescription device statement for the USA only: Caution: Federal law restricts this device to sale by or on the order of a physician.	Vscan Extend system
	Type BF Applied Part symbol (see ‘Classifications’ on *page i-5*)	Vscan Extend system
	Keep dry	Vscan Extend system
	Input, use only Vscan Extend charger.	Vscan Extend system Vscan Extend External Battery charger
	Rechargeable, use only Vscan Extend battery.	Vscan Extend system Vscan Extend External Battery charger
	Input to Vscan Extend battery	Vscan Extend External Battery charger

Table 2-8: Label Icons (Continued)

Label	Purpose	Location
	Manufacturer name and address	• Vscan Extend system • Vscan Extend External Battery charger
	Manufacturing date (year-month)	• Vscan Extend system • Vscan Extend External Battery charger
	Part number	• Vscan Extend system • Vscan Extend External Battery charger
	Serial number	• Vscan Extend system • Vscan Extend External Battery charger
	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 Extend system
	Refer label inside	Vscan Extend system
Assembled in Romania (Romania is a country name)	Identify the customs country of origin of the materials.	Vscan Extend system
	Push button (power switch)	Vscan Extend system

NOTE: As a safety precaution, scanning is not possible when charging the battery.

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: Label for China

Label	Description
	This symbol indicates the product contains hazardous materials in excess of the limits established by the Chinese standard GB/T 26572 Requirements of concentration limits for certain restricted substances in electrical and electronic products. The number in the symbol is the Environment-friendly Use Period (EFUP), which indicates the period during which the hazardous substances contained in electrical and electronic products will not leak or mutate under normal operating conditions so that the use of such electrical and electronic products will not result in any severe environmental pollution, any bodily injury or damage to any assets. The unit of the period is “Year”. In order to maintain the declared EFUP, the product shall be operated normally according to the instructions and environmental conditions as defined in the product manual, and periodic maintenance schedules specified in Product Maintenance Procedures shall be followed strictly. Consumables or certain parts may have their own label with an EFUP value less than the product. Periodic replacement of those consumables or parts to maintain the declared EFUP shall be done in accordance with the Product Maintenance Procedures. This product must not be disposed of as unsorted municipal waste, and must be collected separately and handled properly after decommissioning.

Table 2-10: 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 Extend for Use

Contents:

Package contents

Vscan Extend package contents

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

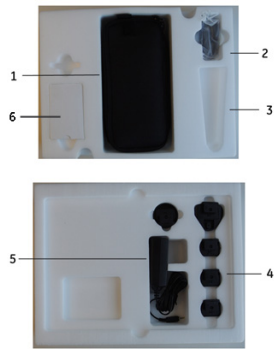


Figure 3-1. Vscan Extend package contents

1. Vscan Extend softcase with device and probe
2. USB cable
3. Gel bottle location
4. Region-specific plugs
5. AC/DC adapter
6. Battery

Table 3-1: Package content

Item	Description
	Vscan Extend Quick Card
	Vscan Extend User Manual
	Service contact information

Environmental requirements

Environmental requirements for the device

Table 3-2: Environmental requirements

Description	Operational	Non operational	Storage and transport
Temperature	0 °C to + 40 °C	- 40 °C to + 70 °C	- 40 °C to + 70 °C
Humidity	90%, non-condensing	15–90%	90%, non-condensing
Air pressure	620 hPa to 1060 hPa	620 hPa to 1060 hPa	620 hPa to 1060 hPa

Transient operating conditions

NOTE: Permissible transient environmental operating conditions:

- Temperature range of 0-40 degrees
- Relative humidity range of 15 to 90% non-condensing

NOTE: Avoid exposing the unit to saline moisture. In case of exposure to saline moisture, clean the unit as described on 'Cleaning and disinfection' on page 6-4.

Refer to Table 3-2 above for additional information regarding storage of the battery.

Image display on the Vscan Extend 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 (see 'Scan Settings' on *page 4-2*) or change your position/location of use.

The time required for the Vscan Extend to warm from minimum storage between uses until the device is ready for use at 20 degrees ambient is approximately 1 minute.

The time required for the Vscan Extend to cool from minimum storage between uses until the device is ready for use at 20 degrees ambient is approximately 1 minute.

The Vscan Extend is transportable in a road ambulance or fixed /rotary wing aircraft.

System description

System overview

Vscan Extend configured with a Sector probe for deep scanning

Figure 3-2. Vscan Extend with a Sector probe

1. Display
2. Sector probe
3. Serial port (For Service ONLY)
4. Power button
5. LED indicates charging status
6. USB port and Power connector

NOTE: Green LED indicates Vscan Extend is fully charged and an amber LED indicates it is charging.

Vscan Extend configured with a Dual probe holding both a phased array and linear array transducer for deep and shallow scanning

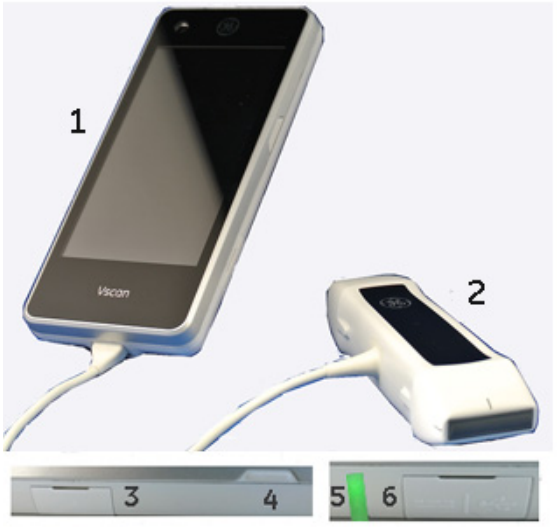


Figure 3-3. Vscan Extend with Dual probe

1. Display
2. Dual probe
3. Serial port (For Service ONLY)
4. Power button
5. LED indicates charging status
6. USB port and Power connector

NOTE: Green LED indicates Vscan Extend is fully charged and an amber LED indicates it is charging.

Vscan Extend Dual Probe

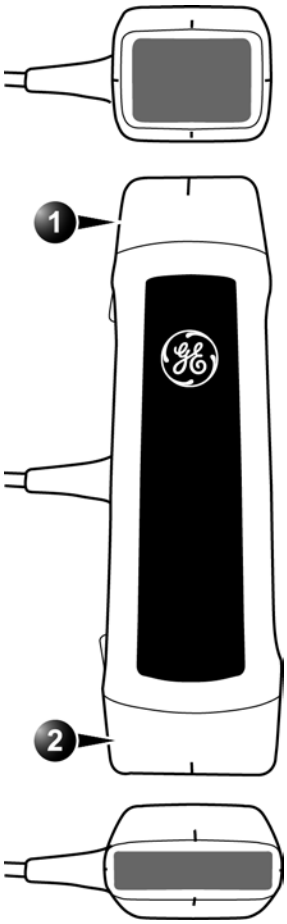


Figure 3-4. The dual probe

1. Phased array transducer (deep scanning)
2. Linear array transducer (shallow scanning)

Accessories and Configurations

Standard and optional accessories

Table 3-3: Standard accessories

Accessory	Figure
1. Global AC adapter with interchangeable region-specific plugs	
2. One rechargeable battery	
3. USB cable	
4. MicroSD memory card (For service personnel only. Not for customer use.*)	
5. Soft case	
6. User Manual	
7. Hardcopy Quick Card	

* The microSD card provided in the device captures error logs and is strictly for Service personnel only. The user must remove this microSD card and insert a blank one when performing data backup. The microSD card that captures error log files is used for troubleshooting by the Repair Depot.

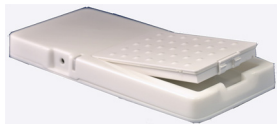
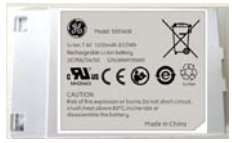
** Not available in all countries

Table 3-3: Standard accessories

Accessory	Figure
8. Gel (60g bottle)**	
* The microSD card provided in the device captures error logs and is strictly for Service personnel only. The user must remove this microSD card and insert a blank one when performing data backup. The microSD card that captures error log files is used for troubleshooting by the Repair Depot. ** Not available in all countries	

Standard and optional accessories (continued)

Table 3-4: Optional accessories

Accessory	Figure
1. Additional Soft case	
2. Robust case to carry complete Vscan Extend set	
3. Robust case to carry only scanner, gel, and potential extra battery	
4. External Battery charger	
5. Additional Battery	
6. Additional AC adapter	
7. Hardcopy User manual	

Connectivity Configurations

Vscan Extend is available in three different connectivity configurations:

1. USB configuration
2. Wi-Fi Access configuration
3. DICOM configuration

The table below describes the standard and connectivity configurations.

Table 3-5: Configurations

Description	USB configuration	Wi-Fi Access configuration	DICOM configuration
Generic image format (jpg, mp4) for data stored on device or exported to PC	A	A	A
Image transfer to PC via USB cable	A	A	A
Manual labeling of exam data with patient ID	A	A	A
FIPS compliant data encryption	A	A	A
Data backup capability on microSD card	A	A	A
Wireless image transfer to shared network folders		A	A
Enterprise grade wireless encryption standards including EAP and WPA2 (PSK)		A	A
Mobile Device Management client support		A	A
Access to GE marketplace to selectively download and install Vscan Extend apps			
Bladder Volume		A	A
Lung Protocol		A	A
Tricefy Uplink		A	A
Wireless reading DICOM Modality Worklist			A
Wireless image export in DICOM format			A
Access to reference materials on Vscan web portal	A	A	A
* The Vscan Extend app represents only the interface to the cloud-based case exchange solution which is separately provided by GE			
A: Available		Blank cells indicates: Not Available	

External battery charger compartment (option)

The external battery charger compartment is used to charge the battery outside the Vscan Extend.

NOTE: The Vscan Extend battery can either be charged in the main unit by directly plugging the AC/DC adapter or externally by placing the Vscan Extend battery on the external battery charger.

NOTE: Scanning is disabled during charging if charged in the main unit.

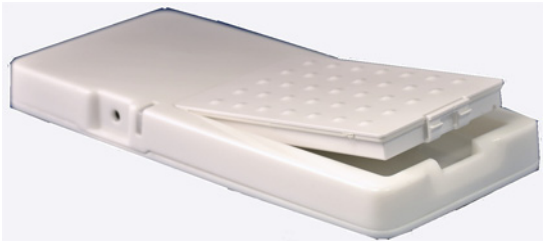


Figure 3-5. External battery charger compartment

The table below lists the units or parts that can be replaced by the user (CRU - Customer Replacable units)

Table 3-6: CRU

Description	Part number
Battery	5693456
AC/DC adapter	5693487
Application Software SD Card	5716858
External Battery Charger	5716861

Display screens

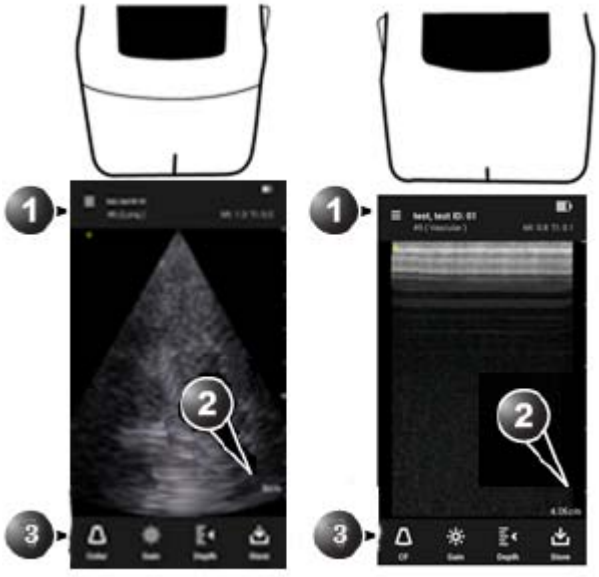


Figure 3-6. Scanning screens (Black and white mode)

Phased array transducer

1. Header
   - Menu icon
   - Patient information
   - Exam number
   - Battery level indicator
   - MI and TI values
2. Depth scale
3. Footer
   - Color icon
   - Gain
   - Depth
   - Store

Linear array transducer

1. Header
   - Menu icon
   - Patient information
   - Exam number
   - Battery level indicator
   - MI and TI values
2. Depth scale
3. Footer
   - Color icon
   - Gain
   - Depth
   - Store

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

Display screens (continued)

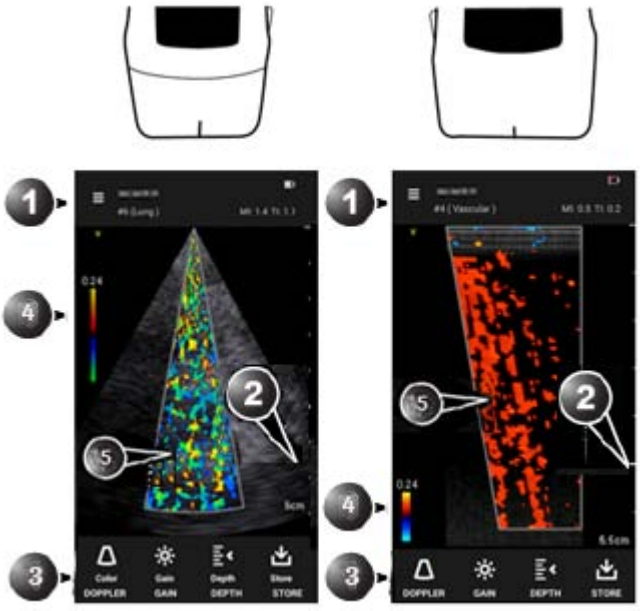


Figure 3-7. Scanning screens (Color mode)

Phased array transducer

1. Header
   - Menu icon
   - Patient information
   - Exam number
   - Battery level indicator
   - MI and TI values
2. Depth scale
3. Footer
   - Color icon
   - Gain
   - Depth
   - Store
4. Color bar
5. Color ROI (Region of Interest)

Linear array transducer

1. Header
   - Menu icon
   - Patient information
   - Exam number
   - Battery level indicator
   - MI and TI values
2. Depth scale
3. Footer
   - Color icon
   - Gain
   - Depth
   - Store
4. Color bar
5. Color ROI (Region of Interest)

Display screens (continued)

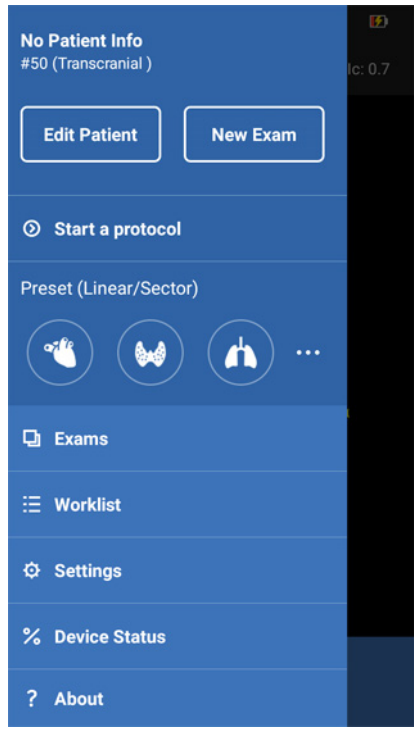


Figure 3-8. Menu screen

Vscan Extend Battery

Battery

The Vscan Extend system is powered by a Li ION battery (Model - U80395). 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 system availability.

The battery must be charged while housed in the Vscan Extend or in the external battery charger.

The Li ION battery, used in Vscan Extend, with the battery code is displayed below.

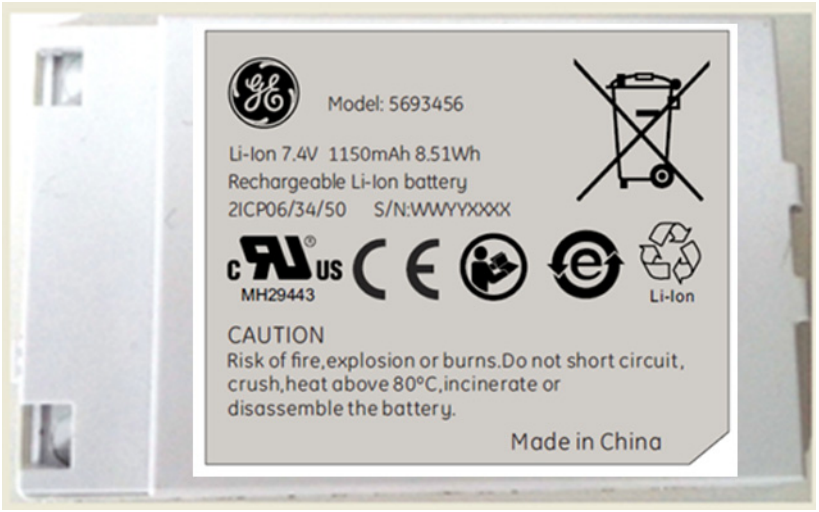


Figure 3-9. Vscan Extend battery

Battery specification

Table 3-7: Battery specification

Items		Unit	Value	Description
Basic	Voltage	mV	7400	MAX
	Current	mA	1150	Avg 1C

Battery (continued)

WARNING

Use only the AC adapter provided with the Vscan Extend.

The Vscan Extend cannot be charged via the USB cable when connected to a PC.

Figure 3-10. Vscan Extend AC adapter

CAUTION

The AC adapter must be kept outside the patient environment (refer to local regulation and EN 60601-1).

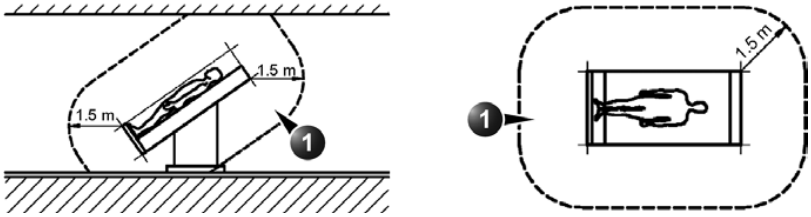


Figure 3-11. Patient environment

1. Patient environment

WARNING

Do NOT simultaneously touch the patient and the charger plug on the AC adapter.

Power plugs

1. Select the country specific plug.

Figure 3-12. Power plugs

1. North America, Japan
2. China
3. Australia, New Zealand
4. UK, Hong Kong, Singapore
5. Continental Europe and Korea (for unearthed electrical outlet)

2. Insert the relevant plug into the adapter.

Figure 3-13. Insert the plug

Voltage requirements

The AC/DC 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/DC adapter.

Charging the battery

1. Insert the battery into the device.

Figure 3-14. Insert the battery

2. Plug the AC/DC adapter into the electrical outlet.

Charging the battery using the optional External battery charger compartment

1. Place the external battery charger on a flat surface.
2. Insert the battery in the compartment.

NOTE: *Do not apply excessive pressure to the battery while inserting it into the compartment. There is no snap provided on the external battery charger. The battery fits smoothly into the compartment without a click.*

3. Plug the charger plug into the charger connector on the external battery charging compartment.

Battery level indicator

The battery level indicator is displayed on the screen. The following icons are displayed.

Table 3-8: Battery level indicator

Icon	Description
	Battery fully charged (>=95%).
	Battery 75% charged (>=70% and <95%).
	Battery 50% charged (>=45% and <70%).
	Battery critical, or low Battery (<45%). Prepare to recharge the battery or have a spare battery available.
	Battery charging.

Inserting/removing the battery

To insert the battery

1. Insert the battery in the compartment until the lid clicks in place.

Figure 3-15. Inserting battery

To remove the battery

1. Power off the Vscan Extend.

CAUTION

Do not attempt to remove the battery without powering off the Vscan Extend.

2. Push the button on the battery compartment lid and lift the battery.

Figure 3-16. Removing battery

Battery specifications

Table 3-9: Battery specification

Item	Specification
Charging time at 90%	About 75 minutes
Capacity	About 1 hour while continuously scanning
Lifetime	At least 300 charges

In order to get maximum charging capacity with your Vscan Extend 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.

When storing the Vscan Extend for a period longer than three months, remove the battery from the Vscan Extend main unit. Recharge the battery every three months to maintain battery performance. When the battery is stored separately, storage can be at least one year before recharging the battery is needed.

NOTE: Make sure to remove the battery from the device before shipping from one place to another.

To minimize battery performance degradation, avoid prolonged storage of the battery outside the Vscan Extend operational temperature range (see ‘Environmental requirements for the device’ on *page 3-3*).

Initial use

First time use

Before Vscan Extend can be used, the following steps must be done:

1. Install the battery. (See ‘To insert the battery’ on *page 3-20 for more information.*)
2. Press the **Power** button to power on Vscan Extend.
3. Activate Vscan Extend. (See ‘Vscan Extend activation’ on *page 3-24 for more information.*)

Power on/off

To power on the Vscan Extend

Press the **Power** button.

Device boots up and scan screen displays within 45 seconds.

NOTE: The Scan screen displays only when the device has been activated. See ‘Activation’ on page 3-24 for more information.

To power off the Vscan Extend

1. Press the **Power** button.
   A pop-up displays prompting to Power off OR Restart.
2. Select **Power off**.

To restart Vscan Extend

1. Press and hold the **Power** button.
2. Select **Restart** to restart the device.

Standby Mode

Vscan Extend enters standby mode when the Power button is quickly pushed. In this mode, Vscan Extend will not have power to the probe or any display.

OR

Vscan Extend enters standby mode automatically while in freeze mode for more than 10 minutes.

Push the Power button again once to resume from standby mode. The device is ready to scan within a second.

NOTE: When resuming the device from standby mode, a new exam is created and the previous exam data is lost, if not previously saved.

Sleep Mode

Vscan Extend enters sleep mode if it continues to be in standby mode for more than 3 hours.

Push the Power button again to resume from sleep mode. The device is ready to scan within approximately 5 seconds.

NOTE: When resuming the device from sleep mode, a new exam is created and the previous exam data is lost, if not previously saved.

Startup procedure

The approximate time taken for the device from switching on until the device is ready for normal use is 40 seconds.

Vscan Extend activation

Activation

There are three possible scenarios to activate Vscan Extend:

1. **Scenario 1**: Activation using Wi-Fi on the Vscan Extend device.
2. **Scenario 2**: Manual activation - activate Vscan Extend by visiting the url: https://vscanactive.gehealthcare.com from a PC.
3. **Scenario 3**: Activation without internet access. If there is no internet access, contact GE Service (see page 1-8 for phone numbers, then see ‘Offline activation’ on page 4-12) to activate Vscan Extend.

Activation using Wi-Fi

The activation process includes steps to register the Vscan Extend device.

NOTE: When Wi-Fi is enabled the device can be activated directly.

Set Language, Date and Time

1. Connect Vscan Extend to a power source.
2. Press the **Power** button to power on Vscan Extend.

   The Startup screen displays, followed by the Language screen.

NOTE: The default language is set to English.

3. To choose another language, press **Change Language**.

Figure 3-17. Select language

4. Choose the desired language. The screen changes back to the Language screen.
5. Press **Next**.

Set Language, Date and Time (continued)

6. The Date and Time screen displays.

NOTE: The current date and time is set by default.

7. Press **Change Date and Time** to change the date and time, if needed.

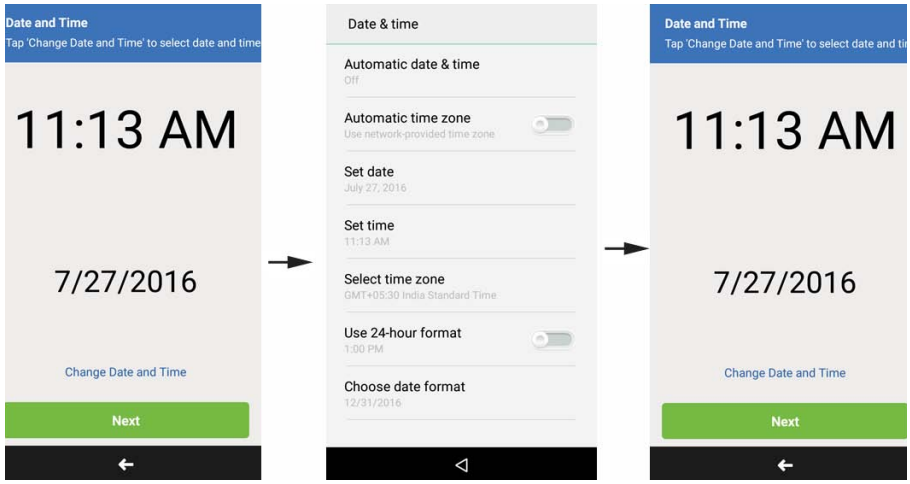


Figure 3-18. Date and Time

Choose either the automatic date and time format which sets the date and time by synchronizing through the internet.

OR

Set the date and time manually.

8. Press **Next**.

Connecting Wi-Fi

NOTE: If Wi-Fi is not detected, configure Wi-Fi. See 'Configuring Wi-Fi' on page 4-23 for more information.

1. Select your Wi-Fi network and enter your Wi-Fi password. (All non hidden Wi-Fi networks are displayed.)

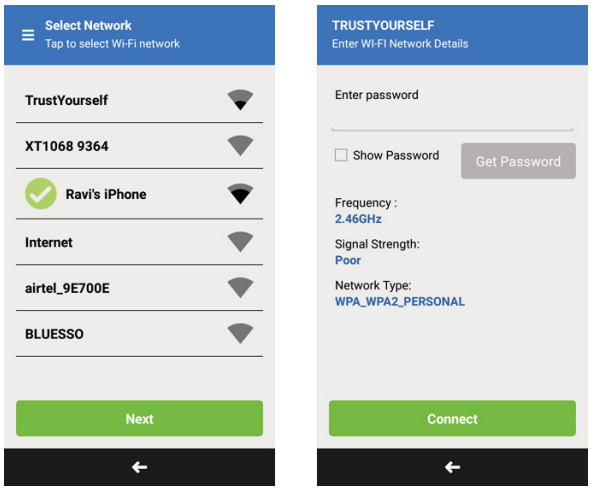


Figure 3-19. Wi-Fi settings

2. Press **Next**.

NOTE: Ensure that the Vscan Extend is connected to a non-clinical Wi-Fi hotspot to start activation.

NOTE: A non-clinical Wi-Fi has access to the public internet, which is not part of the hospital internet. If you are unable to view the non-clinical Wi-Fi or do not have the password, contact your system administrator.

NOTE: If you do not have access to public Wi-Fi, proceed with manual activation of the device. See 'Manual activation' on page 3-35 for more information.

NOTE: If the hospital network does not have an internet connection, proceed with manual activation of the device. See 'Manual activation' on page 3-35 for more information.

Connecting Wi-Fi (continued)

1. Enter the authentication details to connect to the network.

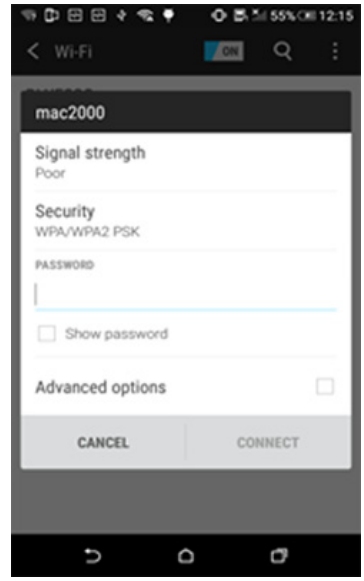


Figure 3-20. Authentication code

2. Once the device connects to the network, press the **Back** arrow to exit the Settings screen.

   The screen changes back to the Wi-Fi screen (Figure 3-19 *on page 3-27*.)

3. Press **Next**.

Registration

Registering the device creates a Vscan Extend account which enables access to the GE Marketplace and other features.

First time registrants

1. First time registrants, press **Register** to create an account. Enter the required details.

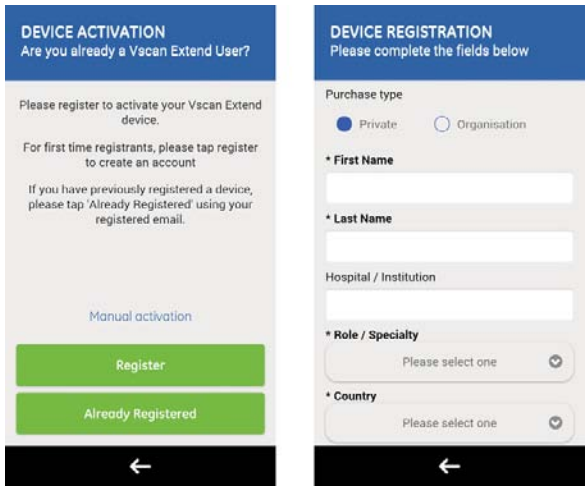


Figure 3-21. Registration details

NOTE: *If you have previously registered a Vscan Extend device, press **Already Registered** using your registered email. See 'Registered users' on page 3-31 for more information.*

HINTS

Press the Arrow key twice to get the letters in all caps and press the number key to toggle between numbers and alphabet.

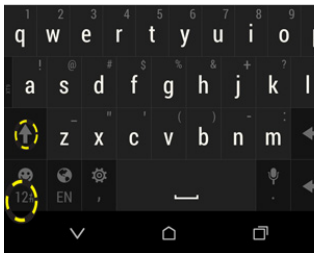


Figure 3-22. Keyboard tips

First time registrants (continued)

2. Check the desired options to either participate in collaborative GE activities or to receive special offers and promotions.

   Press **Register**.

3. An email is sent to the email address used during registration.

NOTE: The email has a link requiring you to change your password for security purposes.

4. Press **Activate my device**.

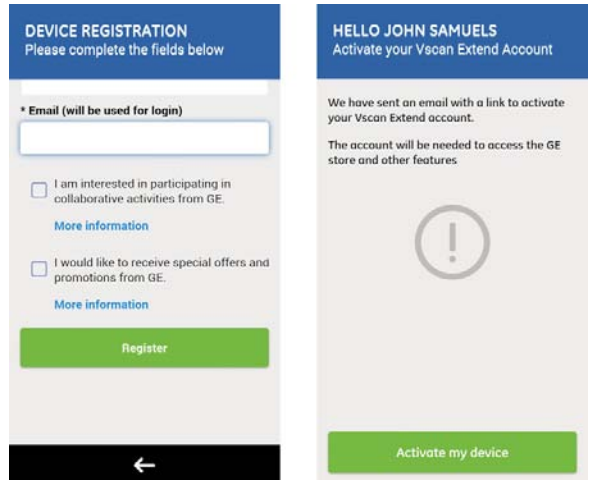


Figure 3-23. Choose an option

5. Vscan Extend has been activated. Press **Start Using Device**.

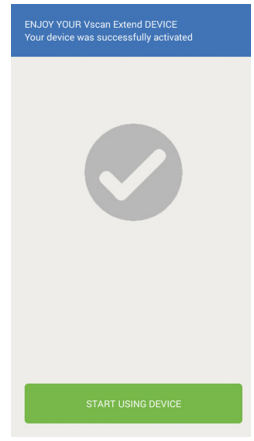


Figure 3-24. Start using Vscan Extend

Registered users

NOTE: Ensure Vscan Extend is connected to a non-clinical Wi-Fi.

1. Press **Already Registered**.
2. Enter your email ID and password.

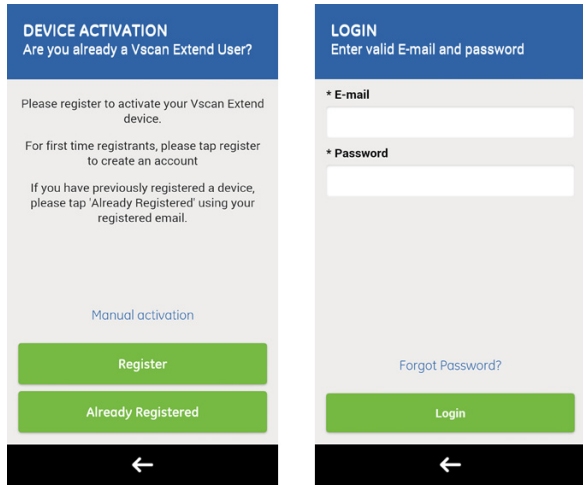


Figure 3-25. Already Registered

NOTE: If you log in with a wrong email ID, a pop-up message displays: "Login error: Your email ID is not confirmed yet". Try again with a valid email ID.

Registered users (continued)

3. While the activation process is in progress, the wireless is connecting to the GE Store and the activation key is being entered automatically.
4. Press **Activate my device**.
5. Vscan Extend has been activated. Start using the device.

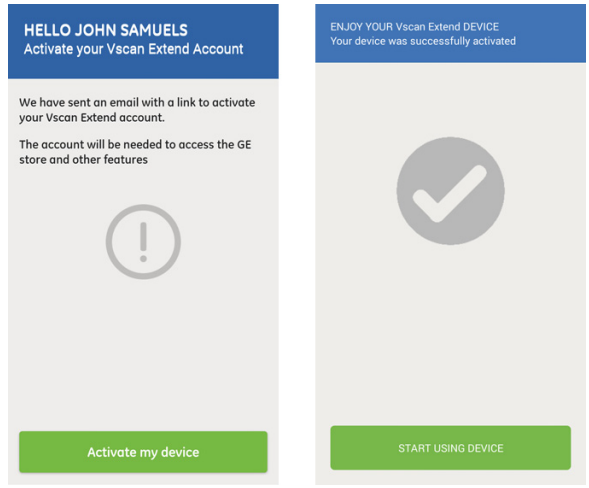


Figure 3-26. Start using Vscan Extend

Already registered users - Forgot password

1. If you forgot your password, press **Forgot Password**.
2. An email is sent to your confirmed email address with a link to reset the password.

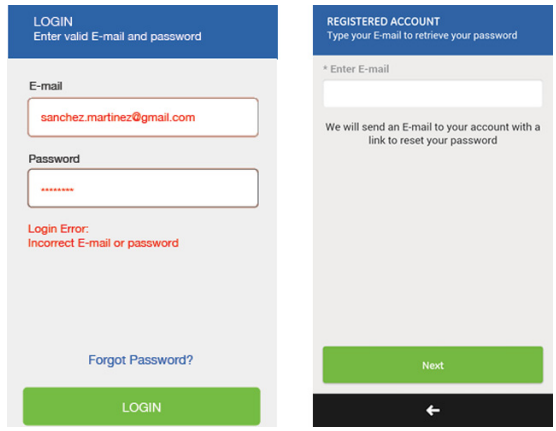


Figure 3-27. Forgot password

3. Click on the link on a personal computer to reset the password.
4. Enter your email ID and new password. The Vscan Extend is activated and ready to use.

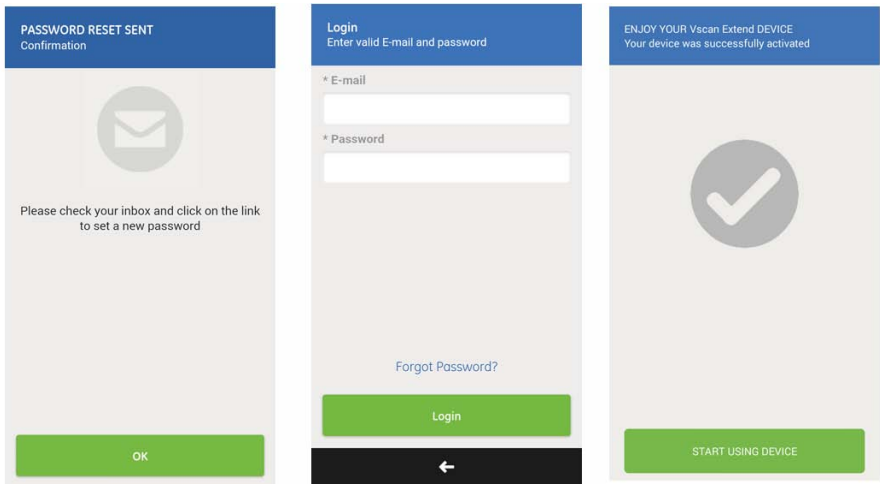


Figure 3-28. Reset password and start using Vscan Extend

Network access failed

1. If you are unable to connect to a Wi-Fi network, press **Retry** and try to activate the device again.

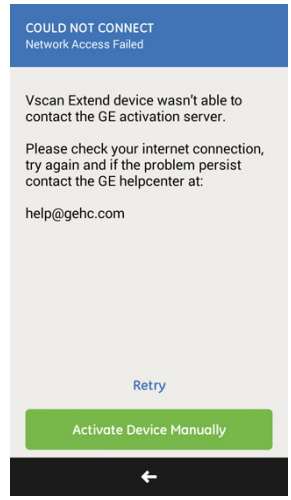


Figure 3-29. Retry

2. If the problem persists, contact your internet service provider and GE at help@gehc.com to connect to the network.
3. If the network is not accessible or you are unable to connect to the network, you can activate Vscan Extend manually. See ‘Manual activation’ on *page 3-35 for more information.*

Manual activation

To activate Vscan Extend without Wi-Fi connection, follow the steps below.

1. Open the URL (https://vscanactive.gehealthcare.com) in the internet browser on your PC.

NOTE: The PC should have internet access. If there is no internet access, call GE Service center or contact your local Sales representative.

2. Follow the directions provided on the site to generate the activation key for Vscan Extend.

   The following information is required:

   - The Vscan Extend serial number written on the rear label of the system.

3. User information as per the figure below.

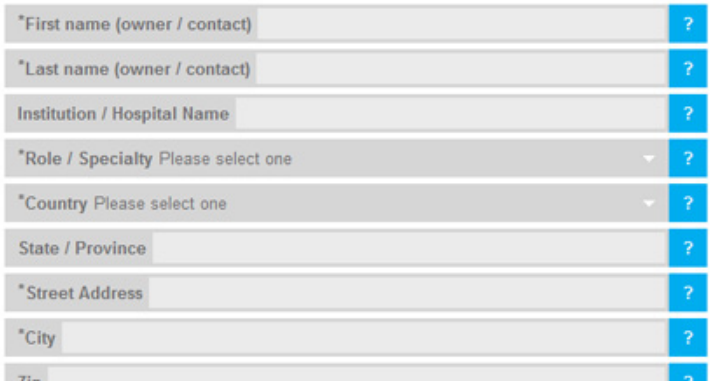


Figure 3-30. User Information

4. Enter other necessary details.

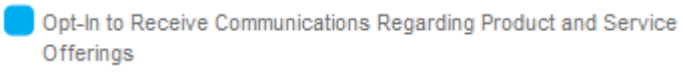


Figure 3-31. Opt-in checkbox

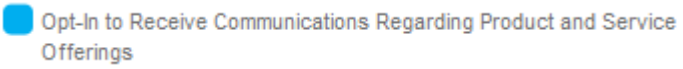


Figure 3-32. Opt-in communication

Manual activation (continued)

5. Press **Submit** to initiate registration.

Figure 3-33. Submit

6. The Activation key is generated. Store the key in a convenient location to enter into the device and for future reference.

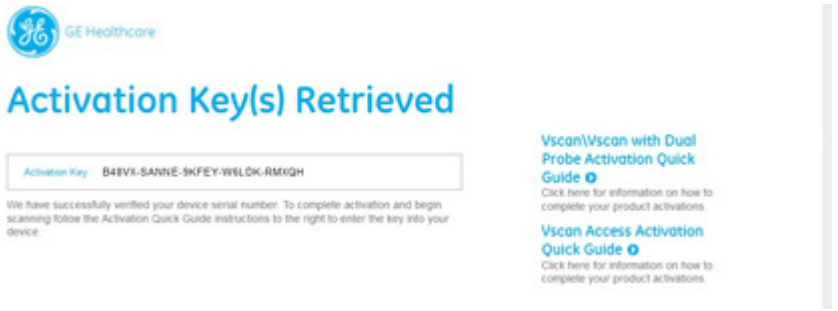


Figure 3-34. Activation key details

Activation key

The *Activation key* screen is displayed on the Vscan Extend.

1. Enter the activation key generated while registering on the portal (https://vscanactive.gehealthcare.com)

Figure 3-35. Enter activation key

HINTS

Press the **Backspace** key if a mistake occurred while entering the activation key.

2. Press **Activate**.

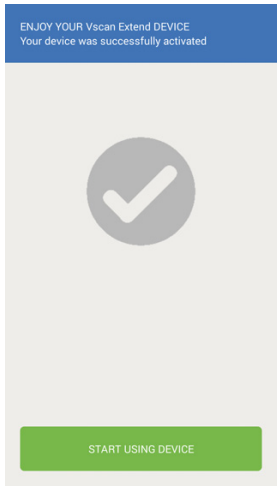


Figure 3-36. Start using the device

3. Vscan Extend has been activated. Start using the device.

Chapter 4

Vscan Extend Settings

Contents:

Settings

The following settings and functions are available under the main Settings menu.

Scan Settings

Press **Menu** -> **Settings**

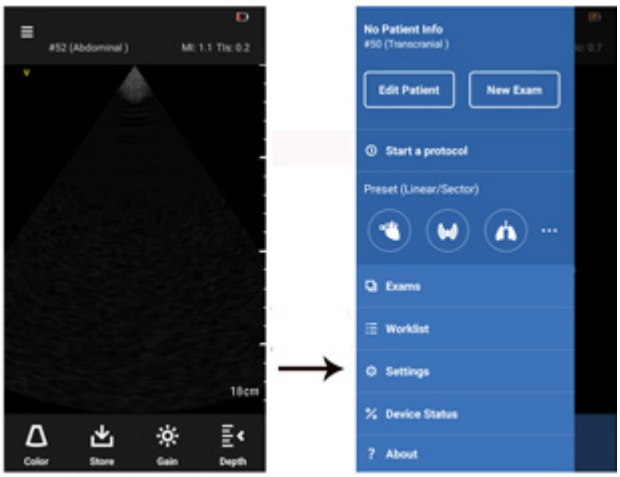


Figure 4-1. Settings

- Brightness - adjusts the screen brightness of the device

  Swipe the brightness level indicator to the left to decrease the brightness and swipe to the right to increase the brightness.

Scan Settings (continued)

Auto Freeze (Probe) - set the auto freeze time.

1. Press **Auto Freeze (Probe)**
2. Choose the desired value
3. Press **OK** to set the value

Video Duration - set duration of the captured Cine loops.

1. Press **Video Duration**
2. Choose the desired value
3. Press **OK** to set the value

Unit of Measurement - set unit of measurement

1. Press **Unit of Measurement**
2. Choose the desired unit
3. Press **OK** to set the value

Set current preset as default

1. Press **Set Current Preset as Default**
2. Press **Yes** to set the displayed preset as default.

Server Settings

Allows to configure the DICOM servers.

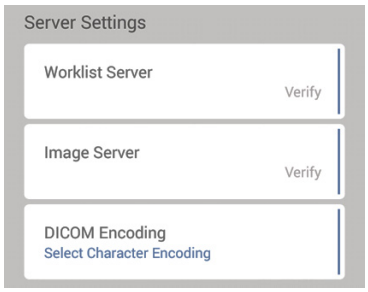


Figure 4-2. Server settings

Worklist Server - gets patient and intended study information

Image Server - remote store location for media (video/images)

DICOM Encoding - Choose the desired encoding type and press **OK**.

Server Settings (continued)

To configure the Worklist server:

HINTS

Press the title bar (the entire top section on the screen) or swipe left most side of the screen to access the Menu.

1. Press **Menu** -> **Settings**

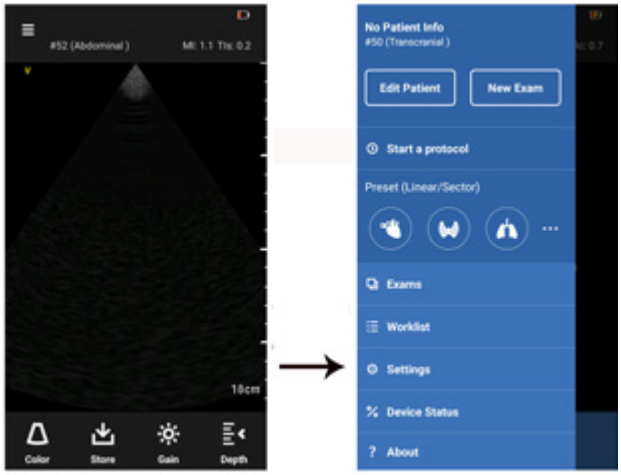


Figure 4-3. Settings

2. Scroll down to Server Settings. Press **Worklist Server**.

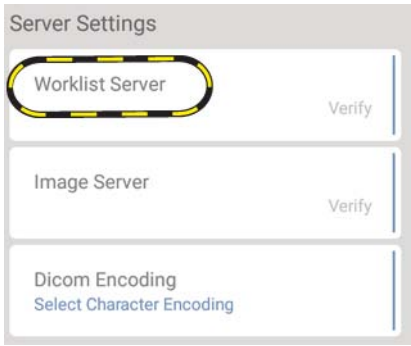


Figure 4-4. Worklist server

Configure Worklist Server

Connect Vscan Extend to the hospital wireless network. See ‘Activation using Wi-Fi’ on *page 3-24 for more information.*

1. Enter all fields to add a new Worklist server.

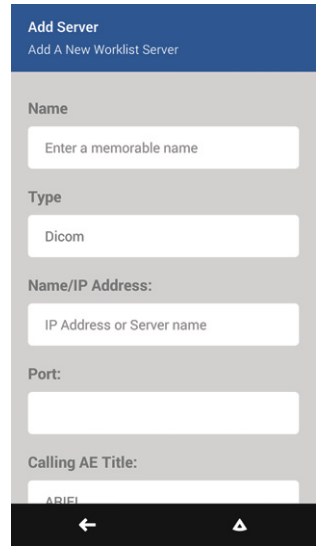


Figure 4-5. Configure Worklist Server

NOTE: Swipe upwards to get the full screen and enter all details. Contact the hospital IT administrator for details.

Configure Worklist Server (continued)

NOTE: *By default, DICOM is listed while configuring the Worklist Server.*

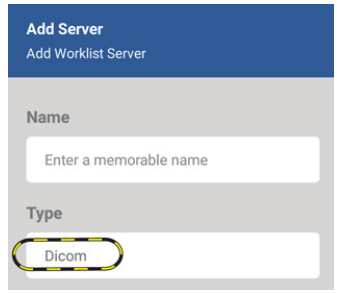


Figure 4-6. DICOM listed

2. Enter any unique name for Calling AE Title (e.g. Nixon Building Schedule).
3. Press **Add Server** to add the Worklist Server.
4. Press **Verify** to verify communication with the Worklist Server.

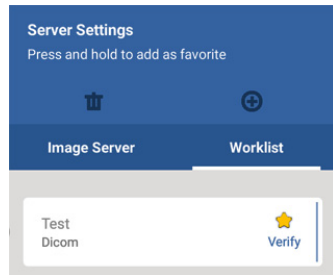


Figure 4-7. Verify Worklist Server

Configure Worklist Server (continued)

"Verify OK" pop-up displays if the communication with the Worklist Server is ok.

If communication fails:

- check the server settings and make necessary corrections.
- Vscan Extend and the DICOM image server are not connected to the same network. Check network settings for all components.

5. Press and hold the selected Worklist entry to add to the favorites list. By default, the first added Worklist server is set as the favorite. To remove a Worklist server from the favorites list, press and hold on the server name. If you wish to change it, press and hold to remove the current favorite and add the preferred server.

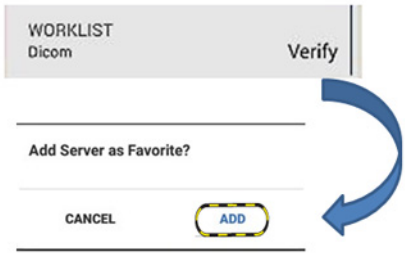


Figure 4-8. Add to favorites

NOTE: If only one DICOM MWL server is configured, it is automatically set as the favorite.

NOTE: The scheduled exam list will automatically be pulled from the favorite server.

Configure Worklist Server (continued)

6. To add another Worklist server, press **Add (+)**.

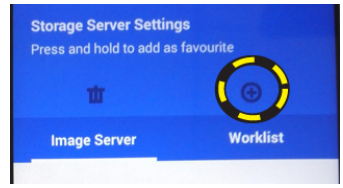


Figure 4-9. Add another Worklist server

7. To delete the Worklist Server, press the **Delete icon**.

Figure 4-10. Delete Worklist

Configure Image Server

1. Press **Menu** -> **Settings**

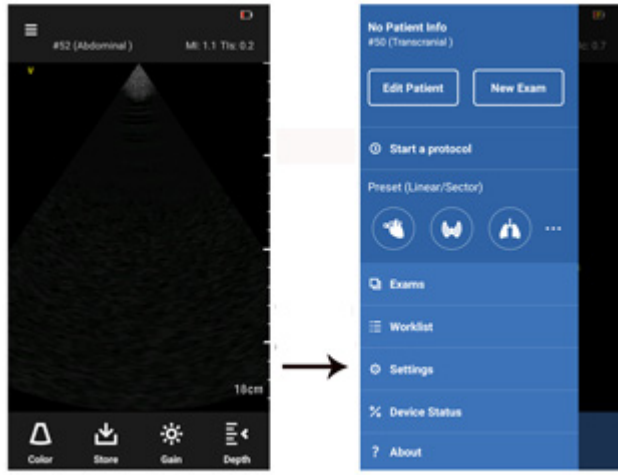


Figure 4-11. Menu

2. Scroll down to Server Settings. Press **Image Server**.

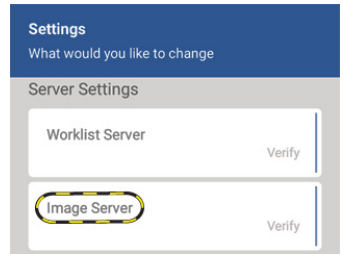


Figure 4-12. Image Server

Configure Image Server (continued)

3. Enter your Image server's IP address, port number, and Remote AE Title.

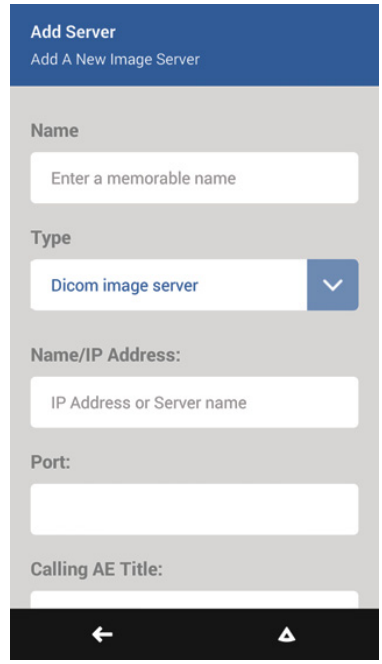


Figure 4-13. Configure Image Server

NOTE: Enter any unique name for Calling AE Title (e.g. Nixon Building Image Archive). Contact the hospital IT administrator for details.

4. Press **Add Server**.

Configure Image Server (continued)

5. Press **Verify** to verify that the communication with the Image Server is ok.

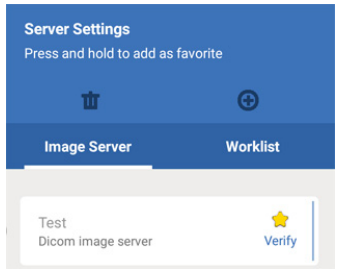


Figure 4-14. Verify Image Server

"Verify OK" pop-up displays if the communication with the Image Server is ok.

If communication fails:

- Check the server settings and make necessary corrections.
- Vscan Extend and the DICOM image server are not connected to the same network. Check network settings for all components.

Configure Image Server (continued)

6. Press and hold the Image Server to add the selected Image Server to favorites.

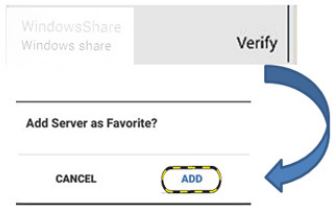


Figure 4-15. Add to favorites

NOTE: When you have added more than one image server, you can set one as a favorite. Once an image server is set as a favorite, saved images are automatically exported once patient information is added or edited for any exam.

Diagnostics

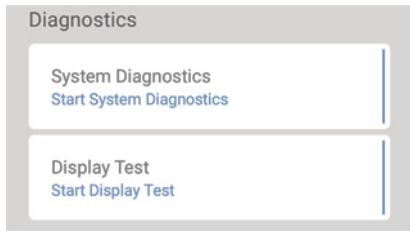


Figure 4-16. Diagnostics

- System Diagnostics - Performs main board or hardware diagnostics
- Display Test - Perform this test if there is a problem with the display. Use a swiping motion to navigate through all the screens. If an issue persists, contact GE Service.

System Settings

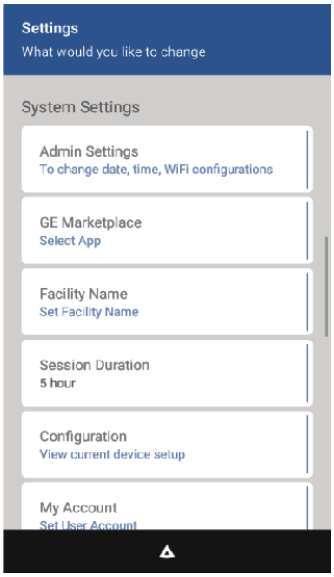


Figure 4-17. System Settings

- Admin Settings - Change date, time and configure Wi-Fi
- GE Marketplace - Select an app
- Facility Name - Set Facility Name
- Session Duration - When the device is idle, data access is active for the duration set. The default duration is 1 hour. The following values are available to set the duration:
  - 5 min
  - 15 min
  - 1 hr
  - 5 hrs
  - 1 day
  - never

WARNING

When the device is idle for the duration set, it is the reponsibility of the user to ensure that the device is not used by unauthorized persons as it may lead to data loss.

System Settings (continued)

- Configuration - Choose the desired option through an option key, either manually (enter the serial number of the device in the portal on a PC to obtain the option key) or (if Wi-Fi is connected, check for updates)

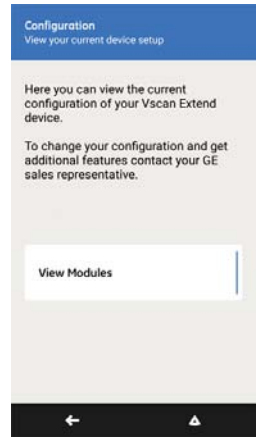


Figure 4-18. Configuration

Press View Modules to obtain the list of enabled modules.

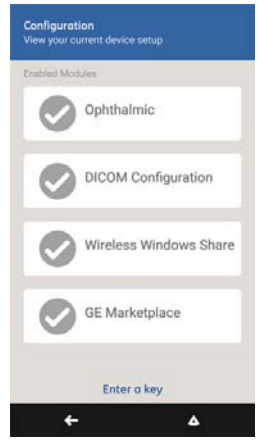


Figure 4-19. Enabled modules

- My Account - Set User account
- About - Provides device information

Administrator Access

For security purposes, the user has to create an admin PIN. This PIN provides access to the Admin settings.

1. Create a new PIN (four digit number e.g. 1234) for security purpose.

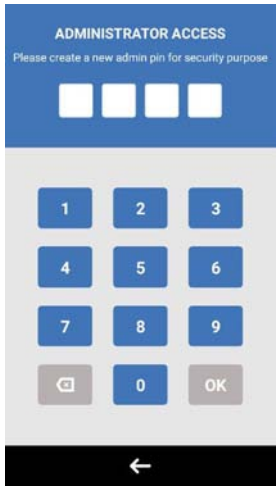


Figure 4-20. Create admin PIN

2. Enter the new PIN again for confirmation.

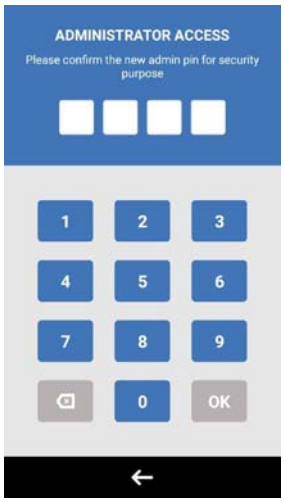


Figure 4-21. Confirm new PIN

NOTE: The PIN is critical to accessing system data. Avoid sharing this PIN with non-administrators and take precautions to not lose this PIN.

Administrator Access (continued)

The new PIN provides access to advanced settings.

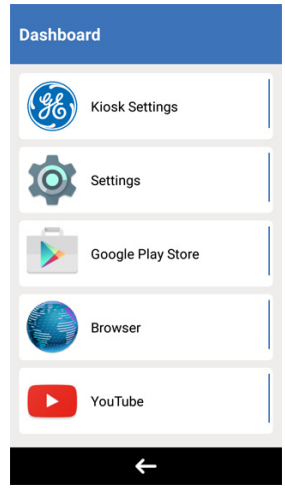


Figure 4-22. Advanced Settings

Storage Access

A device PIN has to be created for security purposes to access or store images/ videos. This PIN is created prior to the first use or after the system has been reset. Once the PIN is set, the user is prompted for the PIN every time the device is powered ON or after the session duration time has expired.

1. Create a new PIN for data storage and access, for e.g., 1234.

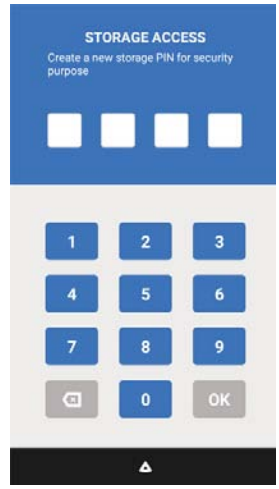


Figure 4-23. User PIN

2. Confirm the new PIN for security purpose. Confirmation is only required after PIN creation.

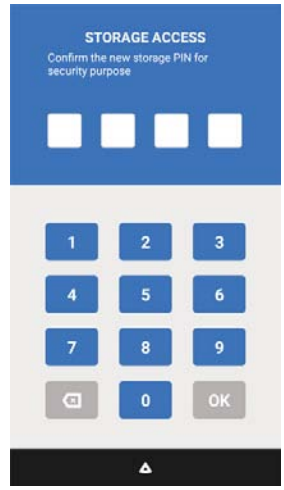


Figure 4-24. Confirm PIN

Storage Access (continued)

A PIN security note also desplays to the user:

This PIN is critical for accessing system data. It is required to access and store system data. Please remember a wrong / incorrect PIN entry can lead to loss of system data. Avoid sharing the PIN to unauthorized users for data protection.

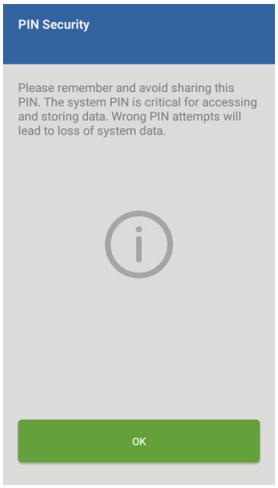


Figure 4-25. Remember PIN

The new PIN provides access to data storage and retrieval during normal use of the Vscan Extend.

Incorrect PIN

The Vscan Extend prompts to enter the PIN after power ON or reboot. User can skip entering the PIN and continue scanning by pressing the scan symbol at the bottom of the screen, see Figure 4-26 *on page 4-19*. In this case, scanning is allowed but images/videos cannot be stored or accessed.

Incorrect PIN (continued)

1. A pop-up message displays when an incorrect PIN is entered.

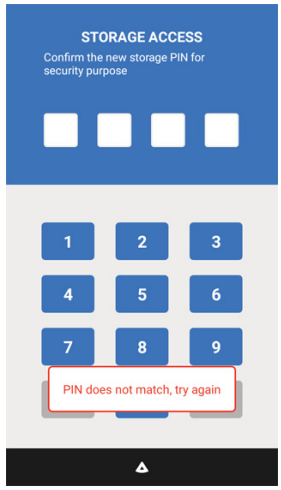


Figure 4-26. Wrong PIN

2. After 5 wrong attempts, the Vscan Extend displays a pop-up message to “Backup” data on a microSD card before the next login. See ‘Backup’ on *page 5-42 for more information.*

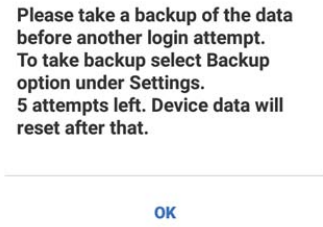


Figure 4-27. Backup data

Incorrect PIN (continued)

3. If backup is not performed after 5 attempts of wrong PIN entry and once again a wrong PIN is entered, a pop-up message displays for every incorrect PIN entry thereafter. For e.g., 4, 3, 2, 1 attempt(s) left.

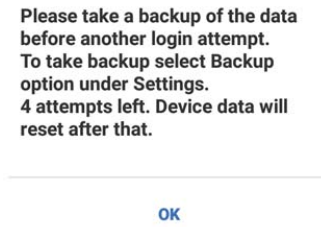


Figure 4-28. Remaining attempts

NOTE: It is highly recommended to back up data on a microSD card before the last attempt.

After the 10th attempt, the system resets and returns to the initial screen where a new pin should be entered see Figure 4-23 *on page 4-17*.

Wi-Fi

Wi-Fi is a local area wireless computer networking technology that allows electronic devices to network.

For Wi-Fi to work on the Vscan Extend:

1. Activate Wi-Fi on the device.
2. Connect to a specific network.

Activating Wi-Fi

To activate Wi-Fi on the Vscan Extend:

1. Press **Menu** -> **Settings** -> **Admin Settings**.

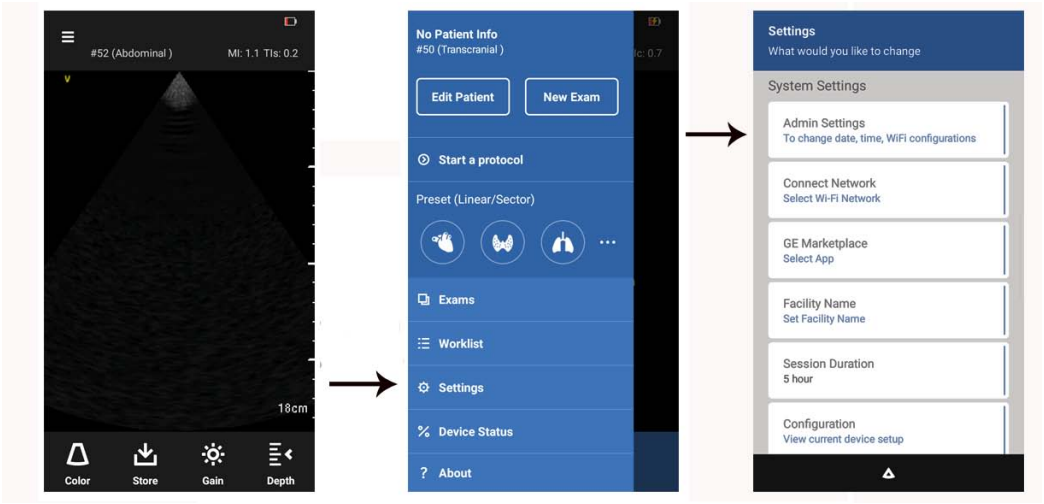


Figure 4-29. Admin Settings

2. Enter the Admin PIN to access advanced settings (settings of the operating system). See ‘Administrator Access’ on *page 4-15 for more information.*

Activating Wi-Fi (continued)

3. Press **Settings** on the Dashboard.

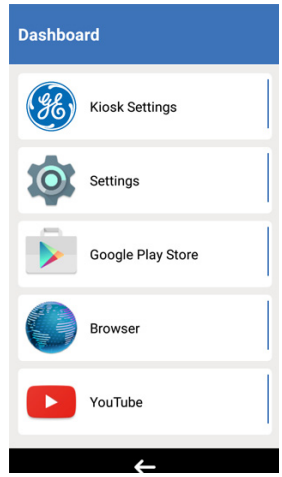


Figure 4-30. Advanced Settings

Configuring Wi-Fi

1. Press the **ON/OFF** button on the right to turn ON Wi-Fi.
2. Press **Wi-Fi**.

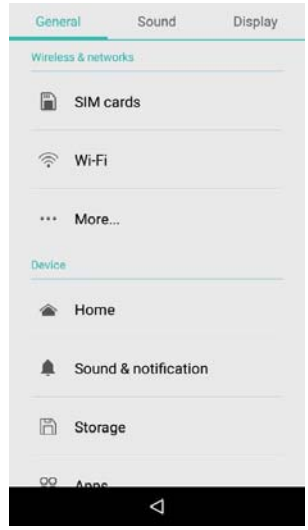


Figure 4-31. Menu

Choose the network if you know the credentials or contact your system administration

Procedure to check the MAC Address

*NOTE: If the Wi-Fi network has been configured with the MAC address, press **MAC Address** on the Advanced Settings screen.*

Figure 4-32. Mac address

Deleting Wi-Fi networks

1. Press **Settings** from the Dashboard.
2. Press **Wi-Fi**.
3. Select the network to be deleted.

   A pop-up displays prompting you to forget or modify the network.
4. Press **Forget network**.

MDM Installation Procedures (Optional)

NOTE: Network administrators use MDM (Mobile Device Management) to manage devices on the network.

1. Press **Google Play Store** on the Dashboard screen. See ‘Configuring Wi-Fi’ on *page 4-23 for more information.*

NOTE: You will be prompted to create a new account or add an existing one. Choose Add new and follow the instructions. Google Play Store is now available on the dashboard.

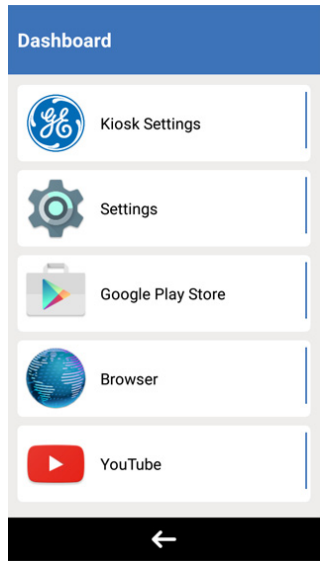


Figure 4-33. Google Play Store

MDM Installation Procedures (Optional) (continued)

2. Install the correct MDM agent from Google Play (Airwatch, Mobile Iron).

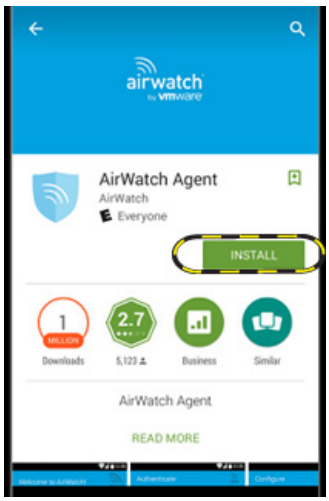


Figure 4-34. MDM

3. View the MDM service client with the help of your IT department.

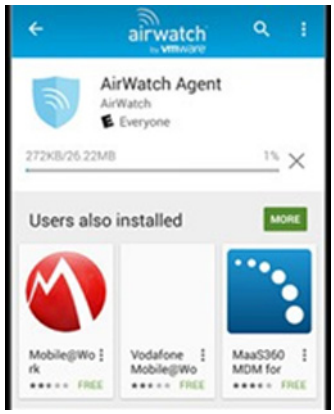


Figure 4-35. MDM installed

MDM Installation Procedures (Optional) (continued)

4. Press the **Back** arrow to go to Dashboard.
5. Press **Kiosk Settings**.

NOTE: Kiosk Settings provides access to advanced settings.

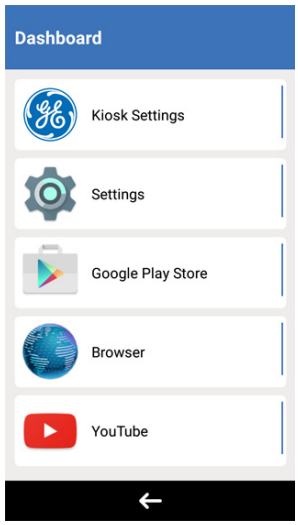


Figure 4-36. Kiosk Settings

6. Press **Admin Console App Chooser**.

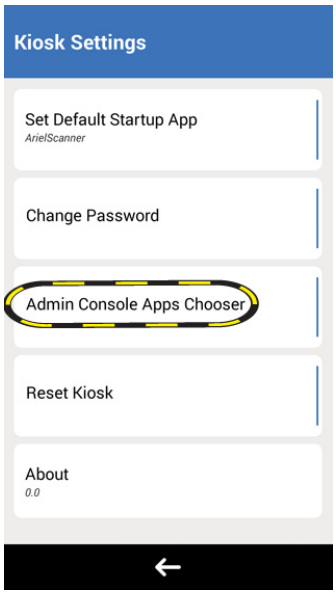


Figure 4-37. Admin Console App Chooser

MDM Installation Procedures (Optional) (continued)

7. Select the MDM **Agent** and press **Update**.

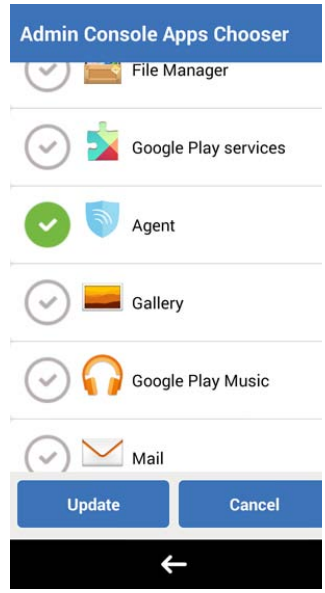


Figure 4-38. Select MDM Agent

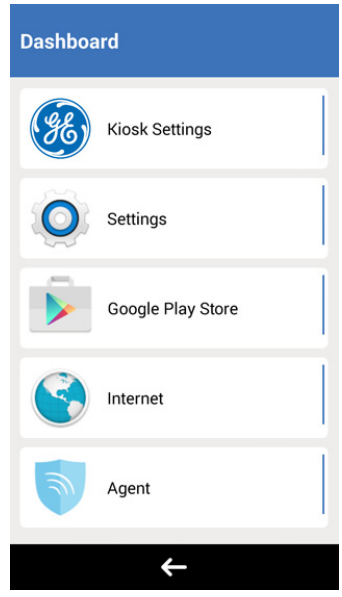


Figure 4-39. Update

The MDM agent is listed in the Dashboard.

Certificate Authority

Trusted certificates are typically used to make secure connections to a server over the Internet.

Use client and Certificate Authority (CA) digital certificates to enable the device to access VPN or secured Wi-Fi networks, and also to provide authentication to online secure servers.

You can get a certificate from your system administrator or download it from sites that require authentication.

1. Press the **...** icon at the bottom of the Wi-Fi Screen.

   Certificate delivery is completed using an over-the-air enrollment method, where the certificate is delivered directly to your Vscan Extend via a browser link.

NOTE: Contact your system administrator to download certificate on device.

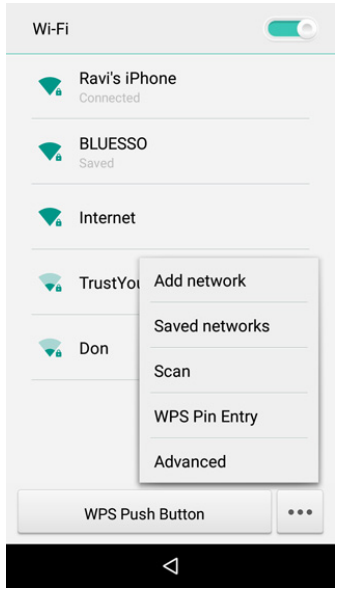


Figure 4-40. Advanced menu

Certificate Authority (continued)

2. Press Install certificate.

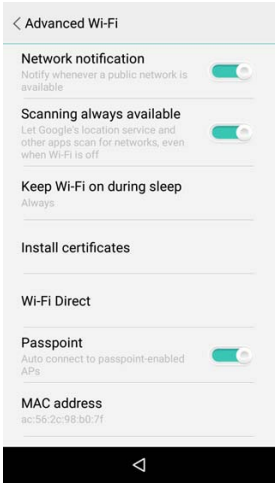


Figure 4-41. Install certificate

To complete the install, you need to add the certificate to your device's security credentials.

- Press **Security** on the Settings screen.
- Select **Install from phone storage** to get the certificate file from the downloads folder of your device.

Certificate Authority (continued)

- Download the certificate from Downloads.
- Now that the certificate has been added to your device's credentials, you can set the certificate name and choose Wi-Fi depending on the certificate's purpose.

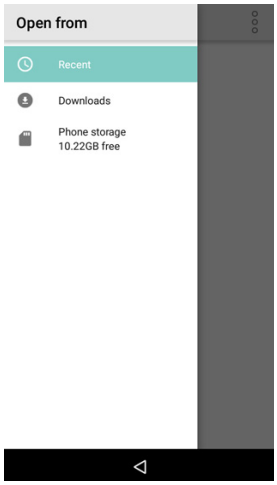


Figure 4-42. Download Certificate

The certificate is successfully downloaded onto your Vscan Extend. You can now choose it while connecting to a certificate based Wi-Fi authentication.

GE Marketplace

Registered users of Vscan Extend (with Wi-Fi Access or DICOM configuration) have access to GE Marketplace to install applications like Bladder Volume, Lung Protocol, Case Exchange and Tricefy on the Vscan Extend.

NOTE: GE Marketplace registration is separate from device registration when activating the Vscan Extend.

NOTE: If the email used during registration is not confirmed, you need to confirm the email to access GE Marketplace.

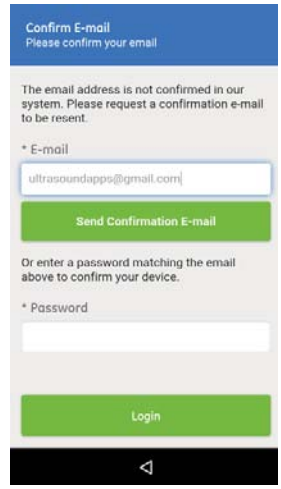


Figure 4-43. Confirm email

A confirmation is sent to the email address to confirm your email and set your password.

Installing Vscan Apps

1. Press **GE Marketplace** on the Settings screen.

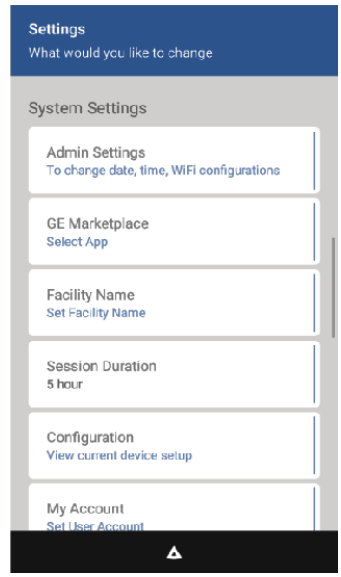


Figure 4-44. GE Marketplace

Figure 4-45. Connecting to GE Marketplace

Installing Vscan Apps (continued)

2. List of available Vscan apps are displayed.

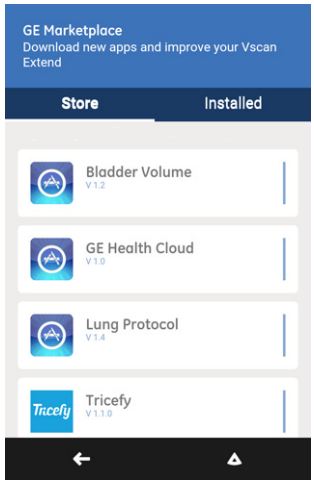


Figure 4-46. List of Vscan Apps

3. Select the App (for example, Bladder Volume). Press **Install**.

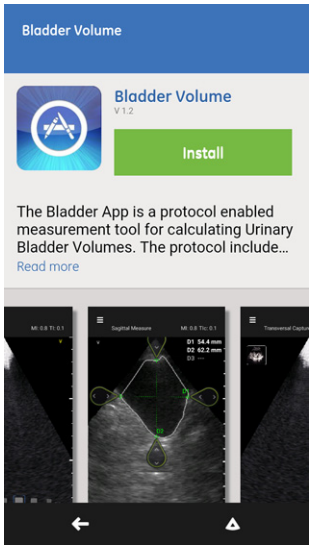


Figure 4-47. Install app

4. The App gets downloaded and prompts you to install. Press **Install**.

Updating the Marketplace

On the Apps screen list, updates are displayed when available. Select the App you wish to update and press **Update** on the App (for example, Lung Protocol).

NOTE: If no apps have been installed, a message displays "You have no apps installed yet."

NOTE: While the apps are updating, there is no loss of data. The updated app requires no new permission.

Uninstalling Apps

1. Press **Menu** -> **Settings** -> **GE Marketplace**. Press the App to uninstall. For example, Bladder volume.
2. Press **Uninstall**.

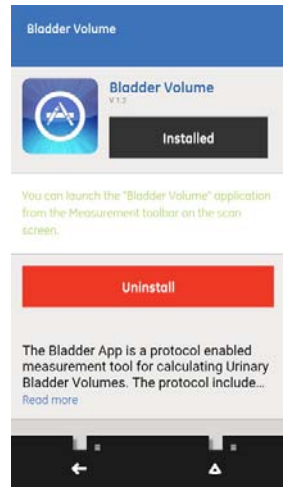


Figure 4-48. Uninstall

Scenarios while trying to access GE Marketplace

Email address not valid

User will not receive a confirmation email if a valid email address is not entered to register the Vscan Extend. The following message displays:

The email address is not confirmed in our system. Request a confirmation to be resent.

OR

Enter a password matching the email to confirm your device.

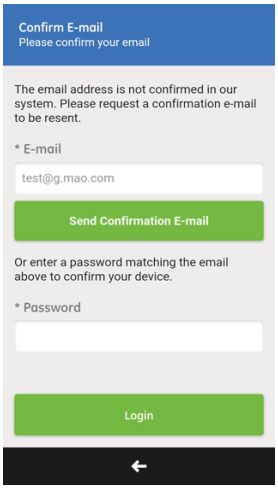


Figure 4-49. Resend confirmation email

Enter a valid email address. A confirmation email is sent. On your PC, set the password.

Figure 4-50. Set password

Email address not confirmed

User has already a registered email address, but the Vscan Extend is yet to be confirmed. Type the registered email address and password. Press **Login**.

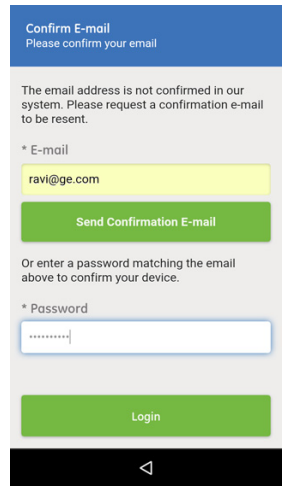


Figure 4-51. Request for confirmation email

A message displays: This Vscan Extend device has been registered to your account.

The user account details page displays.

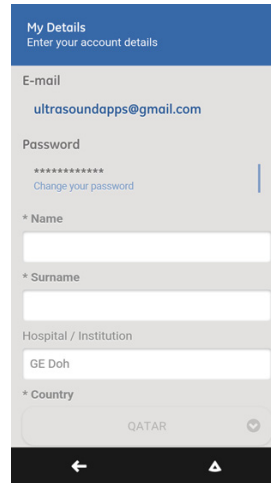


Figure 4-52. Account details

Press the Back arrow and press GE Marketplace.

Chapter 5

Using Vscan Extend

Contents:

Scanning

General scanning recommendations

Before each use:

Inspect the transducer (see ‘Before each use’ on *page 6-3*).

After Each Use

- Inspect the transducer (see ‘Cleaning the probe’ on *page 6-6*)
- Clean the transducer (see ‘Disinfecting the probe’ on *page 6-9*).
- If required, clean the device and the display (see ‘Disinfecting the device’ on *page 6-7*).
- If required, disinfect the transducer (see ‘Disinfecting the probe’ on *page 6-9*).

Ensure that the main unit and the transducer are properly cleaned after each use and before storing in the case.

If any damage is found on the transducer or its cable, DO NOT use the Vscan Extend. Contact GE service.

Use of gel

In order to ensure optimal transmission of energy between the patient and the transducer, 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.

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

Table 5-1: Compatible Gels

	
Aquasonics 100	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: http://www3.gehealthcare.com/en/Products/Categories/Ultrasound/Ultrasound_Probes. Select Dual Probe on Vscan and G3S Probe on Vscan from the Transducer list to get the details.

Other recommendations

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


CAUTION

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

The sector probe is provided with an orientation mark. This mark is used to identify the end of the probe corresponding to the side of the image having the orientation V mark on the scanning screen.

Figure 5-1. Sector probe orientation

1. Orientation marking on probe
2. Orientation marking on screen

The dual probe is provided with an orientation mark and a green LED light. This mark and the LED light are identifying the orientation of the probe using the fixed symbol displayed on the screen. In the case of the dual probe, the LED light is also indicating which probe head is active.

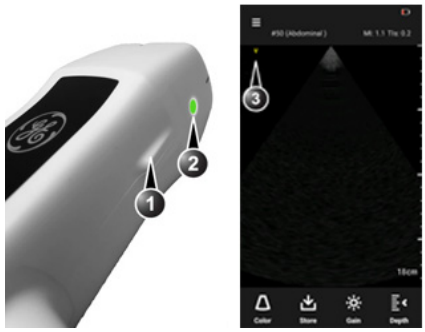


Figure 5-2. Dual probe: Orientation mark, phased array active

1. Orientation marking on probe
2. Green LED light
3. Orientation marking on screen

Probe orientation (continued)

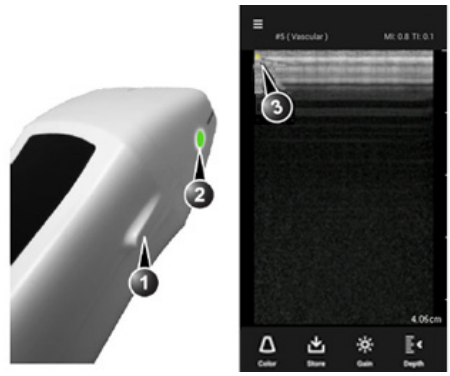


Figure 5-3. Dual probe: Orientation mark, linear array active

1. Orientation marking on probe
2. Green LED light
3. Orientation marking on screen

Patient examination

Creating new exam

A new exam can be created in two ways:

1. The Vscan Extend is powered on and it goes to the scanning mode.
2. Create New Exam from the Menu screen.
   - Press **Menu**.
   - Press **New Exam**.

NOTE: A new exam gets created when Vscan Extend enters Standby mode and also when Vscan Extend is disconnected from a PC.

NOTE: A new exam will not get saved only with patient details. The exam will get saved when an image or video is saved for that exam.

NOTE: It is recommended to enter patient information using alphanumeric characters.

Saving a new exam

When an image or video is stored, the exam is automatically saved.

NOTE: Current exam ends only when a new exam is created.

Editing patient information for an exam

Patient information can be entered in two ways:

- Edit Patient on the Menu screen
- DICOM - Retrieve patient information from DICOM modality worklist

1. Press **Menu** -> **Edit Patient**.

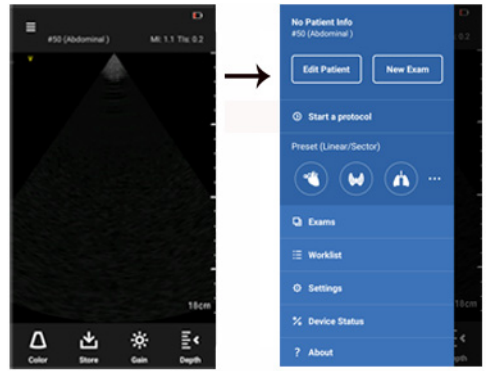


Figure 5-4. Edit patient details

Editing patient information for an exam (continued)

2. Enter patient details and press Save.

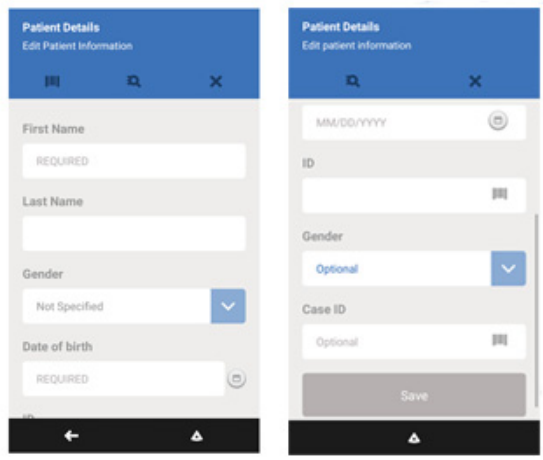


Figure 5-5. Save patient details

3. Retrieve patient information from DICOM modality worklist broker. See ‘DICOM Modality Worklist: Retrieve patient information from DICOM Modality Worklist broker’ on *page 5-37 for more information.*
4. Retrieve the patient information from the DICOM modality worklist broker. Press **Save**.
5. Patient information also gets saved when the patient is associated with an exam with images.

Search Patient

A patient can be searched from either My Worklist or by entering the patient name or ID.

1. Press **Menu** -> **Edit Patient**.

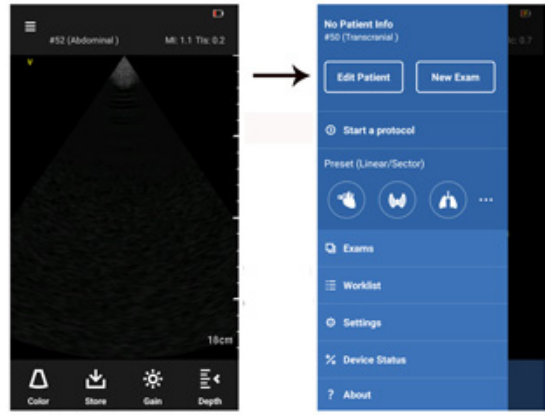


Figure 5-6. Edit patient

2. Press **Search** icon.

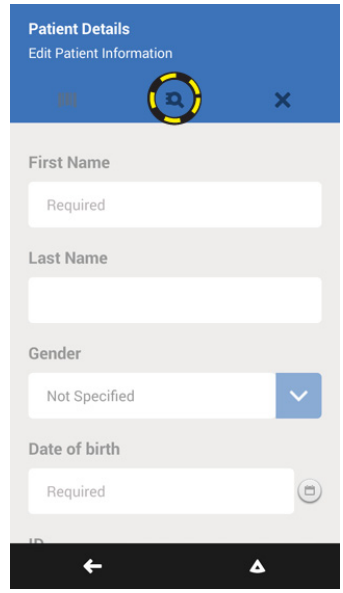


Figure 5-7. Search icon

Search Patient (continued)

3. Type the patient name or patient ID in the search field

NOTE: Press the Other tab to type the patient name or ID in the search field.

4. Find patient information on My Worklist (Optional)

   If the device is configured for DICOM (depending on the configuration purchased), patient information can be pulled from My Worklist. Perform the exam for this patient and press Save.

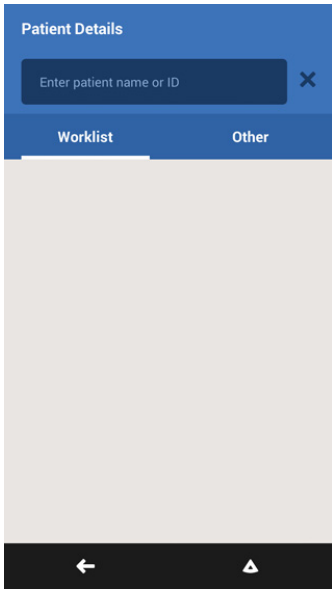


Figure 5-8. Search patient

NOTE: Patient information can be modified, if needed, using the Edit Patient feature.

Probe and Presets

The following table indicates the imaging modes supported by the probes.

Table 5-2: Supported imaging modes

Probe	Black and white imaging	Color flow
G3S Phased array	X (Harmonic)	X
Dual probe (G3S phased array and G8L linear array)	X (Harmonic for G3S phased array)	X

To ensure optimal image quality, the Vscan Extend has predefined scanning settings optimized for different applications (e.g. Cardiac, Abdominal). Refer to the tables below to select the correct probe and preset combination before scanning.

Table 5-3: Phased array transducer in G3S and Dual Probe (deep scanning) presets

Phased array transducer in G3S and Dual Probe (deep scanning)	Preset		Optimized for
		Cardiac	• Heart • Aorta • Lung
		Abdominal	• Liver • Kidney • Gall bladder • Spleen • Urology • Selective peripheral vascular
		Obstetrics	OB/Gyn
		Adult Cephalic	Various cephalic structures
		Aorta	Abdominal Aorta

Probe and Presets (continued)

Table 5-4: Linear transducer in Dual Probe (shallow scanning) presets

Linear transducer in Dual Probe (shallow scanning)	Preset		Optimized for
		Vascular	• Veins • Arteries
		Soft tissue	• Small organs • Pediatric (recommended minimum weight: 4 kg) • Musculoskeletal - including Long bone, Hip, Knee, Shoulder and Elbow
		Lung	• Thoracic/Pleural motion • Fluid detection
		Adult Cephalic	Various cephalic structures
		Ophthalmic*	Ophthalmic
* Ophthalmic is available as an option for certain countries but is NOT available in the USA, China and Japan.			

NOTE: Vscan Extend with Dual probe (shallow and deep) can be used for procedural guidance.

To change the preset and probe

1. Press **Menu**.
2. Press the **...** on the Preset tab.

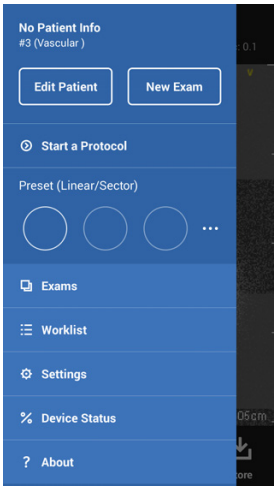


Figure 5-9. Menu page

3. The presets for the available probe(s) are displayed. The preset automatically selected activates the probe for that preset.

   Select the desired probe/preset.

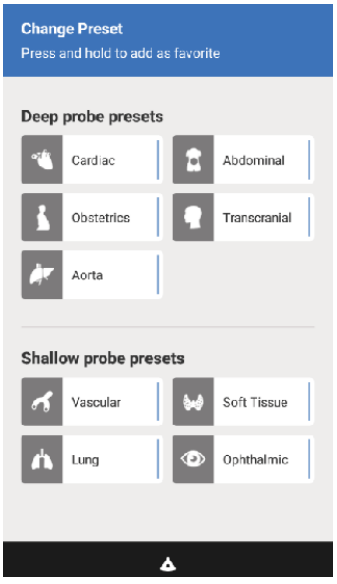


Figure 5-10. Change Preset

Creating preset favorites

Up to three presets can be saved as favorites and are available for quick access on the Menu page.

To save favorites:

1. Press **Menu**.
2. Press the **...** on the Preset tab.

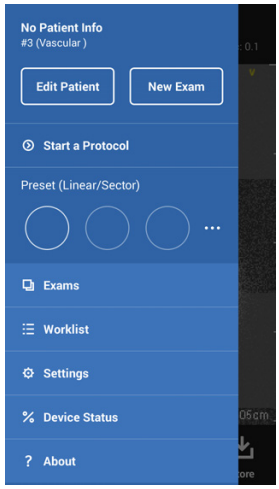


Figure 5-11. Menu page

3. Press and hold the preset icon to select the desired favorite. The icon changes to blue to indicate the saved favorite.

Figure 5-12. Presets favorites

1. Probe/Preset Availability
2. Preset Favorites (blue icon)

Creating preset favorites (continued)

The Menu page displays the selected favorites.

Figure 5-13. Menu page

NOTE: Only three presets can be selected as favorites at one time. Deselect a current favorite in order to add another preset as a favorite.

To deselect a favorite, press and hold the preset icon. The color of the icon changes to gray (Figure 5-11).

Black and white imaging

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.

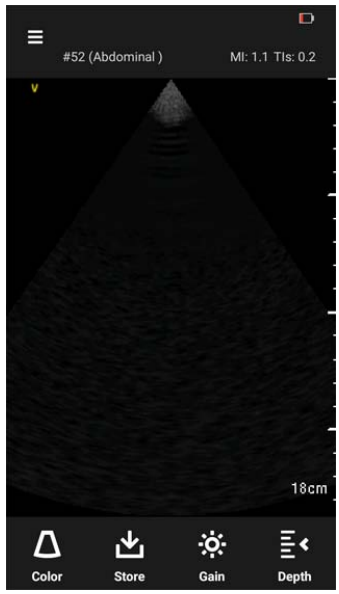


Figure 5-14. Black and white scan screen

NOTE: As a safety precaution, scanning is not possible when charging the battery.

Black and white imaging (continued)

Black and white imaging adjustments

The following adjustments can be done to further improve the image quality:

1. 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.
   - Press the **Gain** icon.

     The gain slider disappears after a few seconds. Press **Gain** again to activate the slider.
   - Use the gain slider to increase or decrease gain.
   - Press the **Gain** icon again to hide the control.

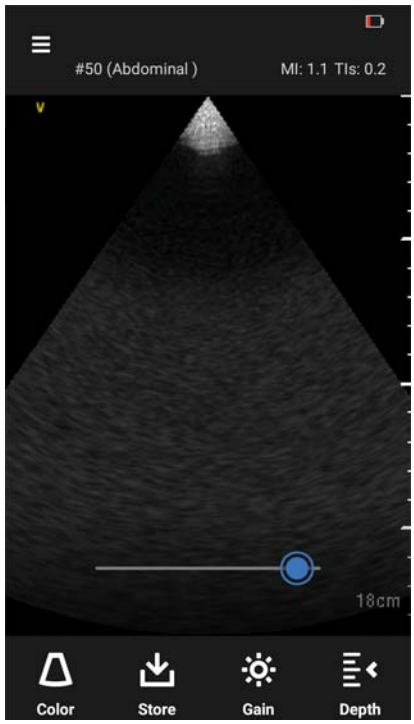


Figure 5-15. Gain

Black and white imaging adjustments (continued)

- 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.
- Press the **Depth** icon.
- Use the depth slider to increase or decrease depth.

  The depth slider disappears after a few seconds. Press the **Depth** icon again to activate the control.
- Press the **Depth** icon again to hide the depth control, if needed.

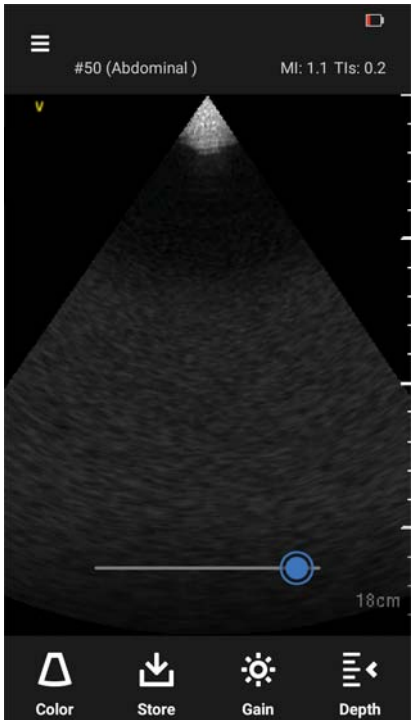


Figure 5-16. Depth

Color imaging

Color imaging is intended to add color coded qualitative information concerning the relative velocity and direction of fluid motion within the black and white image.

1. Press the **Color** icon.

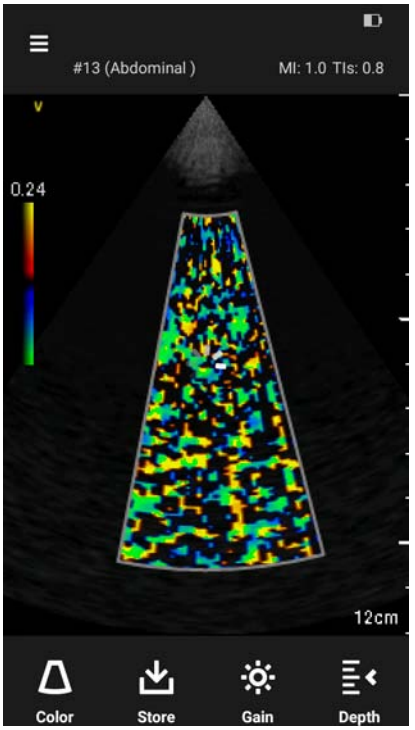


Figure 5-17. Color scan

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

2. Press and hold the color region of interest. The region of interest changes to yellow, indicating it is ready to be moved within the scan area. Drag the region of interest to the desired area of interest.

Color imaging (continued)

3. Press **Gain** to access the color gain control.

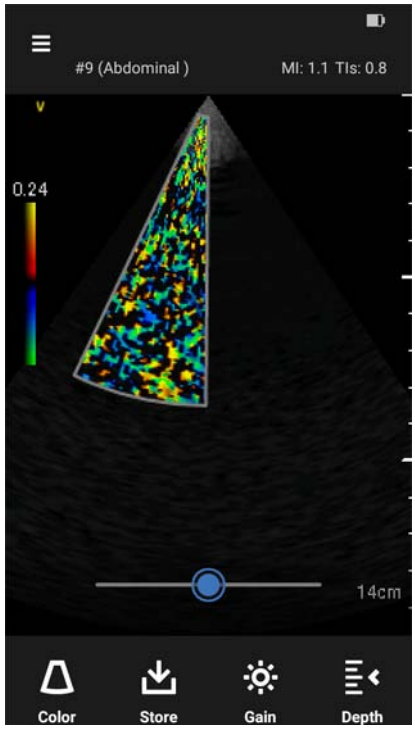


Figure 5-18. Color gain

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

Color imaging Scanning Adjustments

Color Aliasing

If the blood flow velocity exceeds the maximum velocity range the system can cover, based on the sampling rate used, aliasing occurs.

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

The maximum velocity is displayed on top of the color bar.

Color steer

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

Press and hold the color region of interest. The region of interest changes to yellow, indicating it is ready to be steered in a different direction. Drag the region of interest to the left or right depending on the desired angle.

NOTE: Angle Steer applies only to the linear functionality of the Dual Probe.

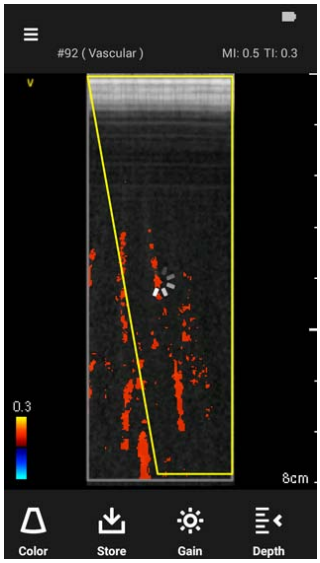


Figure 5-19. Color steer

Auto freeze

If Vscan Extend 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. See ‘Scan Settings’ on *page 4-2 for more information.*

AutoCycle

Vscan Extend does not include an ECG interface as often found on larger ultrasound systems intended for cardiovascular applications. The AutoCycle feature detects a complete cardiac cycle by analyzing the cyclicity of the ultrasound intensity data. The resulting time-stamps are used for storing and playing cineloops smoothly. The AutoCycle feature should typically detect heart rates in the range 46–100 beats per minute. If the detected heart cycle is outside this range, or if the cyclicity quality is too poor, a default 2 sec loop will be used instead. The detected start and stop times for the AutoCycle are not necessarily in phase with the QRS complex. Since adequate cyclicity can only be expected in cardiac applications, all other applications will use the default config settings.

Use of sterile sheath

It is recommended to use a sterile sheath around the probe and main unit if Vscan Extend is used as an aid to needle guidance or in any clinical situation where contamination could be a concern.

Measurements

Taking measurements

Vscan Extend enables distance measurement on frozen images in both black and white and color imaging. Up to eight measurements can be performed on an image. Measurements can be done during image review or on recalled stored images.

To perform a measurement:

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

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

Figure 5-20. Measurement

Taking measurements (continued)

4. Press **Add New** to make additional measurements on the displayed image. Up to 8 measurements can be made on a single image.

Figure 5-21. Add new measurement

5. Press **Delete** to delete a single measurement.

Review and recall of stored data

Backups Recommended

During live scanning, acquired images or videos are stored in the internal memory (image buffer). When the internal memory reaches 45% to 50% of its capacity, it is recommended to perform backup. To prevent loss of any images and videos, previously acquired images and videos must be stored to the microSD card. See ‘Backup’ on *page 5-42 for more information.*

NOTE: The number of images and videos that can be stored depends on the internal memory of the device.

NOTE: Backup data at regular intervals. If backup is not performed, the internal memory data can be lost and cannot be retrieved.

Reviewing and recalling images or videos from an exam list

1. Press **Menu**.
2. Press **Exams**.

   A list of exams, with stored images and videos, display.
3. Press on the desired patient and then press the image or video to get the full screen view.

Reviewing and recalling images or videos from an exam list (continued)

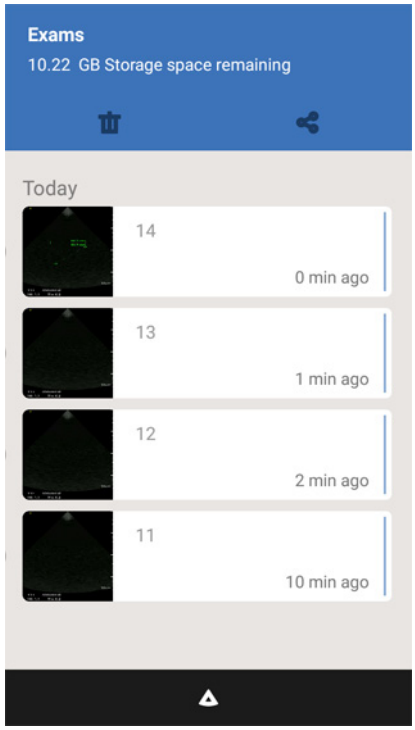


Figure 5-22. View stored images and videos

NOTE: Press on the image in the Exams screen. Use the right/left arrow to naviagte through the images/videos.

Deletion of data

To delete a file

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

Deleting individual images or videos

1. Press **Menu**.
2. Press **Exams**.
3. Select the Exam from which images or videos are to be deleted.
4. Press **Delete**.
5. Select the images or videos to be deleted.

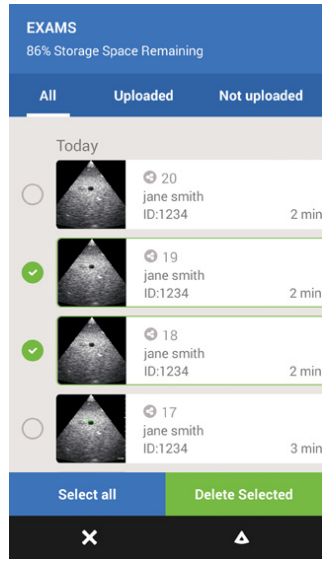


Figure 5-23. Images to be deleted

6. Press **Delete** to delete the images.

   OR

7. Press **Cancel** to cancel deletion.

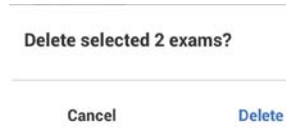


Figure 5-24. Delete or cancel

Delete images from an exam list

1. Press **Menu**.
2. Press **Exams**.
3. Select the exam from the list.

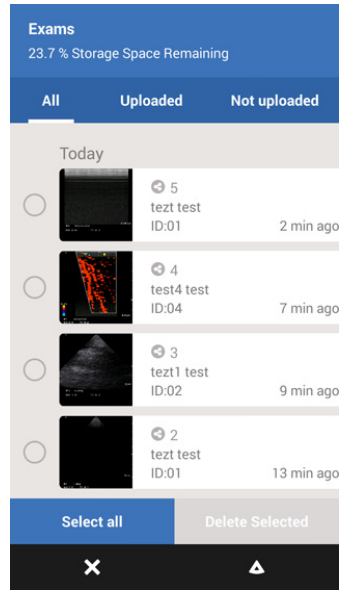


Figure 5-25. Images to be deleted

4. Press **Delete** to delete the images.
   OR
5. Press **Cancel** to cancel deletion.

Data Export

Data can be exported to a PC (‘USB Export’ on *page 5-31*), shared to a PC, exported to a DICOM server (‘DICOM Store: exporting DICOM images from Vscan Extend to DICOM image server’ on *page 5-39*), through Windows Share (‘Windows Share’ on *page 5-32*) or to GE’s separate cloud-based case exchange solution, if available on the device purchased.

NOTE: GE’s separate cloud-based case exchange solution is available in the U.S. and UK only.

Audit Logs

The Vscan Extend has audit logs of various types of events and activities.

The audit logs captured in the microSD card can be exported to a PC. A report can be generated using these audit logs.

The audit logs capture the following information:

1. Device Start/Shut-down time
2. Incorrect password attempts
3. Additions and modifications to system configuration, including:
   - DICOM connection
   - Windows Share connection
   - Wi-Fi connection and security details (SSID, Network disconnect/connect timings)
   - Application software install/uninstall/upgrade
   - Registration of partnering apps
4. Events related to Patient Data, including the following details:
   - Date/Time of data access
   - Type of action (addition, deletion, modification, reviewed)

   NOTE: Audit logs do not show the transfer of data to the PC.
   - Applications used (Bladder Volume, Lung Protocol, etc.)
5. Data Export
   - Date/Time of data export, including end point and Wi-Fi SSID information
   - Data Backup/Restore details
6. Invalid Device PIN attempt
7. Kiosk admin mode login success and failure

USB Export

Patient images and videos can be transferred from Vscan Extend to a Personal Computer (PC) using a USB cable.

The images or videos have the following details:

- Color ROI
- Depth marker
- Probe indicator
- Exam ID

Export files

JPG and MPEG files, stored on the device internal memory, can be exported to a PC with a USB cable. The folder and file names start with the device ID (serial number), then exam ID and NNNNN. The folder structure looks like:

....\Archive\EEEEEEE-XXXXXXX\EEEEEE-NNNNN-XXXXXXX.mpg

....\Archive\EEEEEEE-XXXXXXX\EEEEEE-NNNNN-XXXXXXX.jpg

where

EEEEEEE is the device ID.

XXXXXX is the exam ID.

NNNNN is the file number in the folder.

The files, file names, and folder names are non-patient identifiable.

Import data

The files exported to the PC can be copied back to a specific folder to the device with the USB cable (...\Import)

Windows Share

Windows share allows the system to send ultrasound images to a PC.

1. Press **Windows share** from the list. Enter the required details - Domain name, IP address, User name and Password.

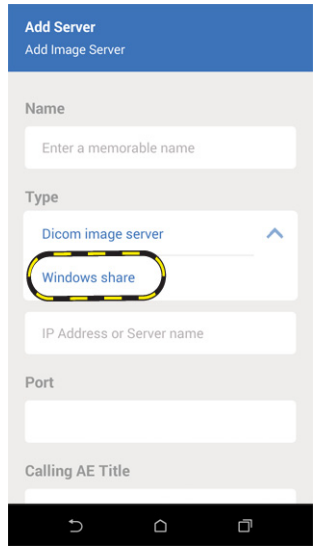


Figure 5-26. Windows share

2. Press **Add server**.

NOTE: All the required fields need to be entered.

3. Press **Verify**.

   A Verify OK message displays.

4. Create a shared folder on the PC and provide the credentials and domain name.
5. Provide access to users who need access to the shared folder.

NOTE: Windows Share can also be added as a favorite and can be deleted as a favorite.

NOTE: Share option is enabled only when any one of the fields in the patient details page is entered. Only images and videos are exported to the PC with the patient information anonymized.

Share images

1. Press **Menu** on the scan screen.
2. Press **Exams** to be exported.
3. Press **Upload Selected**.
4. Select the created Windows Share destination.
   The exported folder is as as shown in the Figure 5-27 below.

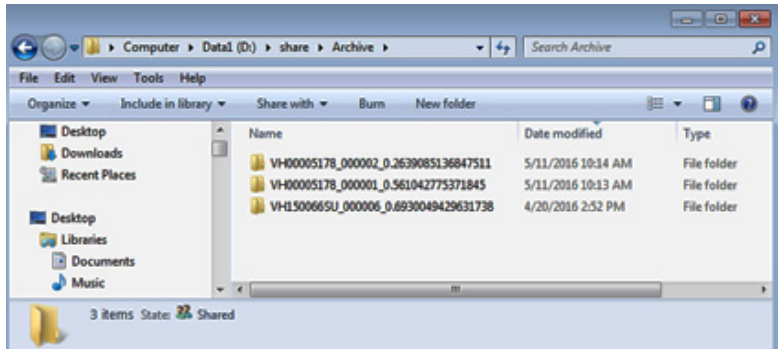


Figure 5-27. Exported image folder

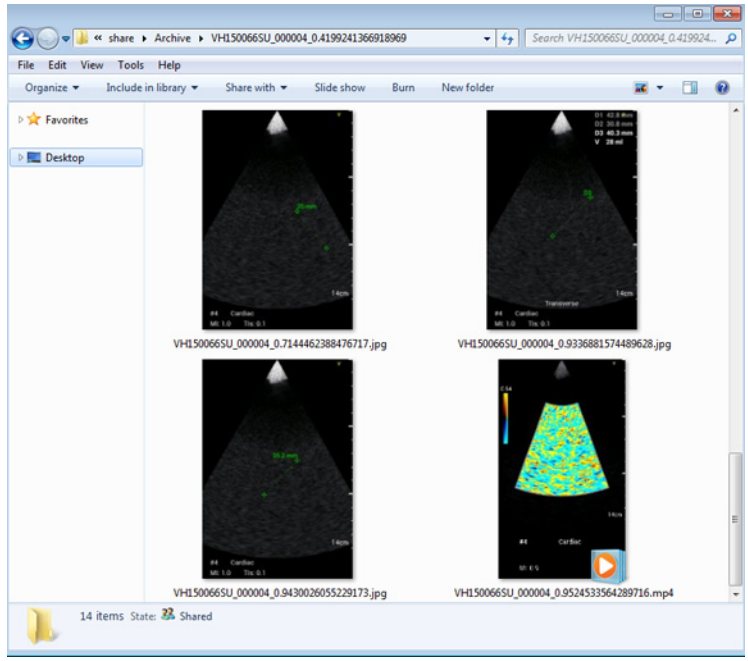


Figure 5-28. Images inside the exam folder

Share images (continued)

5. If the exported image does not get transferred to the PC or if the transfer fails, a red icon appears next to the image.

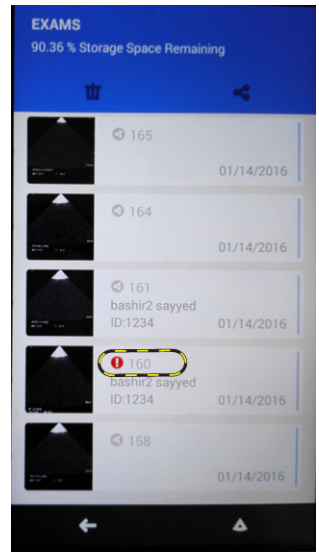


Figure 5-29. Transfer failed

Device Status

To monitor/control DICOM and Windows share jobs, press **Settings** -> **Device Status**.

The exam screen displays the job status, which range from:

- in progress
- success
- failed
- not started

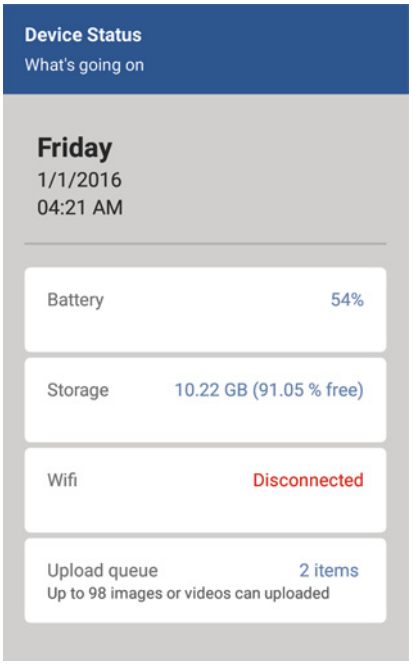


Figure 5-30. Device Status

DICOM

NOTE: This feature is available with the DICOM configuration.

Overview

Vscan Extend supports the following DICOM functionality:

- Verify. See ‘Configure Worklist Server’ on *page 4-5 for more information.*
- Modality Worklist
- Store

DICOM users can use:

1. DICOM Modality Worklist: Retrieve patient information from DICOM modality worklist broker
2. Add patient identifying information to exam.
   - manually
   - selecting from modality worklist
3. DICOM Store: Export DICOM images from Vscan Extend to the DICOM image server.

DICOM modality worklist server

To configure the DICOM modality worklist server, See ‘Configure Worklist Server’ on *page 4-5 for more information.*

DICOM Modality Worklist: Retrieve patient information from DICOM Modality Worklist broker

Vscan Extend can download and refresh a DICOM modality worklist. An exam can be linked to an existing patient pulled from the worklist, prior to exporting to the DICOM image server.

NOTE: It is not necessary to refresh the modality worklist for each exam.

NOTE: When data is accessed for the first time, the device prompts for a 'PIN'; enter the pin for security purposes.

1. Press **Menu** - > **Worklist**.

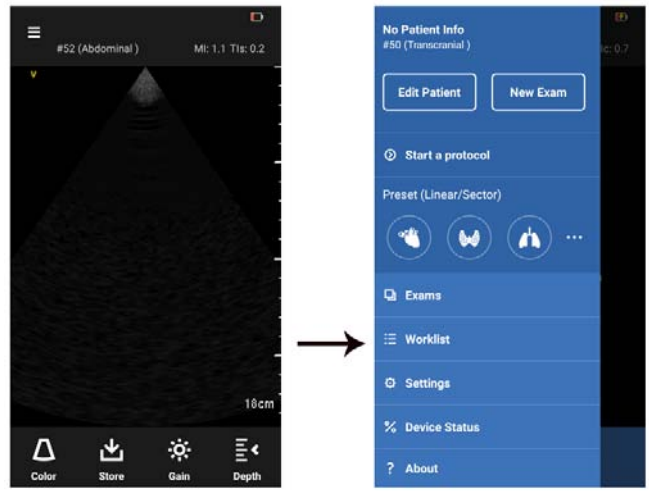


Figure 5-31. Worklist

DICOM Modality Worklist: Retrieve patient information from DICOM Modality Worklist broker (continued)

2. Press **Refresh** to download Worklist entries.

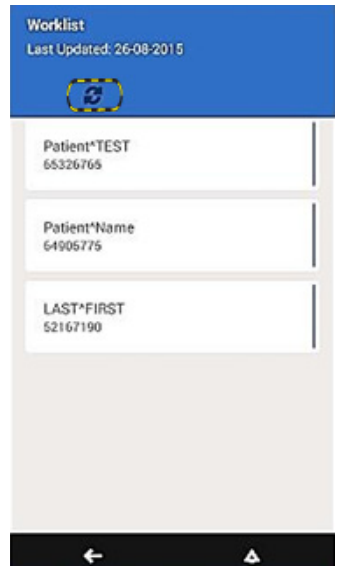


Figure 5-32. Refresh Worklist

NOTE: It is not be possible to change the following DICOM attributes received from worklist: Patient Name, Patient ID and Accession Number.

DICOM Store: exporting DICOM images from Vscan Extend to DICOM image server

At the end of an exam, ensure the Patient ID is linked to the exam. This is required before exporting images or videos. See ‘Patient examination’ on *page 5-7 for more information.*

1. Press **Menu** -> **Exams**

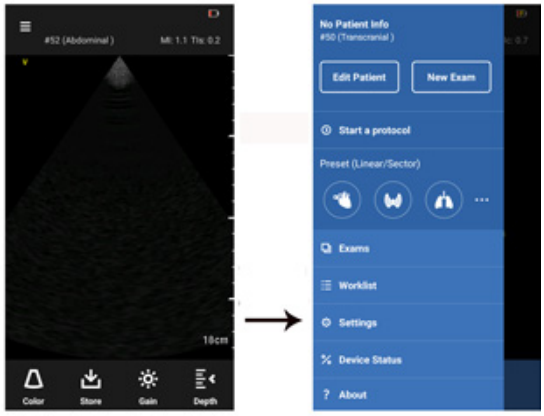


Figure 5-33. Exams

2. Press the **Export** icon.

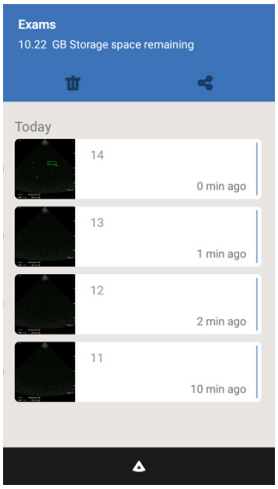


Figure 5-34. Export

NOTE: Individual images from an exam or an entire exam can be selected for export.

NOTE: At least one of the required fields in patient details need to be filled in before export is enabled.

DICOM Store: exporting DICOM images from Vscan Extend to DICOM image server (continued)

3. If more than one storage destination is configured, select the desired destination.

Figure 5-35. Choose destination

4. Press **Upload Selected** to export the exam.

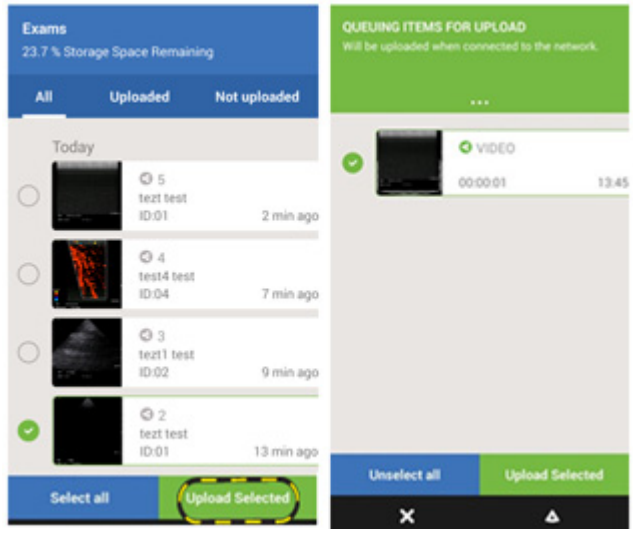


Figure 5-36. Upload selected exam

The selected exam(s) are exported to the DICOM server.

DICOM Store: exporting DICOM images from Vscan Extend to DICOM image server (continued)

5. A green icon indicates a successful export.

   A gray icon indicates the export was initiated and is pending upload.

   If an exported image does not successfully transfer to the DICOM server, a red icon appears next to the image.

   If the user did not attempt to export an image, no icon displays next to the image.

NOTE: To refresh the screen to see the current status, exit the page and return to the same page.

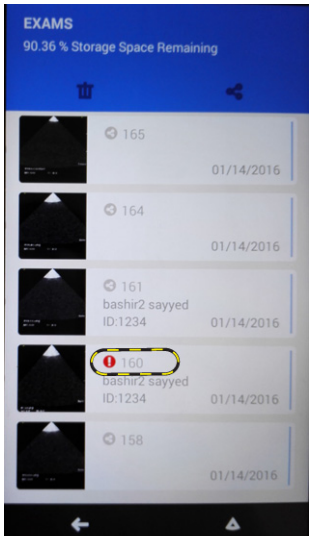


Figure 5-37. Transfer failed

All still images can be sent to the DICOM image server. Videos may be sent to the DICOM image server only if “Enable MultiFrame DICOM” is selected in the DICOM server configuration.

Up to 100 images can be exported at one time.

The multiframe video is limited to 4 seconds.

NOTE: If the export is unsuccessful, it takes about 20 minutes until a failure message appears as the device attempts to resend the images/videos.

Backup

It is highly recommended to backup patient data on a microSD card, at regular intervals, to avoid data loss.

The microSD card inside the device captures the error log files.

WARNING

It is important to retain these error logs. It is also recommended to perform a backup of these logs for specified dates. GE is not responsible for loss data of these logs.

Backup MUST be performed before sending the system to the repair depot as the data is wiped from the internal memory and cannot be retrieved.

NOTE: The microSD card backup requires a length of time to process, the time being dependent on the number of images/videos requiring backup. For example, 1000+ videos in 50 to 60 exams takes approximately 14 minutes to back up to the microSD card.

To backup patient data:

1. Power OFF the Vscan Extend.
2. Remove the Battery. See ‘Inserting/removing the battery’ on *page 3-20 for more information.* Remove the microSD card containing the log files from the device and insert a blank microSD card.
3. Remove the microSD card containing the log files from the device and insert a blank microSD card. See Figure 6-3 *on page 6-12* to insert the SD card.
4. Press **Menu** -> **Settings** -> **Backup**.

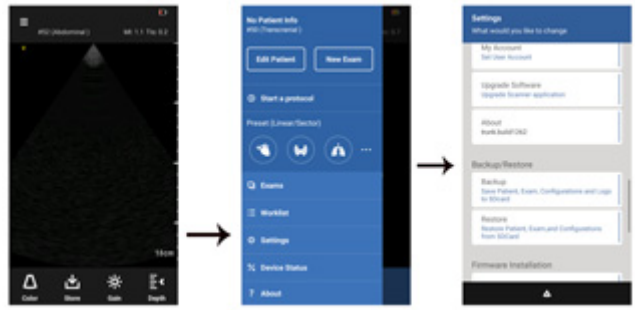


Figure 5-38. Backup

Backup (continued)

5. A pop-up displays.

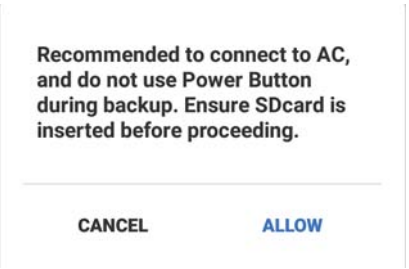


Figure 5-39. Backup data message

Press **Allow** to initiate backup OR **Cancel** to stop the backup process.

6. If the backup process is successful, the patient, exam, logs, and configuration data are backed up on the microSD card. The following message displays.

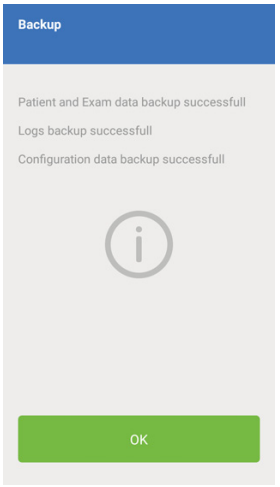


Figure 5-40. Backup successful

Backup (continued)

If the backup process is unsuccessful, a failed message displays.

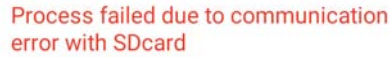


Figure 5-41. Backup failed

NOTE: *If the available memory on the microSD card is less than 50% when initiating backup, the process fails.*

Retry backup. If still unsuccessful, insert a new microSD card and try again.

7. After backup is complete, power OFF the Vscan Extend. Remove the battery. Remove the backup microSD card and store in a safe place.
8. Insert the original microSD card, containing the error logs, into the device. Power ON the Vscan Extend.

Restore

CAUTION

The restore procedure overwrites the existing data on the Vscan Extend.

When restoring previously-backed up patient data, you must first backup the current patient data as the restore procedure overwrites the existing data. See ‘Backup’ on *page 5-42 for more information.*

Make sure to insert the correct microSD card.

NOTE: The restore operation does not restore backed up logs.

1. Power OFF the Vscan Extend.
2. Remove the Battery. See ‘Inserting/removing the battery’ on *page 3-20 for more information.* Remove the microSD card containing the log files from the device and insert a blank microSD card.
3. Remove the microSD card containing the log files from the device and insert the microSD card with the backed up data. See Figure 6-3 *on page 6-12* to insert the SD card.
4. Press **Menu** -> **Settings** -> **Restore**.

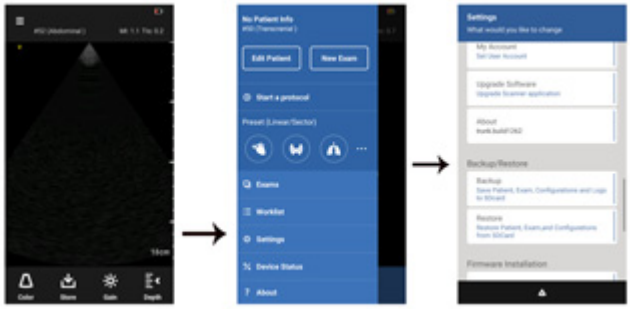


Figure 5-42. Restore

Restore (continued)

5. A pop-up displays.

Figure 5-43. Restore Confirmation

Press **Allow** to initiate restore OR **Cancel** to stop the restore process.

6. If the restore procedure is successful, the patient, exam, and configuration data are restored to the device.

   If the restore procedure fails, a pop-up displays.

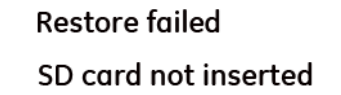


Figure 5-44. Restore failed

If the microSD card does not contain any patient details to restore, a pop-up displays. The system automatically shuts down.

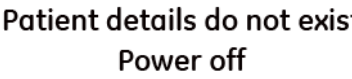


Figure 5-45. Power off

7. After restore is complete, power OFF the Vscan Extend. Remove the battery. Remove the backup microSD card and store in a safe place. The data is still retained on the microSD card.
8. Insert the original microSD card, containing the error logs, into the device. Power on the Vscan Extend.

Using Vscan Extend Apps

Overview

There are four Apps avaiable on the Vscan Extend:

- Bladder Volume
- Lung Protocol
- Tricefy Uplink

Bladder Volume

The Bladder Volume App calculates the bladder volume using 3 distance measurements from two orthogonal images (transverse and sagittal).

Two distances are taken from the transverse image and one distance from the sagittal image, at the widest points, to calculate the bladder volume.

Installing the Bladder Volume application

1. Press **Menu** -> **Settings** -> **GE Marketplace**.

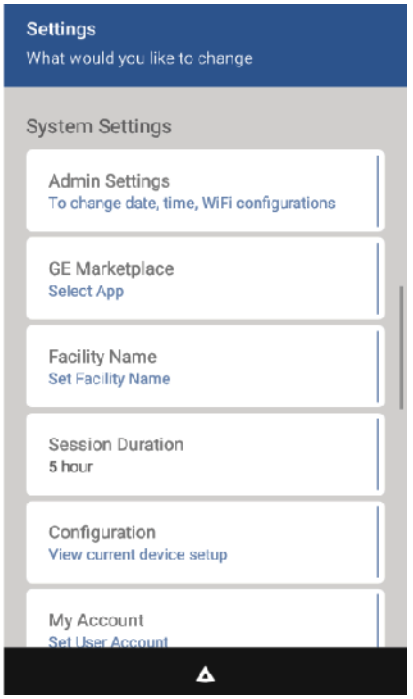


Figure 5-46. GE Marketplace

   A list of available apps displays.
2. Press **Bladder Volume App** to view details.
3. Press **Install**. See ‘Installing Vscan Apps’ on *page 4-32 for more information.*

   The Bladder app installs.

Bladder Volume settings

1. Press **App Settings** from the Settings menu. A pop-up displays.

Figure 5-47. Bladder Volume app settings

2. Press on the desired formula.

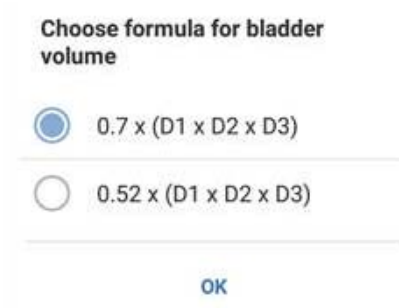


Figure 5-48. Bladder volume formula

- [0.7 x (D1 x D2 x D3)]
- [0.52 x (D1 x D2 x D3)]

Using Bladder Volume

To use the bladder app, the following are prerequisites:

- Install the app using GE Marketplace.
- Phased array probe is active.
- Live image is frozen.

The Bladder Volume App runs an algorithm on the currently displayed image frame, finding the widest points on the bladder contour and placing the measurement calipers at these widest points.

1. On the scanned transverse image, press to **Freeze**.

   The Bladder Volume App icon displays at the bottom of the screen.

Figure 5-49. Bladder App icon

2. Scroll to select a suitable frame.

Using Bladder Volume (continued)

3. Press the **Bladder** icon to start the bladder measurement.

   The measurement cursors appear to perform the measurement.

   The widest points (D1 and D2) in a transverse image are perpendicular to each other.

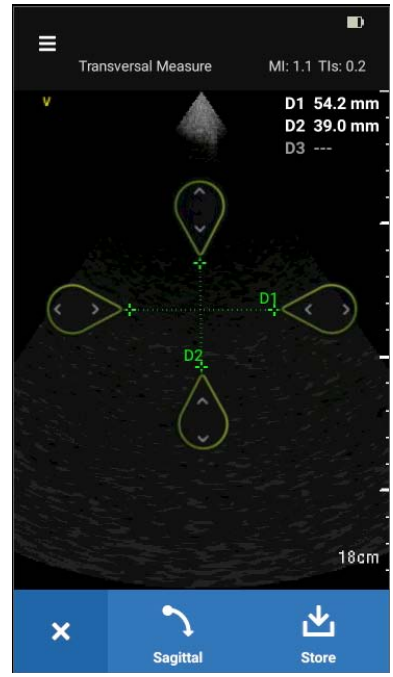


Figure 5-50. Transverse

1. D1 - Longitudinal maximum length
2. D2 - AP diameter

NOTE: The Transverse Measure screen is displayed by default.

Using Bladder Volume (continued)

4. Adjust the measurement calipers manually, if required.
5. Press **Store**. The screen enters sagittal capture.
6. Press to **Freeze**. Scroll to select the best frame.
7. Press **Measure Frame**.

Figure 5-51. Measure Frame

The image, along with the measurement values and volume, displays.

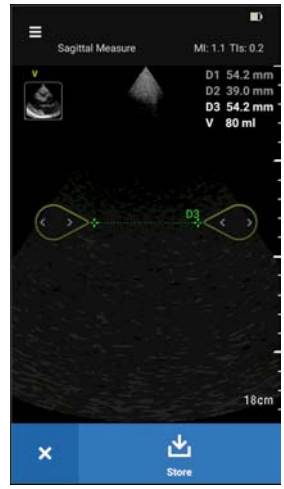


Figure 5-52. Measurement values

8. Press **Store**.

Using Bladder Volume (continued)

NOTE: The image is saved with the measurement values and volume embedded on it.

View the saved images from the gallery.

NOTE: The Bladder app cannot be used on stored images in the gallery.

*NOTE: If a sagittal image is acquired first and the step needs to be changed to sagittal, press the **Sagittal** toggle button.*

Figure 5-53. Toggle button

Exiting Bladder Volume

1. Press **Close** to exit the Bladder Volume App.

Figure 5-54. Exit Bladder Volume App

1. Close
2. Quit

A pop-up displays for confirmation.

2. Press **Quit** to exit the Bladder Volume app.
3. Press **Cancel** to continue using the Bladder Volume app.

Lung Protocol

Lung Protocol application guides you through a step by step lung ultrasound exam.

The application performs the following functions:

1. Automatic lung preset selection
2. Guides or helps assessing the stored images
3. Helps to calculate a total lung score
4. Generates a simple report at the end of the exam

Installing the Lung Protocol application

1. Press **Menu** -> **Settings** -> **GE Marketplace**.
   A list of available apps displays.
2. Press **Lung Protocol** to view details.
3. Press **Install**.
   The Lung Protocol app installs.

Lung Protocol settings

1. Press **Start a protocol** on the Menu screen.
2. Press the **Lung Protocols Settings** icon on the Protocols screen to choose the desired settings.

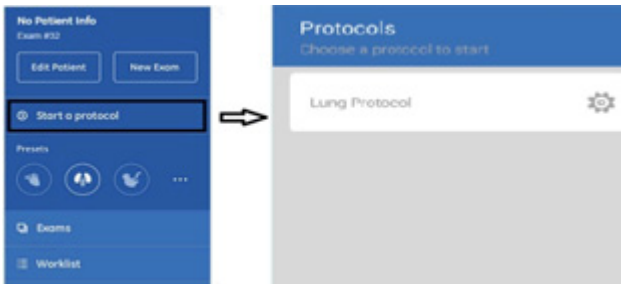


Figure 5-55. Start a protocol

Lung Protocol settings (continued)

The Settings screen displays.

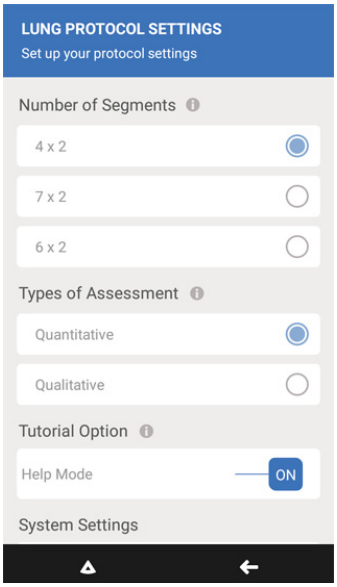


Figure 5-56. Settings

The Settings menu has the following functions:

- choose the number of segments to be scanned
- choose the type of assessment
- enter the Help mode.

Number of segments

Three different configurations are available for the number of segments. Press on the radio button to choose any one of the following:

- 4 x 2
- 7 x 2
- 6 x 2

Lung Protocol settings (continued)

Types of Assessment

Two types of assessment are available. Press on the radio button to choose the desired type of assessment.

- Quantitative
- Qualitative.

Help mode

Help mode is required to guide the user through the Lung Protocol.

Swipe from left to right to turn ON the Help mode on the Lung Protocol Settings menu. See Figure 5-56 *on page 5-55*.

Help mode assists in the following:

- Skip - when you enter the next segment, swipe from right to left to skip the current segment.
- Next - swipe from right to left to enter the next segment.
- When multiple images are scored in the same segment, a pop-up appears:

  “Only latest saved image will be available for review”.

Lung Protocol settings (continued)

3. Press the **Back** arrow to return to the Protocols screen.

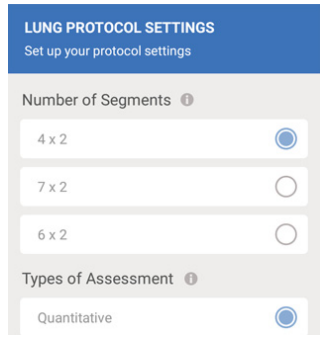


Figure 5-57. Back arrow

4. Press **Lung Protocol** to start using the lung protocol.

NOTE: The settings are automatically saved. If the settings need to be changed, stop the current protocol on the menu screen and modify the current settings on the Settings menu.

Using Lung Protocol

1. Press **Menu**.
2. Press **Start a protocol**.
3. Press **Lung Protocol**.

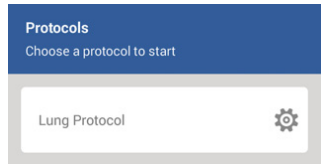


Figure 5-58. Lung protocol

Using Lung Protocol (continued)

4. The lung linear preset is automatically applied. The lung preset is added as favorite in the Preset menu.

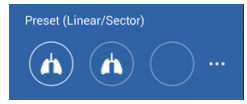


Figure 5-59. Preset menu

The scan screen displays.

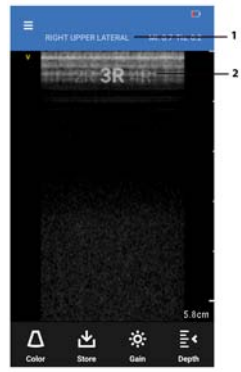


Figure 5-60. Lung protocol scan screen

1. Displays current segment name
2. Displays previous, current and next segments

5. Press **Store** to save the images or Cine loops for the current segment. The saved image icon appears at the upper left corner of the scan screen.
6. Swipe from right to left to move to the next segment, for example 1R to 2R, where 1R is the first segment of the right lung. Similarly, 1L is the first segment of the left lung.

   OR

   Swipe from left to right to move to the previous segment.

   The number of segments that can be scored depends on the number of segments selected on the Settings menu.

NOTE: The user is able to store multiple images per segment. Only the latest saved image, for a particular segment, is available for review. However, the user can view all the images in the Gallery under the current exam.

NOTE: The appearance of the 'Gallery' icon indicates if an image and/or video is stored in the segment.

Review and score images

After all the images are stored for all the segments, a pop-up displays:

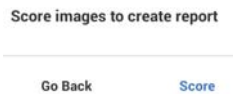


Figure 5-61. Score images

Press **Score** to score the images. Choose the score for each segment.

OR

Press **Go Back** to acquire more images.

Depending on the type of assessment chosen on the Lung Protocol Settings menu, either Quantitative or Qualitative assessment scores are displayed. Both the screens are shown below.

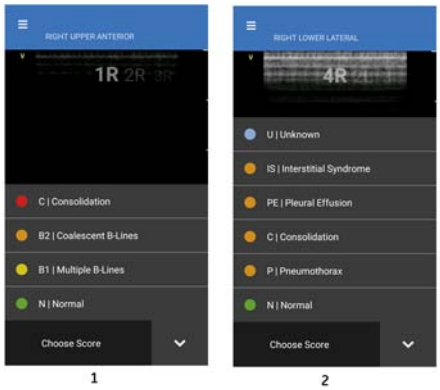


Figure 5-62. Quantitative and Qualitative Scores

1. Quantitative
2. Qualitative

NOTE: It is not mandatory to score all images.

Lung Protocol report

After reviewing and scoring the last segment, swipe from right to left to enter the report screen.

The report shows the current patient name, patient ID, and total lung score.

Figure 5-63. Quantitative report

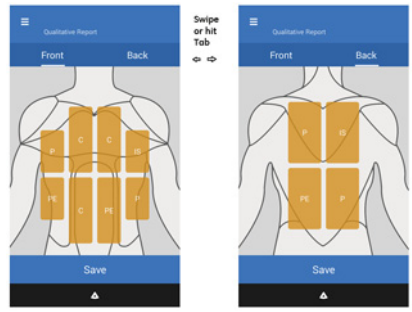


Figure 5-64. Qualitative report

Press **Save** to save the report. The report is stored with all the images and videos from the gallery.

Press **Exams** on the Menu screen to view the images and the report.

Exit Lung Protocol

1. Press **Menu** on the Lung protocol screen.
2. Press **Stop current protocol**. A pop-up displays.

Figure 5-65. Stop current protocol

3. Press **Exit** to stop the protocol.

Tricefy

Tricefy Uplink helps to upload exams to the cloud.

1. Press **Menu** -> **Settings** -> **GE Marketplace**
2. Press **Install**.

   The Tricefy Uplink app installs.

Using Tricefy

1. Press **Menu** -> **Settings** -> **Server Settings**
2. Press **Tricey** under Image Server

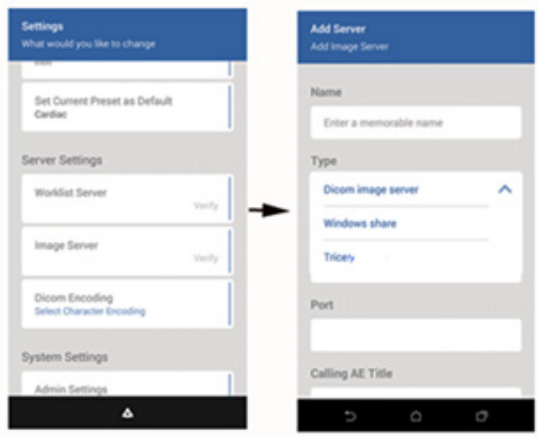


Figure 5-66. Tricefy

Using Tricefy (continued)

3. Enter your email address to register for Tricefy and press Activate. OR if you have a Tricefy login, enter that address and press Login.

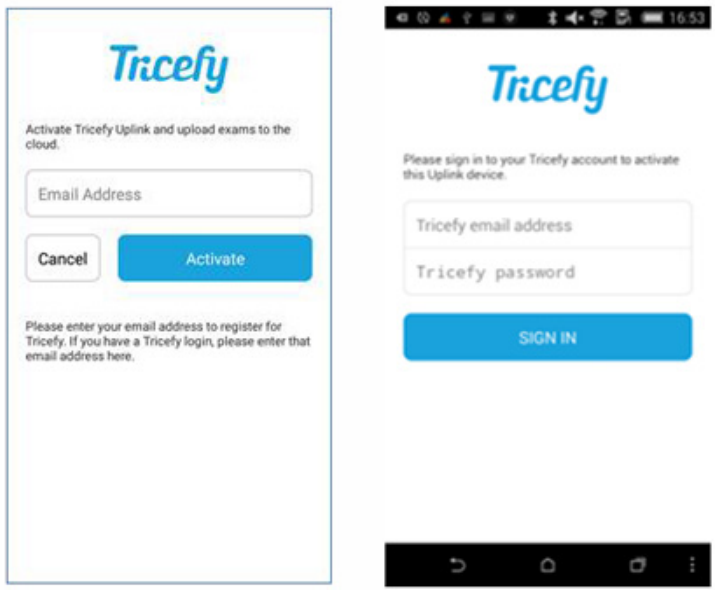


Figure 5-67. Tricefy Activate or login

4. Press **Add Server** and **Verify**.

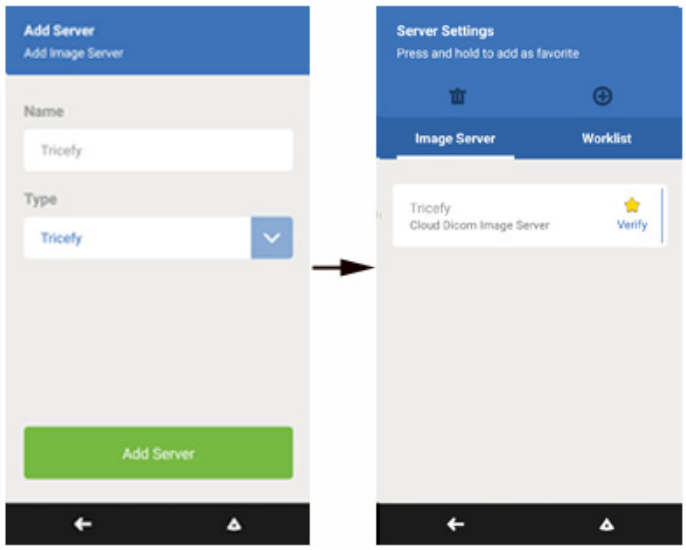


Figure 5-68. Add Ticefy and Verify

Using Tricefy (continued)

5. Press **Menu** -> **Export** icon.

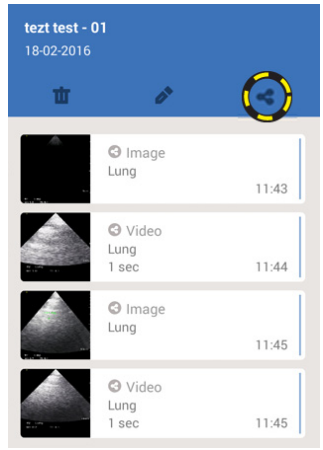


Figure 5-69. Export

6. Press **Upload Selected** to export the exam.

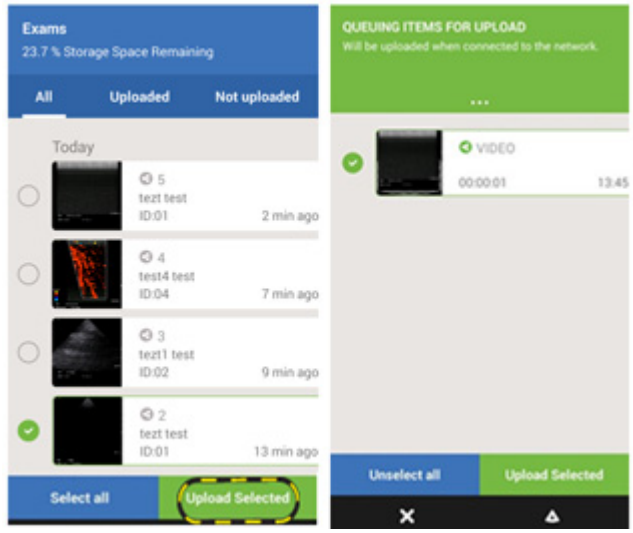


Figure 5-70. Upload selected exam

The selected exam(s) are exported to the Tricefy server.

Chapter 6

Vscan Extend Maintenance

Contents

System care and maintenance

Overview

The user must ensure that safety inspections are performed at least every 12 months according to the requirements of the patient safety standard EN/ES/IEC 60601-1 and its national deviations or according to the requirements of the IEC62353 standard, medical electrical equipment – recurrent test and test after repair of medical electrical equipment.

Only trained persons should perform the safety inspections.

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

The expected service life of the Vscan Extend is 5 years.

To ensure that the Vscan Extend 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 Extend

If any defects or damages are found on the control unit, the probe or its cable, DO NOT use the Vscan Extend. Contact GE service.

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

- Connectors on cables, for any mechanical defects
- Entire length of electrical cables, for cuts or abrasions
- Equipment for cracks, loose or missing hardware.

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

Before each use

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

Cleaning and disinfection

Cleaning the device

Make sure the device is disconnected from the AC/DC adapter before cleaning.

1. Power off the Vscan Extend.
2. Moisten a soft, non-abrasive cloth with a mild, general purpose, non-abrasive soap and water solution.
3. Wipe the Vscan Extend.
4. Wipe dry with a soft towel.

Do not spray the soap and water solution directly onto the Vscan Extend.

Reprocessing recommendation (Frequency)

After Each Use

- Inspect the transdducer (see ‘Inspecting the Vscan Extend’ on *page 6-3*)
- Clean the transducer (see ‘Disinfecting the probe’ on *page 6-9*).
- If required, clean the device and the display (see ‘Disinfecting the device’ on *page 6-7*).
- If required, disinfect the transducer (see ‘Disinfecting the probe’ on *page 6-9*).

Ensure that the main unit and the transducer are properly cleaned after each use and before storage in the case.

If any defects or damages are found on the probe or its cable, DO NOT use the Vscan Extend. Contact GE service.

Special Label Designations, Warnings and Precautions

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

Do not soak or saturate probes with solutions containing bleach, ammonium chloride compounds or hydrogen peroxide.

Special accessories

Special accessories are not applicable.

Point-of-Use Processing

No point-of-use processing is required prior to cleaning.

Cleaning instructions

CAUTION

Avoid any liquid making contact with the internal device components, including the micro USB connector and battery terminal contacts, which are not designed for making contact with liquids.

Cleaning the probe

1. Remove the gel by wiping the probe lens with a soft cloth.
2. Wipe the probe and cable with a soft cloth moistened with a warm soap and water solution (<80 ^{0}F/27 ^{0}C).
3. Wipe the probe and cable with a soft cloth moistened with clean water (<80 ^{0}F/27 ^{0}C) until all soap is removed.
4. Wipe dry with a soft towel.

Cleaning the USB door

1. Open the USB door.
2. Wipe the inside of the door with a soft cloth moistened with a mild, general purpose, non-abrasive soap and water solution.
3. Wipe dry with a soft cloth.

Figure 6-1. Open the USB door

Method of cleaning: Manual

CAUTION

DO NOT use brush, abrasives, sharp tools or any other methods that may damage the inside or surface of the device.

DO NOT scratch or press any part of the Vscan Extend with a sharp object, such as pencils or pens, as this may result in damage to Vscan Extend.

Disinfecting the device

After cleaning, the device may be wiped with a tissue sprayed with a recommended germicide.

Recommended germicides

In order to provide users with options in choosing a germicide, GE routinely reviews new medical germicides for compatibility with the Vscan Extend and its probe. Although a necessary step in protecting patients and employees from disease transmission, liquid chemical germicides must also be selected to minimize potential damage to the probe.

Table 6-1: Germicides

	
PI-Spray	Pharmaceutical Innovations
PI-Spray II	Pharmaceutical Innovations
	
CaviWipes	Metrex
Cleanisept wipes	Dr. Schumacher GmbH
Septiwipes	Dr. Schumacher GmbH
Sani-Cloth HB	PDI

NOTE: Refer to the cleaning agent labeling for preparation and use instructions.


WARNING

Use only compatible germicides. In addition, refer to the local / national regulations.

NOTE: Follow the manufacturer's instructions for storage, use and disposal of the disinfection solution.

NOTE: No special accessories are required for disinfection.

Cleaning agents

Follow the instructions described below while using CaviWipes and Sani-Cloth HB.

CaviWipes

1. Use one CaviWipes towelette to completely preclean the surface of the device, probe and cable.
2. Ensure that no debris and bioburden are left behind.
3. Discard used towelette.
4. Use a second CaviWipes towelette to thoroughly wet the surface in order to disinfect the precleaned surface. Repeated use of the product may be required to ensure that the surface remains visibly wet for 3 minutes at room temperature (20 degrees).

Sani-Cloth HB

1. Use one Sani-Cloth HB towelette to completely preclean the surface of the device, probe and cable
2. Ensure that no debris and bioburden are left behind.
3. Discard used towelette.
4. Use a second Sani-Cloth HB towelette to thoroughly wet the surface in order to disinfect the precleaned surface. Repeated use of the product may be required to ensure that the surface remains visibly wet for 10 minutes at room temperature (20 degrees).

Disinfecting the probe

After cleaning, the probe and cable may be wiped with a tissue sprayed with a recommended germicide.

In order to provide users with options in choosing a germicide, GE routinely reviews new medical germicides for compatibility with the materials used in the transducer housing, cable and lens. Although a necessary step in protecting patients and employees from disease transmission, liquid chemical germicides must also be selected to minimize potential damage to the probe.

Refer to the internet link below for the latest list of compatible cleaning solutions and disinfectants:

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

WARNING

Never use any cleaning solutions and disinfectants other than the ones mentioned in the Ultrasound Probes web page.

Disinfecting the probe (continued)

WARNING

Do not immerse the probe in any liquid beyond the level specified (see Figure 6-3).

The probe should not be exposed to the germicide longer than specified in order to achieve the desired effect.

Rinse the part of the probe which is in contact with the germicide according to the germicide manufacturer's instructions.

Wipe dry with a soft towel.

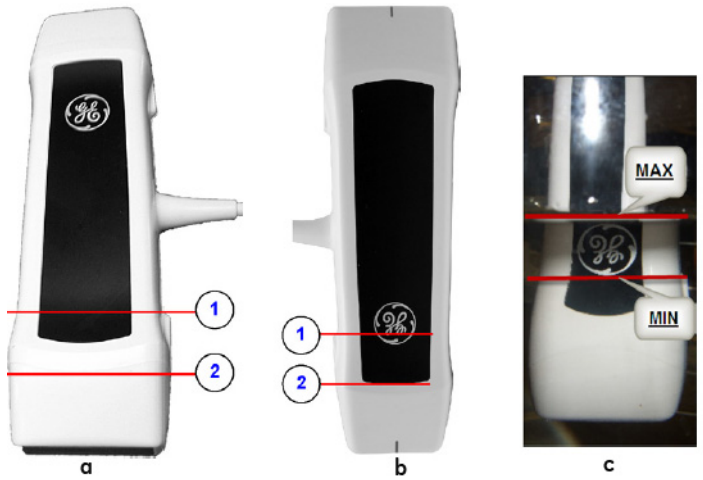


Figure 6-2. Probe immersion level

1. Maximum saline level
2. Minimum saline level

a. Linear array transducer
b. Phased array transducer
c. G3S probe

WARNING

Use additional precautions (e.g. gloves and gown) when decontaminating an infected probe.

The probe should not be exposed to the germicide longer than specified in order to achieve the desired effect.

Disinfecting the probe (continued)

WARNING

CREUTZFELDT-JAKOB DISEASE

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

Biological Hazard

Rinsing and Lubricating Agents

No rinsing and lubricating agents are required.

Upgrade software

Scanner software

You can upgrade the currently installed software to a software version equal to or greater than your current version.

NOTE: Before proceeding with the upgrade, ensure that the battery is fully charged and the charger is plugged in.

To perform a software upgrade:

1. Remove the battery. See ‘To remove the battery’ on *page 3-20 for more information.*
2. Remove the microSD card that captures the error log files from the device (lightly push the SD card holder and pull out the SD card).
3. Insert the application software microSD card.

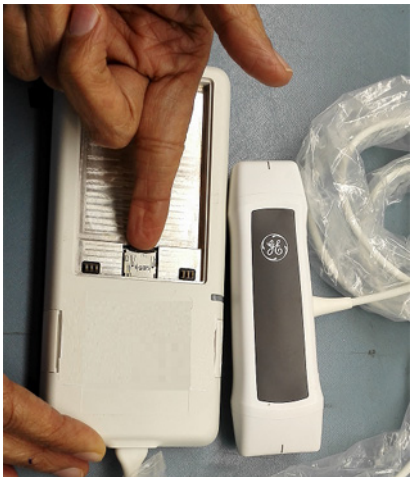


Figure 6-3. Insert SDcard

Scanner software (continued)

4. Press **Settings** on the Menu screen.
5. Press **System Settings**.
6. Press **Upgrade Software**.

   The following message displays:

   Current software version is:

   New software version is:
7. Press **OK** to proceed with the upgrade.

NOTE: You cannot upgrade the Scanner software to a software version lower than the currently installed software. If you try to do so, a message displays: "Not allowed to proceed".

The Vscan Extend may have security patches which need an update.


WARNING

GE is not responsible for any virus affecting the Vscan Extend device which may result in data loss.

Troubleshooting

Vscan Extend troubleshooting

Table 6-2: Troubleshooting

Problem	Possible cause	Solution
Vscan Extend has no power.	Battery not inserted.	Insert battery (see page 3-20)
	Battery not charged.	Charge the battery (see page 3-18)
	Battery defect or end of life.	Contact GE Service (see page 1-10)
	Broken battery connection.	Contact GE Service (see page 1-10)
Vscan Extend is not charging.	Battery not inserted.	Insert battery (see page 3-20)
	Battery defect or end of life.	Contact GE Service (see page 1-10)
	Broken battery connection.	Contact GE Service (see page 1-10)
	Defective AC adapter or charger.	Contact GE Service (see page 1-10)
	Mains power is down.	
	Temperature is outside the specified limits.	Ensure the ambient temperature is within the specified limits (see ‘Environmental requirements for the device’ on *page 3-3*)
Display screen is blank when the device is powered on.	Connection broken during software loading.	Contact GE Service (see page 1-10)
Parts of the image is missing when scanning.	Channels are missing.	Contact GE Service (see page 1-10)
Noise when moving the probe cable.	Defective probe cable.	Contact GE Service (see page 1-10)
No image displayed when scanning.	Defective probe.	Contact GE Service (see page 1-10)

Table 6-2: Troubleshooting (Continued)

Problem	Possible cause	Solution
Vscan Extend display is flashing while scanning.	Automatic reduction of the frame rate due to increase of the operating temperature after extended scanning.	Restart the Vscan Extend to restore the normal frame rate. *NOTE: To maintain the operating temperature of the Vscan Extend at an optimal functional level, it is recommended to hold the Vscan Extend so there is good contact between the device and the hand. This will also ensure a longer scanning time with maximum frame rate*
Vscan Extend is not entering the scan screen and stays on the GE start-up screen.	Battery may not have sufficient charge.	Charge the Vscan Extend battery for at least 60 minutes.

System Warning Messages

System errors

- System overheats

System is overheating and will shut down.

If the problem persists, contact GE service.

- Probe overheats

Probe is overheating and the system will shut down.

If the problem persists, contact GE service.

- Battery low

Battery is critically low or below 15%.

Plug in charger.

- System voltage critical

System voltage is at critical level and will shut down.

If the problem persists, contact GE service.

System Warning Messages (continued)

- Connectivity error

Unable to connect.

Check Wi-Fi connection.

- Acquisition level

Check battery and recharge the system.

If the problem persists, contact GE service.

System messages

- Perform system backup

System internal memory usage is 50 to 60%.

Perform system backup.

- Scanning not allowed

Scanning is not allowed when AC is connected.

Scanning is not allowed when connected to a PC.

Chapter 7

Appendix

Contents:

Specifications

Dimension and weight

System dimension and weight

- Main unit (approximately): 170 x 78 x 21 mm
- Weight (Main unit with Sector probe, without battery): 365g
- Weight (Main unit with Dual probe, without battery): 400g
- Battery Weight: 65g

Probe dimension and weight

- Dimension (L x B x H) Sector Probe:129 x 32 x 25 mm
- Dimension (L x B x H) Dual Probe: 129 x 39 x 28 mm
- Sector probe Weight (including cable): 85g
- Dual probe Weight (including cable): 120g

Phased array transducer for deep scanning

- Field-of-view for black and white imaging: up to 70 degrees with maximum depth of 24 cm
- The color flow sector represents blood flow within an angle of 40 degrees.
- Broad-bandwidth sector probe: from 1.7 to 3.8 MHz
- Footprint: 13 x 19 mm

Linear transducer for shallow scanning

- Field-of-view for black and white imaging: aperture width of 2.9 cm with maximum depth of 8 cm
- The color flow sector represents blood flow over image with full aperture and entire depth.
- Broad-bandwidth linear probe: from 3.3 to 8.0 MHz
- Footprint: 9 x 35 mm

Acoustic Output Reporting Tables

Definitions, symbols and abbreviations

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

Table 7-1: Definitions, symbols and abbreviations

IEC	FDA	Meaning—IEC 60601-2-37 / FDA & NEMA UD2, UD3
a	a	*Acoustic Attenuation Coefficient* / Derating factor (usually 0.3 dB/cm-MHz)
A_{aprt}	A_{aprt}	*-12db Output Beam Area* / Active aperture area
C_{MI}		*Normalizing Coefficient*
D_{eq}	d_{eq}	*Equivalent Aperture Diameter* / (same)
d_{-6}	d_{-6}	*Pulse Beam Width* / Beam diameter at –6 dB
d_{eq}	D_{eq}	*Equivalent Beam Diameter*
awf	f_c	*Acoustic Working Frequency* / Center frequency
I_{pa}	I_{pa}	*Pulse-Average Intensity*
$I_{pa,a}$	$I_{pa.3}$	*Attenuated Pulse-Average Intensity*
I_{pi}	PII	*Pulse-Intensity Integral*
$I_{pi,a}$	$PII_{.3}$	*Attenuated Pulse-Intensity Integral*
$I_{ta}(z)$	I_{TA}	*Temporal-Average Intensity*
$I_{ta,a}(z)$	$I_{TA.3}(Z)$	*Attenuated Temporal-Average Intensity* / (at depth z)
$I_{zpta}(z)$	$I_{SPTA}(Z)$	*Spatial-Peak Temporal-Average Intensity*
$I_{zpta,a}(z)$	$I_{SPTA.3}(Z)$	*Attenuated Spatial-Peak Temporal-Average Intensity*
MI	MI	*Mechanical Index*
P	W_o	*Output Power* / Time average acoustic power at the source
P_a	$W_{.3}(Z)$	*Attenuated Output Power* / Time average acoustic power derated to depth z

Table 7-1: Definitions, symbols and abbreviations (Continued)

IEC	FDA	Meaning—IEC 60601-2-37 / FDA & NEMA UD2, UD3
P_1	W_{o1}	*Bounded Output Power* / Power emitted from the central 1cm of aperture
p_i	PII	*Pulse Pressure Squared Integral* / Pulse intensity integral
p_r	p_r	*Peak-Rarefactional Acoustic Pressure* / (same)
p_{ra}	$p_{r.3}$	*Attenuated Peak-Rarefactional Acoustic Pressure* / (same)
prr	PRF	*Pulse Repetition Rate* / Pulse repetition frequency
TI	TI	*Thermal Index* / (same)
TIB	TIB	*Bone Thermal Index* / (same)
TIC	TIC	*Cranial-Bone Thermal Index* / (same)
TIS	TIS	*Soft-Tissue Thermal Index* / (same)
t_d	PD	*Pulse Duration* / (same)
X, Y	x_{-12},y_{-12}	*-12 dB Output Beam Dimensions* / (same)
z	Z	*Distance from the Source to a Specified Point* / (same)
z_{bp}	Z_{sp}	*Depth for TIB* / Depth at which the relevant index is maximum
z_{bp}	Z_{bp}	*Break-Point Depth* / (same)
z_s	Z_{sp}	*Depth for TIS* / Depth at which the relevant index is maximum

Explanation of Footnotes

The mechanical and thermal indices may be replaced by one of the following footnotes because of the reasons listed:

- a: Display of this index is not required for this operating mode.
- b: This probe is not intended for transcranial or neonatal cephalic uses.

If so, the table entries are replaced by a “#”, meaning: no data are provided for this operating condition since the maximum reported value is not reported for the reason listed.

If neither an index or a footnote is given, this means that the index is irrelevant for this probe/mode combination.

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

Dual Probe

Phased array transducer

Operating Mode: black/white

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			1,47	0,17		0,24		0,64
Index component value				0,17	0,17	0,24	0,24	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1,98					
	P	(mW)		32,7		45,4		36,4
	P_{1x1}	(mW)		20,4		28,4		
	z_s	(cm)			2,2			
	z_b	(cm)					4,1	
	z_{MI}	(cm)	4,3					
	$z_{pii,\alpha}$	(cm)	4,3					
	f_{awf}	(MHz)	1,80	1,71		1,79		1,68
Other Information	prr	(Hz)	1714					
	srr	(Hz)	21,9					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	219,7					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	16,4					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm^2)	28,0					
	p_r at z_{pii}	(MPa)	2,53					
Operating Conditions	Depth (cm)		8	10		8		10
	Width (°)		60	60		60		60
	Application		Ob	Abdo		Ob		Cranial

Figure 7-1. Phased array transducer - black/white

Dual Probe

Phased array transducer

Operating Mode: black/white and color

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			1,40	0,50		0,30		1,79
Index component value				0,50	0,50	0,30	0,30	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1,88					
	P	(mW)		72,3		45,9		102,2
	P_{1x1}	(mW)		45,2		28,7		
	z_s	(cm)			2,2			
	z_b	(cm)					4,0	
	z_{MI}	(cm)	3,9					
	$z_{pii,\alpha}$	(cm)	3,9					
	f_{awf}	(MHz)	1,8	1,71 / 2,4		1,80 / 2,34		1,7/2,4
Other Information	prr	(Hz)	2800					
	srr	(Hz)	12,2					
	n_{pps}		5					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	202					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	6,7					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm^2)	10,9					
	p_r at z_{pii}	(MPa)	2,27					
Operating Conditions	Depth (cm)		6	6		6		24
	Width(°) black and white		60	60		60		60
	ROI center(cm)		5	max		max		max
	Width(°) color		30	30		30		30
	Application		Ob	Cardiac		Ob		Cranial

Figure 7-2. Phased array transducer - black/white and color

Dual Probe

Linear array transducer

Operating Mode: black/white

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			0,93	0,17		-		-
Index component value				0,17	0,17	-	-	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2,28					
	P	(mW)		10,4		-		-
	P_{1x1}	(mW)		7,1		-		
	z_s	(cm)			1,1			
	z_b	(cm)					-	
	z_{MI}	(cm)	1,68					
	$z_{pii,\alpha}$	(cm)	1,68					
	f_{awf}	(MHz)	6,01	4,97		-		-
Other Information	prr	(Hz)	6219					
	srr	(Hz)	43,2					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	279,1					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	12,2					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm^2)	24,5					
	p_r at z_{pii}	(MPa)	3,19					
Operating Conditions	Depth (cm)		4	6,5		-		-
	Width (-)		max	max		-		-
	Application		Lung	Vascular		-		-

Figure 7-3. Linear array transducer - black/white

Dual Probe

Linear array transducer

Operating Mode: black/white and color

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			0,89	0,53		-		-
Index component value				0,51	0,51	-	-	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2,19					
	P	(mW)		24,9		-		-
	P_{1x1}	(mW)		22,2		-		
	z_s	(cm)			1,2			
	z_b	(cm)					-	
	z_{MI}	(cm)	1,78					
	$z_{pii,\alpha}$	(cm)	1,78					
	f_{awf}	(MHz)	5,99	6,09 / 4,98		-		-
Other Information	prr	(Hz)	6219					
	srr	(Hz)	7,2					
	n_{pps}		18					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	267,6					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	0,9					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm^2)	1,9					
	p_r at z_{pii}	(MPa)	3,16					
Operating Conditions	Depth (cm)		4	4		-		-
	Width(-) black and white		Max	Max		-		-
	ROI center(-)		Default	2		-		-
	Width(-) color		60%	50%		-		-
	Application		Lung	Vascular		-		-

Figure 7-4. Linear array transducer - black/white and color

Sector probe

Phased array transducer G3S

Operating Mode: black/white

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			1,43	0,15		0,27		0,56
Index component value				0,15	0,15	0,27	0,27	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1,92					
	P	(mW)		30,1		52,4		31,9
	P_{1x1}	(mW)		18,8		32,7		
	z_s	(cm)			2,2			
	z_b	(cm)					4,4	
	z_{MI}	(cm)	4,3					
	$z_{pii,\alpha}$	(cm)	4,3					
	f_{awf}	(MHz)	1,80	1,70		1,75		1,75
Other Information	prr	(Hz)	1714					
	srr	(Hz)	22					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	215,7					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	16,7					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm^2)	28,6					
	p_r at z_{pii}	(MPa)	2,46					
Operating Conditions	Depth (cm)		8	10		8		10
	Width (°)		60	60		60		60
	Application		Ob	Abdo		Ob		Cranial

Figure 7-5. Phased array transducer - black/white

Sector probe

Phased array transducer G3S

Operating Mode: black/white and color

Index Label			MI	TIS		TIB		TIC
				At Surface	Below surface	At Surface	Below surface	
Maximum: Index Value			1,35	0,45		0,27		1,23
Index component value				0,45	0,45	0,27	0,27	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1,81					
	P	(mW)		61,9		64,4		70,1
	P_{1x1}	(mW)		38,7		40,2		
	z_s	(cm)			2,2			
	z_b	(cm)					4,0	
	z_{MI}	(cm)	3,9					
	$z_{pii,\alpha}$	(cm)	3,9					
	f_{awf}	(MHz)	1,8	1,75 / 2,4		1,80 / 2,36		1,7/2,4
Other Information	prr	(Hz)	2800					
	srr	(Hz)	12,2					
	n_{pps}		5					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	181					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	6,0					
	I_{spta} at z_{pii} or $z_{sii,\alpha}$	(mW/cm^2)	9,7					
	p_r at z_{pii}	(MPa)	2,21					
Operating Conditions	Depth (cm)		6	6		6		24
	Width(°) black and white		60	60		60		60
	ROI center(cm)		5	max		max		max
	Width(°) color		30	30		30		30
	Application		Ob	Cardiac		Ob		Cranial

Figure 7-6. Phased array transduce - black/white and color

Measurement accuracy

Basic Measurements

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 and Doppler 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. The percent accuracy when stated applies to the measurement obtained (not the full scale range). Where the accuracy is stated as a percent with a fixed value, the expected inaccuracy is the greater of the two.

Table 7-2: Measurement accuracy

Measurement	Unit	Useful range	Accuracy	Probe
Distance				
Axial	cm	Full screen	±3% or ±1 mm, whichever is greater	Both probes
Lateral	cm	Full screen	±5% or ±1 mm, whichever is greater	Shallow

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).

Chapter 8

Privacy and Security

Contents

Introduction

Overview

This chapter describes Privacy and Security considerations for the use of the Vscan Extend. It describes the expected intended use, the Privacy and Security capabilities included, and how they are configured and used appropriately.

This chapter assumes that the reader understands the concepts of Privacy and Security. Privacy is the property of protecting the personal private interests of patients. Security protects both system and information from risks to confidentiality, integrity, and availability. Security protects Privacy but also protects more broadly against these risks. Privacy requires security. In Healthcare one must balance privacy, security, and safety. Most of the time there isn't a conflict between these three domains of risk. The healthcare provider organization is encouraged to use risk management procedures to assess and prioritize privacy, security, and safety risks. Through the use of risk management one can determine how to best leverage the capabilities provided in the Vscan Extend Ultrasound product.

How to contact GE

For privacy and security concerns regarding GE products, please see: http://www.ge.com/security

Privacy and Security Environment

The GE Healthcare Vscan Extend Ultrasound product has been designed for an intended use with the following expectations of Privacy and Security protections included in the environment where this product will be used:

1. The system should be connected to a secured network, not open to unintended users.
2. The Vscan Extend should be physically secured in a way that it is not accessible for unintended users.
3. The Vscan Extend supports device PIN-based management.
4. External media (microSD card) containing images, patient data, reports and logs should be secured. When no longer used, the data should be securely erased and/or the media should be securely deleted.
5. The display of the Vscan Extend should be placed in a way limiting the visibility to the user only.

Privacy and Security Capabilities

The GE Healthcare Vscan Extend incorporates a broad assortment of capabilities to enable Privacy and Security. This section describes the capability and use of these Privacy and Security capabilities.

Access Controls

The access control features may be used to help control access to sensitive information. Access control includes user account creation and assigning privileges.

Identity Provisioning

The Vscan Extend device supports PIN authentication. A PIN is created by the user when accessing the device and storing the image for the first time.

The device provides PIN access at two levels:

1. Storage access
2. Admin access

The user MUST set the Admin PIN when trying to access the Admin mode.

PIN restrictions

The restrictions on a PIN are:

1. The PIN should be 4-digits long.
2. When the device is idle for a certain amount of time set in the session duration, it is the reponsibility of the user to ensure that the device is not used by unauthorized individuals as it may lead to data loss.

User Authentication

The Vscan Extend device is operated using a PIN. Only one PIN is used by different users to access the device. The Vscan Extend does not support user profiles.

Assigning Access Rights

The Admin mode is used to change the System level configuration.

A user can access the Admin mode by entering the Admin PIN.

Patient Privacy Consent Management

Patient Privacy Consent Management is the process to support the patient to express their privacy requirements. This is different from other forms of consent such as the consent to treat.

There is no integrated functionality in the system for Patient Privacy Consent Management. If needed, operational routines must be established.

Privacy and Security Audit Logging and Accountability Controls

Privacy and Security Audit Logging and Accountability Controls support Security surveillance and Privacy investigations and reporting.

The Vscan Extend has an integrated functionality for audit logging, including audit logging of privacy related events.

Audit logging content

The following events are captured by the audit logging of the Vscan Extend:

1. Device Start/Shut-down time
2. Incorrect password attempts
3. Addition and Modifications to system configuration, including:
   a. DICOM connection
   b. Windows Share connection
   c. Application software installation/uninstallation/software upgrade
   d. Registration of partnering apps
4. Events related to Patient Data, including details of:
   e. Data access Date/Time including type of action (addition, deletion, modification, reviewed) excluding the PC connect scenario
   f. Details of applications used (Bladder app, Lung protocol, etc.)
5. Data Export
   a. Data export Date/Time including end point and Wi-Fi SSID information
   b. Data Backup/Restore detail
6. Invalid Device PIN attempt
7. Kiosk admin mode login success and failure

Management of Audit logs

Back up of audit logs

Back up of audit logs can be done by exporting audit logs to an external device. The export happens through USB export.

Remember that audit logs and exported audit log files do contain Personal Information (PI) and must be handled according to applicable regulations and guidelines for handling of PI/PHI.

Note that exported audit log files are stored unencrypted.

Network Connectivity

Overview

Network connection for the Vscan Extend is required by several system features:

1. DICOM connectivity to other DICOM devices
2. Disk Management/Backup towards Windows share
3. Image/Video storage via the “JPG/MPEG” feature

System interconnections

The figure below shows the possible interconnections for the Vscan Extend Ultrasound system. For a particular installation, typically a subset of the interconnections is utilized.

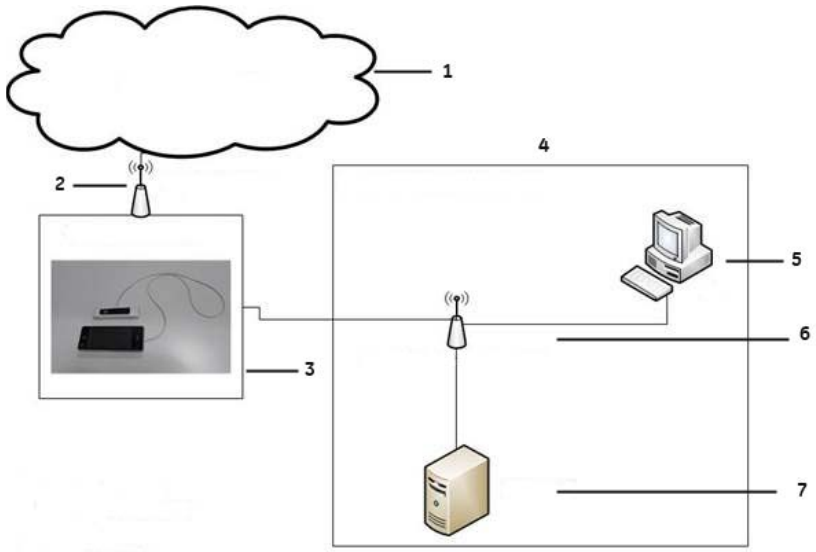


Figure 8-1. Vscan Extend network diagram

1. GE Health Cloud
2. Hospital Public Wireless infrastructure
3. Vscan Extend Device
4. Hospital Clinical Network
5. PACS
6. Hospital Clinical Wireless infrastructure
7. Windows PC

System interconnections (continued)

Device features

- Supported Wireless

  Protocols include WEP, WPA2 with PSK and EAP with certificates
- Log files
- Data backup/restore
- Software upgrade

Wireless Networks are configured by Hospital IT administrators or device owners. The Wi-Fi encryption depends upon on the hospital IT infrastructure and the device enterprise grade protocols with the certificate mechanism.

DICOM image transfer and anonymized images/video transfer to a Windows machine is supported over a hospital clinical wireless network and a hospital public wireless service that are used for GE cloud connectivity to push the data using SSL/TLS.

The table below describes interconnections in more detail:

Table 8-1: Interconnections

Source/destination	Network service	Description
PACS/DICOM server	DICOM	Optional connection to PACS/DICOM server for patient and image archiving/retrieval. DICOM storage, DICOM Query/Retrieve and DICOM Worklist are supported
Windows share	Windows file sharing	Some dataflows can be configured to use a windows share as output. This includes MPEG, videos.
USB export	USB cable	If the feature is enabled, an USB cable can be connected to a PC for exporting images and videos.

For details regarding protocols, port numbers and firewall configurations see ‘Inbound firewall configuration’ on *page 8-10*, ‘Outbound firewall configuration’ on *page 8-11*.

Network Requirements

Host Characteristic

1. TCP/IP network
2. Both DHCP and static IP allocation are supported

Network Protocols

Wireless network protocols

The following wireless protocols are supported:

1. IEEE 802.11b
2. IEEE 802.11g
3. IEEE 802.11n

Internet Protocol Version:

1. IPv4
2. IPv6

Information Protection

Overview

This section of the manual focuses on Privacy and Security operations, and contains information to guide in the preparation of a secure environment for the Vscan Extend Ultrasound system.

Security operations is best implemented as part of an overall “defense in depth” information assurance strategy; this is used throughout an Information Technology system that addresses personnel, physical security and technology. The layered approach of defense in depth limits the risk that the failure of a single security safeguard will allow compromise of the system.

Network Security

GE strongly recommends that medical information systems are operated in a secure network environment that is protected from unauthorized intrusion. There are many effective techniques for isolating and protecting medical information systems, including implementing firewall protection, demilitarized zones (DMZs), Virtual Local Area Networks (VLANs) and network enclaves.

To assist in secure network design, the following network profile outlines the required network services for the Vscan Extend Ultrasound system.

The Vscan Extend is supported with an internal firewall. The following two sections describe the configuration of the firewall and the guidance for configuring the IT infrastructure where it is connected.

Inbound firewall configuration

All inbound connections are blocked by the Vscan Extend Ultrasound system's internal firewall, with the exemptions listed in the table below.

The column "Recommended configuration of network infrastructure" describes the suggested configuration of the network infrastructure regarding the different network services.

Table 8-2: Inbound Firewall configuration

Local port	Remote port	Protocol	Programs	Recommended configuration of network infrastructure	Network service
104[1]	Any	TCP	All	Open to DICOM server(s) connected to the Vscan Extend, but only if DICOM Retrieve is used. Closed towards internet.	DICOM Retrieve from connected DICOM server(s)

[1] Port 104 or another port configured for the DICOM Retrieve service.

Outbound firewall configuration

All outbound connections are blocked by the Vscan Extend Ultrasound system's internal firewall, with the exemptions listed in the table below.

The column "Recommended configuration of network infrastructure" describes the suggested configuration of the network infrastructure regarding the different network services.

Table 8-3: Inbound Firewall configuration

Local port	Remote port	Protocol	Programs	Recommended configuration of network infrastructure	Network service
Any	104[2]	TCP	DICOM	Open to DICOM server(s) connected to the Vscan Extend. Closed towards internet.	DICOM store
Any	104[3]	TCP	DICOM	Open to DICOM server(s) connected to the Vscan Extend, but only if DICOM Query is used. Closed towards internet.	DICOM Query
Any	104[4]	TCP	DICOM	Open to DICOM server(s) connected to the Vscan Extend, but only if DICOM Worklist is used. Closed towards internet.	DICOM Worklist
Any	445	TCP	Windows Share	Windows	Windows Share

[2] Port 104 or another port configured for the DICOM Storage service.

[3] Port 104 or another port configured for the DICOM Query service.

[4] Port 104 or another port configured for the DICOM Worklist service.

Local Archive - Security capabilities

The Vscan Extend is provided with an internal archive, for storing images and patient data locally on the system. The local archives file repository and patient database do not support file sharing or remote connection. These can only be accessed locally.

The patient database is protected with the authentication for access requirements and no possibility of remote access.

DICOM connections – Security capabilities

The DICOM connection works as defined by DICOM guidelines. The application accepts connection only to/from DICOM entities with IP-address, AE Title and port number matching the configured parameters in the Vscan Extend Ultrasound system.

The communication sessions are on demand and are always initiated locally from the system.

The Vscan Extend Ultrasound system's internal firewall has exemptions for ports used by the defined DICOM dataflows in the system. Defining a new DICOM dataflow, or changing an existing dataflow, will cause the internal firewall configuration to automatically change. This ensures that only ports configured for a dataflow have an exemption in the internal firewall.

Windows share

Windows share access can be secured by defining a dedicated user on the server side. The user credentials for the network share user must be entered in the configuration UI on the Vscan Extend Ultrasound system.

NOTE: There is no network file share on the Vscan Extend Ultrasound system.

Network infrastructure

The infrastructure of the network where the Vscan Extend is connected must be configured to allow traffic as described in Inbound firewall configuration and Outbound firewall configuration sections. All other traffic to and from the Vscan Extend can be blocked in the network infrastructure to prevent unintended access.

Wireless Security

Due to the broadcast nature of wireless communication, wireless devices require special security considerations. There are effective techniques and tools for improving the security of wireless communication devices.

Wireless security protocols

The following security protocols are supported on the wireless interface:

1. WEP
2. WPA/WPA2 PSK
3. 802.1x EAP - (PEAP, TLS, TTLS, PWD, SIM, AKA)

Removable Media Security

Data stored on removable media, such as a microSD card, is stored encrypted on the media. The storage device and the content on the storage device must be physically protected and handled according to applicable regulations and guidelines for handling personal information (PI) / protected health information (PHI).

Data can also be exported through a USB cable to a PC. Only the images or videos will be exported. The patient information will not be displayed.

Removable media on the Vscan Extend Ultrasound system

The Vscan Extend supports USB cable connection to export images and videos to a PC.

The removable microSD cards are used for the following:

1. Backup encrypted patient data – empty microSD card
2. Error log storage – original microSD card delivered with the Vscan Extend
3. Upgrade the application software – Application microSD card

Data destruction for portable media

The Vscan Extend does not have the internal functionality to securely delete data stored on the removable devices.

Approved procedures and tools should be used to securely remove data stored on removable media, according to applicable regulations and guidelines for handling patient information / personal information (PI) / protected health information (PHI).

Data at Rest Security

Patient data is encrypted and images/videos/logs are unencrypted.

Back-up

The Vscan Extend backup feature stores data in an encrypted format. Only images are backed up; no patient information is displayed.

The backup device must be secure, whether it is removable media or a server, to ensure no unauthorized intrusion.

External dataflows

The Vscan Extend supports interconnections to external storage systems. This includes connections to Remote Archives (Windows Share) and DICOM servers. The security of data stored on these systems must be secure.

d on the external storage system (outside the scope of the Vscan Extend Ultrasound system).

Data Integrity Capabilities

To ensure the integrity of any software update, the Vscan Extend has additional security installed to detect any malicious modifications to a software update package.

Integrity assurance is implemented to software updates packages for the Vscan Extend Ultrasound system. Malicious modifications to a software update packages will be discovered at install time, and the installation of the malicious software will be prohibited.

The Vscan Extend has integrated audit log capabilities that logs changes to the data. See ‘Privacy and Security Audit Logging and Accountability Controls’ on *page 8-4 for more information.*

Business Continuity

To ensure business continuity, several options must be considered related to data storage. The target for the images and patient archive must be chosen to ensure safe storage of the data. Both internal and external alternatives are supported.

Patient archive solutions

The Vscan Extend supports several alternatives for storing images and patient information, both internal and external:

1. Local Archive: local storage on the Vscan Extend Ultrasound system
2. Remote Archive: Only anonymized images can be stored on Windows share. Patient information is not visible.
3. DICOM storage: storage on DICOM/PACS server

See ‘System interconnections’ on *page 8-6 for more information.*

Securing data on Local Archive and Local Archive Shared

If local archive is used, backup and/or transfer procedures must be established for the local archive. If disk management is not performed within a pre-defined period, a warning message displays.

Securing data on Remote Archive and DICOM/PACS servers

If external archive is used, a backup procedure must be established for the external archive. The business contingency planning of data stored on DICOM/PACS servers is outside the scope of this document.

Off-line mode

The Vscan Extend can operate in stand-alone mode, with the use of Local Archive. If there are data network related problems, which prevents the Vscan Extend from connecting to an external patient archive, the device can be fully functional by storing patient data/images to the Local Archive.

System Protection

Vscan Extend – system protection

The System needs to be configured and maintained in a way that continually protects Privacy and Security.

The GE Healthcare Vscan Extend contains additional features to improve local operational security.

No system access

Users of the Vscan Extend do not have access to the Android system nor to the MST system (Linux) on the Vscan Extend Ultrasound system.

Hence the users will have no access to internet web-browsing, e-mail clients, installing any software on the system nor adding files (except for application related files through the application)

Android features controlled

Android operating system is controlled through an Admin PIN. The user does not have access to the Android system.

Vscan Extend operating system

Table 8-4: Operating system

Family	Product
Vscan Extend	DaVinci 6446 / 128MB / 64MB; Android 4.4.2/ 1.5 GB

The Vscan Extend is based on Android and Linux operating systems, but have been customized for Ultrasound use.

Personal Information Collected by the Product

Information collection and use

The Vscan Extend collects patient demographic information, personal and/or protected health information for the use within the system.

Information entered for users defined in application user management is also stored on the system.

The following types of information are collected for the purposes of patient medical diagnosis, user management, audit logging and/or debug logging:

1. Patient demographics
2. Medical diagnostics and measurements
3. Ultrasound images
4. Facility information
5. Provider information
6. Device data

Patient information collected is either entered manually by the user or is received through one or more of the system's dataflows.

Details on what data is collected, used and disclosed can be obtained by contacting GE Healthcare.

Manual information collection

Only PI required for the purpose of treatment or healthcare operations should be collected. The system supports collection of PI that is related for such usage only. However the system might support collection of more data than will be used for a particular installation. The user should limit the collect of PI to what is really needed.

Only PI required for the purpose of treatment or healthcare operations should be collected. Even though the Vscan Extend supports PI collection for treatment or healthcare operaitons, the system might support collection of more data than is needed for a particular installation. Limit the PI collection to the content needed.

The user should not enter personal identifiable information in free text fields on the system as this information is not anonymized by the de-identification procedure.

Information disclosure

If the Vscan Extend is connected to external archives, patient demographics, medical diagnostics, measurements and ultrasound images will be communicated to/from the external archives. The same applies for remote network shares and external media, like a microSD card and USB cable used to export images to a PC. See ‘System interconnections’ on *page 8-6 for more information.*

Retention and destruction of personal information

Retention and destruction of patient data

The information collected is stored on the system until it is manually removed.

Requirements and policies for limited collection and/or destruction of Patient Information on the system must be implemented by establishing appropriate procedures. There is no support for such functionality in the system.

Retention and destruction of user information, local users

User information created and managed on the device remains on the system until manually removed.

Requirements and policies for limited collection and/or destruction of user information on the system must be implemented by establishing appropriate procedures. There is no support for such functionality in the system.

Protection of personal information

Individuals authorization for collection, use and disclosure of PI/PHI

Some users of Vscan Extend system might face requirements and policies for letting individuals (the patients) authorize the collection, use and disclosure of PI/PHI. There is no support for such functionality in the system. Such requirements can only be implemented by operational procedures.

Information to individuals of collection, use and disclosure of PI/PHI

Some users of the Vscan Extend may have certain requirements and policies to inform individuals (patients) about the collection, use and disclosure of PI/PHI. There is no support for such functionality in the system. Such requirements can only be implemented by procedures.

Potential Hazardous Situations Resulting From Failures of the IT Network

Hazardous situations

The following situations have been identified as potentially hazardous as a result of the IT network failing to provide the required characteristics specified above.

1. Delayed or impaired access to images or other exam information or patient data.
2. Permanent loss of images or other exam information or patient data.
3. Corruption of images or other exam information or patient data.

Warning

In addition to the hazardous situations identified above, connection of the Vscan Extend to a network that includes other equipment could result in other unidentified risks to patients, operators or third parties. The responsible organization should identify, analyze, evaluate and control these risks on an ongoing basis. Re-evaluate the risks if any of the following occurs:

1. Changes in network configuration
2. Connection of additional items to the network
3. Disconnecting items from the network
4. Update of equipment connected to the network
5. Upgrade of equipment connected to the network

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