Technical Publications

Vscan

Version 1

CE 0470

User Manual

GM092207 — English

Rev. 02

Operating Documentation

Regulatory requirement

This product complies with regulatory requirements of the following European Directive 93/42/EEC concerning medical devices.

CE 0470

This manual is a reference for the Vscan. It applies to all sub-versions of the software version 1 for the Vscan ultrasound system unless otherwise specified.

This manual is a reference for the Vscan gateway software. It applies to all sub-versions of the software version 1 for the Vscan gateway software unless otherwise specified.

Manual status:
GM092207-02
26 February 2014

Manufacturer:
GE VINGMED ULTRASOUND AS
Strandpromenaden 45
N-3191 Horten, Norway
Tel.: (+47) 3302 1100 Fax: (+47) 3302 1350

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 Vingmed Ultrasound. Ignoring this advice may compromise the regulatory approvals obtained for the product.

This product complies with the regulatory requirement of the following:

Standard/Directive	Scope
93/42/EEC	Medical Devices Directive (MDD)
EN55011	Emitted noise according to Class B requirements
IEC60601-1 EN60601-1 UL60601-1 CAN/CSA-C22.2 No 601.1-M90	Medical Electrical Equipment, Part 1; General Requirements for Safety
IEC60601-2-37	Medical electrical equipment - Part 2-37. Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
IEC1157 / EN61157	Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment.
IEC60601-1-2 EN60601-1-2	Medical Electrical Equipment - part 1-2. Collateral standard: Electromagnetic compatibility - Requirements and tests.
IEC60601-1-4 EN60601-1-4	Medical Electrical Equipment - part 1-4. Collateral standard: Programmable electrical medical systems
IEC60601-1-6	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.
ISO10993-1	Biological evaluation of medical devices

Country Specific Approvals

- JAPAN

  MHLW Approved Number: 221ABBZX00252000
- CHINA

  SFDA: SFDA (I) 20113231266

  Product Standard Number: YZB/NOR 0732-2011

产品名称	超声诊断仪
型号	Vscan
中国境内售后服务机构	通用电气医疗系统贸易发展（上海）有限公司售后服务中心（电话：800-810-8188）

- KOREA

  KFDA: 10-1194

Certifications

- GE Vingmed Ultrasound is ISO 9001 and 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 is internally powered battery operated during hand held scanning.
- The AC adapter is Class II.
- Vscan has type BF Applied Part.
- Degree of protection against harmful ingress of water:

  Vscan parts and accessories except probe tip: ordinary equipment (IPx0)

  Probe tip: IPX1

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.

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

Environmental requirements for the unit

Requirement	Temperature	Humidity non-condensing	Air Pressure
Operational	10–40 °C	30–80%	700–1060 hPa
Non operational	-20–70 °C	30–90%	700–1060 hPa

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

Original Documentation

- The original document was written in English.

Table of Contents

Chapter 1

Introduction

Contents:

General description

Vscan is a battery operated pocket-sized general purpose ultrasound imaging system.

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. Sophisticated design with computer control offers a system with extensive features and functions which is user-friendly and easy to use.

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.

All information in Chapter 'Safety' on *page 7-1* should be read and understood before operating the ultrasound unit.

Indication for use

The Vscan ultrasound unit is intended for the following applications:

- Cardiac adult and pediatric
- Abdominal
- Pediatric
- Urology
- Fetal
- Peripheral vascular
- Thoracic/Pleural motion and fluid detection

Contraindication

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

For USA only:

United States law restricts this device to sale or use by, or on the order of a physician.

Warnings

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

- Vscan is a precision instrument. Handle Vscan and its accessories with care. Do not subject Vscan 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 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.
- If any liquid from 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 immerse or expose the battery to water.
- 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.

- 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.

Conventions used in this manual

Buttons and other controls on the Control panel or on the monitor screen are indicated by bold type.

Program windows, *screens* and *Dialogue* boxes are indicated by italic type.

The following icons, highlight safety issues as follow:

d  DANGER

Indicates that a specific hazard exists that, given inappropriate conditions or actions, will cause severe or fatal personal injury with or without substantial property damage.

w  WARNING

Indicates that a specific hazard exists that, given inappropriate conditions or actions, can cause severe or fatal personal injury with or without substantial property damage.

c  CAUTION

Indicates that a potential hazard may exist that, given inappropriate conditions or actions, can cause minor injury or property damage.

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

GE Healthcare TEL: (1) 800-437-1171

Ultrasound Service Engineering FAX: (1) 414-721-3865

9900 Innovation Drive

Wauwatosa, WI 53226

Clinical Questions

Please contact your local Applications or Sales 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 system ID is unknown, please give the Temporary System ID “VSCAN” to be properly routed for support.

Americas

Region	Telephone	Location
United States	800-437-1171	Milwaukee
Canada	800-668-0732	Moncton
Mexico	0800 9043400	Sao Paulo
Puerto Rico	0800 4371171	Sao Paulo
Brazil	0800 122345	Sao Paulo
Argentina	0800 3331984	Sao Paulo
Chile	0800 367000	Sao Paulo

Europe, Middle East and Africa

Region	Telephone	Location
Algeria	+21321484612	
Andorra	902 400 246	
Austria	0800244260	Vienna
Belgium Dutch	+32 262 638 38	Diegem
Belgium French	+32 262 638 39	Diegem
Bulgarian	+35929712040	Sofia
Denmark	80404944	Stockholm
Egypt	+202 19434 [hot line]	Cairo
Finland	0981710182	Stockholm
France	0800139140	Velizy
G. D. Luxembourg	080022973	Diegem
Germany	08004373784	Solingen
Greece	302109690660	Athens
Holy See	800 827168	Milan
Hungary	+36-23-410-510	Budapest
Ireland	1800992557	Dublin
Israel	Contact local distributor	Tel Aviv
Italy Central	800 827168	Milan
Italy North-East	800 827166	Milan
Italy North-West	800 827164	Milan
Italy South	800 827170	Milan
Liechtenstein	0041 44 809 9293	
Monaco	0800139140	
Netherlands	8000994442	Diegem
Northern Ireland	08000720248	Belfast
Norway	80062043	Stockholm
Portugal	800 834 004	Madrid
Russia	+7 495 739 69 75	Moscow
San Marino	800 827168	Milan
Saudi Arabia	800 1243002	Saudi Arabia

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

Asia and Pacific

Region	Telephone	Location
China	8008108188	Beijing
Hong Kong	(852) 21006288	Hong Kong
Taiwan	0800-021-770	Taipei
India	(91) 1800-425-8025	Bangalore
Singapore	(65) 62773444	Singapore
Australia	1-800-659-465	Brisbane
New Zealand	0800 65 94 65	Brisbane
Japan	0120-055-919	Tokyo
Korea	(82) 2-1544-6119	Seoul
Bangladesh	(880) 29135488	Dhaka
Sri Lanka	(94) 114891178	Colombo
Bhutan	Contact GE India	
Maldives	Contact GE India	
Nepal	Contact local distributor	
Malaysia	1800 88 3911	Kuala Lumpur
Thailand	(66) 26248400	Bangkok
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 AS
Strandpromenaden 45
N-3191 Horten, Norway
Tel.: (+47) 3302 1100 Fax: (+47) 3302 1350

Chapter 2

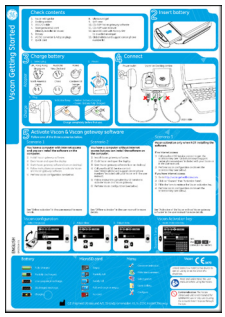
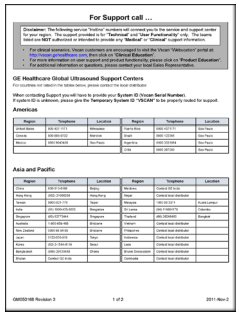
Preparing the Vscan for use

Contents:

Package contents

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

1. Vscan unit
   Storage microSD card installed in Vscan
2. Soft bag
3. USB 2.0 cable
4. Battery (GM-BAT)
5. Coupling gel
6. SD card adapter

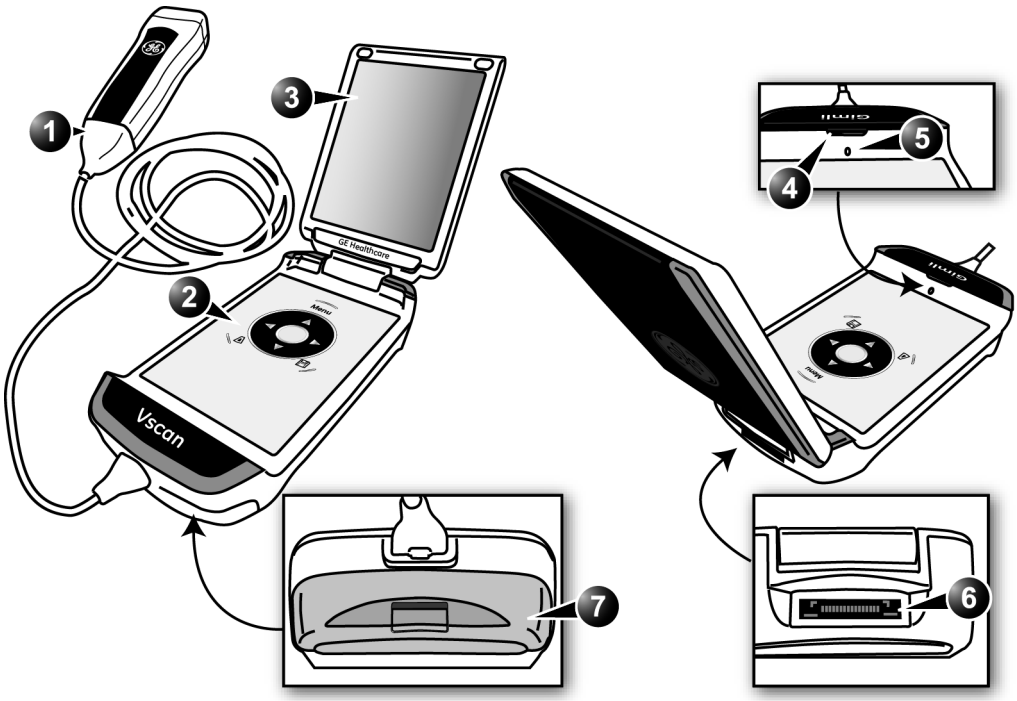
	Quick card
 	CD-ROM Vscan gateway software CD-ROM user manual
	Service contact information
	microSD card with factory SW (In a sealed envelope – only to be used in agreement with service organization)

1. Docking station
2. AC/DC converter
3. Adapter plugs

System description

System overview

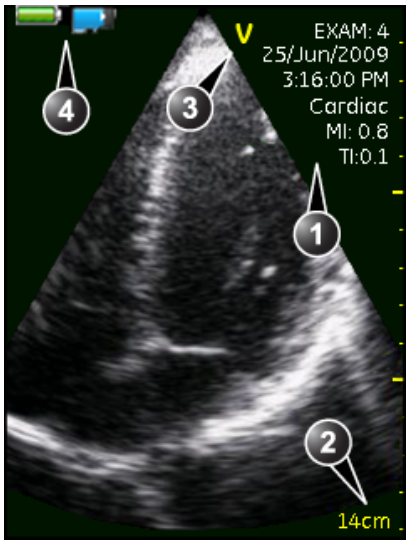
The Vscan device



1. Probe G3S
2. Control panel
3. Display
4. Loud speaker
5. Microphone
6. Docking station connector
7. Battery (GM-BAT) and microSD card compartment lid

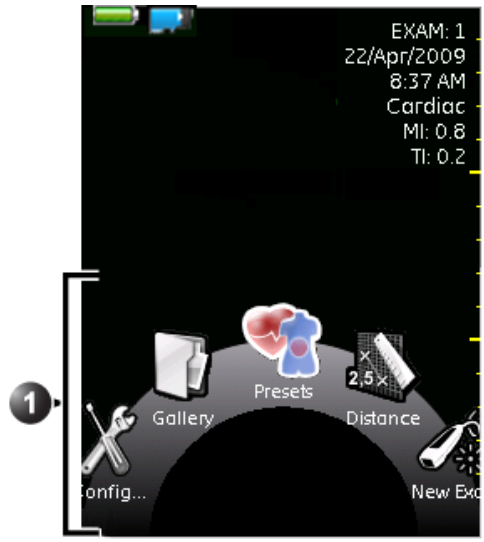
Figure 2-1. The Vscan device

The display



Black and white scanning screen (default)

1. Scanning information
   - Examination number (page 3-5)
   - Current date
   - Current time
   - Scanning preset (page 3-6)
   - Mechanical and Thermal Index (page 7-16)
2. Depth scale (page 3-7)
3. Orientation marker (page 3-5)
4. Header
   - Battery level indicator (page 2-14)
   - Memory indicator of the microSD card (page 2-19)

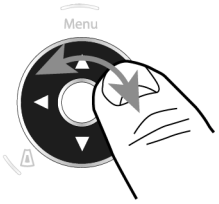


Menu screen (displayed when pressing **Menu**.)

1. Menu items
   - New Exam: create new examination (page 3-5).
   - Distance: make a measurement (page 3-9).
   - Presets: select an acquisition preset (page 3-6).
   - Gallery: review stored examinations (page 3-11).
   - Config: configure the Vscan (page 5-1).

Figure 2-2. Screens

The Control panel

Key	Usage	
	Select key • Freeze/unfreeze in live mode. • In a menu or a dialog: select highlighted item. • Press and hold to return to black and white imaging.	
	◀	• Navigate in menus. • Navigate through examinations in the Gallery screen. • Move color area and caliper.
	▶	• Navigate in menus. • Pause/play movie. • Navigate through examinations in the Gallery screen. • Move color area and caliper.
	▲	• Decrease Depth. • Navigate through files in Gallery screen. • Move color area and caliper.
	▼	• Increase Depth. • Navigate through files in Gallery screen. • Move color area and caliper.
	Rotate function • Adjust Gain. • Scroll in a movie when in pause.	
	Color imaging key • Enter/exit color imaging.	

Key	Usage
	Store key • Store current acquisition (movie or single frame). • Press and hold to start voice notation. Press any key to end voice notation.
	Menu key • Enter the system menu. • Move one level up in system menu. • Exit the system menu.

The Docking station

The Docking station is used to:

- Connect the Vscan to a computer.
- Charge the Vscan battery.
- Store the Vscan when not in use.

NOTE: The Docking station is designed for in-house use only. Do not use the Docking station in ambulance or other vehicles.

1. Vscan cradle
2. Probe holder
3. Vscan connector
4. Charger (GM-CHA) connector
5. USB port to computer

Figure 2-3. Docking station

The External battery charging compartment (option)

The external battery charging compartment is used to charge spare battery outside the Vscan.

1. Charger (GM-CHA) connector

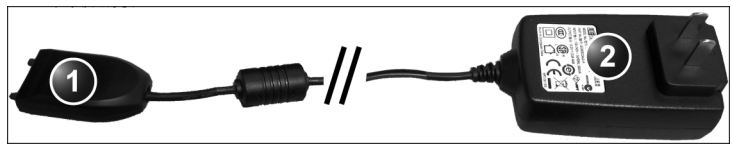
Figure 2-4. External battery charging compartment

Battery

The Vscan is powered by a Lithium Polymer battery (GM-BAT). The battery is not fully charged at shipment. To maximize time of use, it is recommended to recharge the battery before use for at least 1.5 hour. Make sure to establish a routine for charging the battery to maximize system availability.

It is recommended to charge the battery (GM-BAT) in the Vscan placed on the Docking station, or by using the external battery charging compartment as described below.

Use only the AC adapter provided with the Vscan.

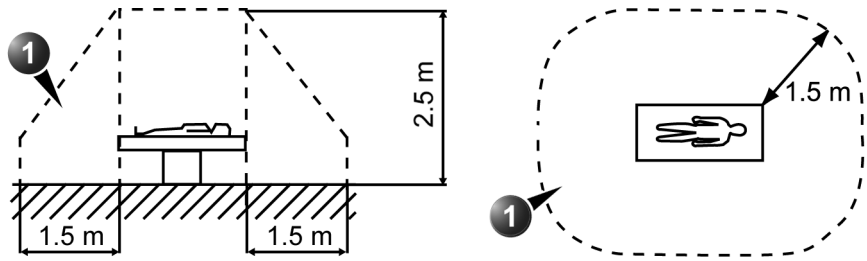


1. Charger (GM-CHA)
2. AC/DC adapter

Figure 2-5. The Vscan AC adapter

CAUTION

The AC adapter, the Docking station and the external battery charging compartment must be kept outside the patient environment (refer to local regulation and EN 60601-1).



1. Patient environment

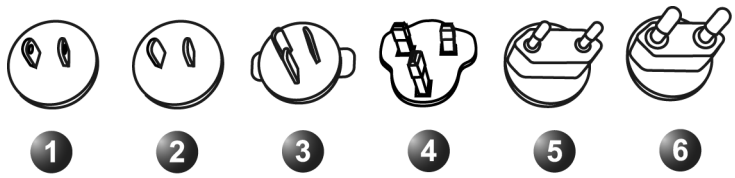
Figure 2-6. Patient environment

CAUTION

Do NOT touch simultaneously the patient and the charger plug on either the AC/DC adapter, the Docking station or the external battery charger.

Power plug adapter

1. Select the country specific plug.



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

2. Place the plug onto the AC/DC adapter.
3. Press the button and turn the plug clockwise until it locks in place.

Charging the battery using the Docking station

1. Place the Vscan on the Docking station.

2. Plug the charger (GM-CHA) plug into the charger connector on the Docking station.

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

CAUTION

Only use mains power of 100 – 240 VAC. Voltage outside this range can cause malfunction or destroy the AC/DC adapter.

The charge lamp on the charger (GM-CHA) is lit in amber when charging the battery and turns green when the battery is fully charged.

Charging the battery using the External battery charging compartment

1. Insert the battery (GM-BAT) in the compartment until the lid clicks in place.
2. Plug the charger (GM-CHA) plug into the charger connector on the external battery charging compartment.

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

CAUTION

Only use mains power of 100 – 240 VAC. Voltage outside this range can cause malfunction or destroy the AC/DC adapter.

The charge lamp on the charger (GM-CHA) is lit in amber when charging the battery and turns green when the battery is fully charged.

Battery level indicator

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

Icon	Description
	Battery fully charged.
	Battery partially discharged.
	Low Battery, prepare to recharge the battery or have a spare battery available.
	Discharged battery, recharge the battery or replace with a spare battery.
	Battery charging.

Removing / inserting the battery (GM-BAT)

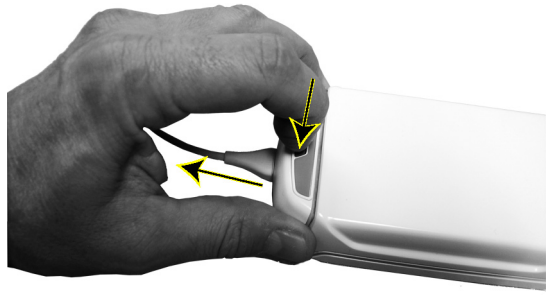
To remove the battery

1. Close the display.

CAUTION

Do not attempt to remove the battery without closing the display.

2. Push the button on the battery compartment lid and pull the battery (GM-BAT) out.



To insert the battery

1. Insert the battery (GM-BAT) in the compartment until the lid clicks in place.

Battery (GM-BAT) specifications

Item	Specification
Charging time	About 1.5 hour
Capacity	About 1 hour and 15 min active use*
Lifetime	At least 300 charges
* Assuming mixed black and white (80%) and color imaging usage and a new battery. Batteries generally degrade by aging and number of recharging cycles, and will have reduced capacity over time.	

In order to get maximum charging capacity with your Vscan battery (GM-BAT), you should allow the battery to be fully charged and then fully discharged at least three times. The unit can be used as normal during these cycles. Once these initial charging/discharging cycles are performed, the following is applicable without reducing the life time of the battery:

- It is not necessary to completely discharge the battery before re-charging it.
- 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.

The microSD card

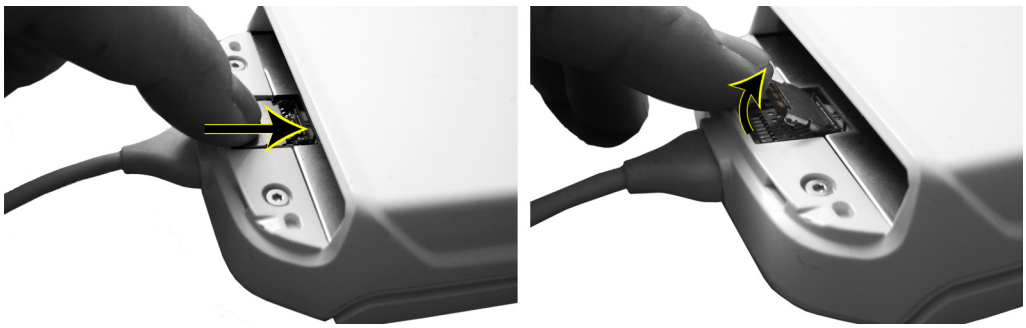
Image acquisitions and voice notation recordings are stored to a microSD card (MicroSD or MicroSDHC, speed grade 6 or lower).

The microSD card is located under the battery.

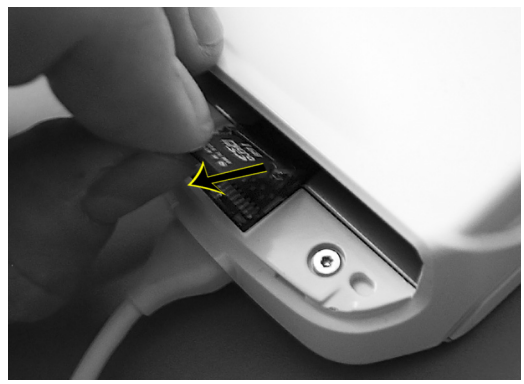
Removing / inserting the microSD card

To remove the microSD card

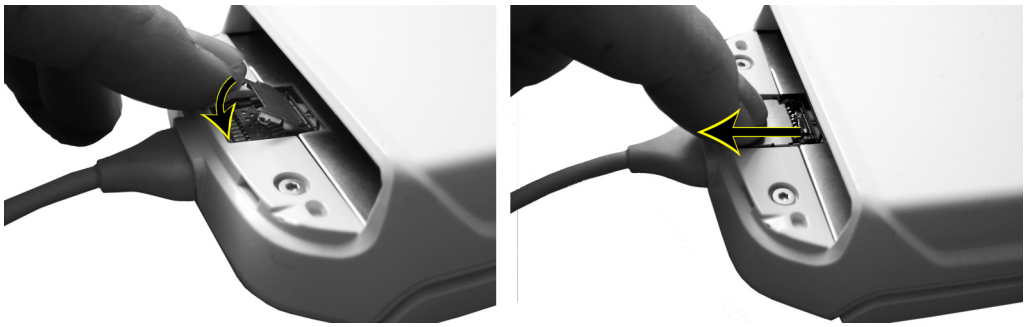
1. Remove the battery (GM-BAT) (see page 2-15).
2. Slide and raise the card slot.



3. Remove the microSD card from the card slot.

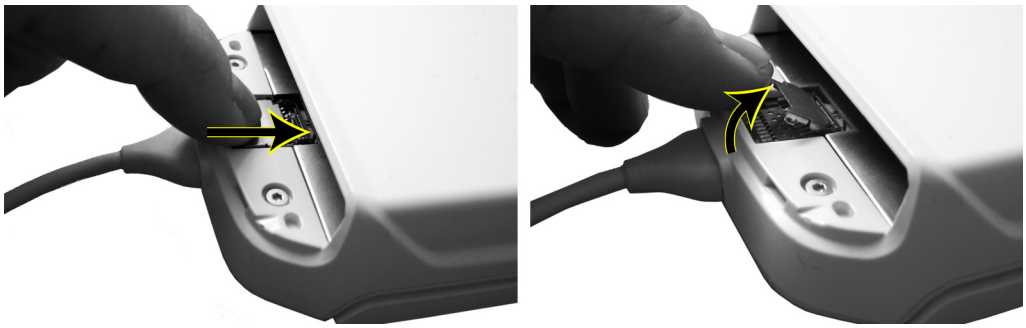


4. Lower and slide the slot card back in place.

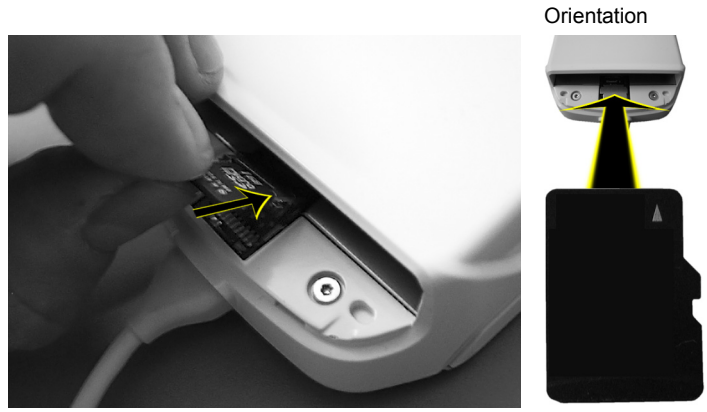


To insert the microSD card

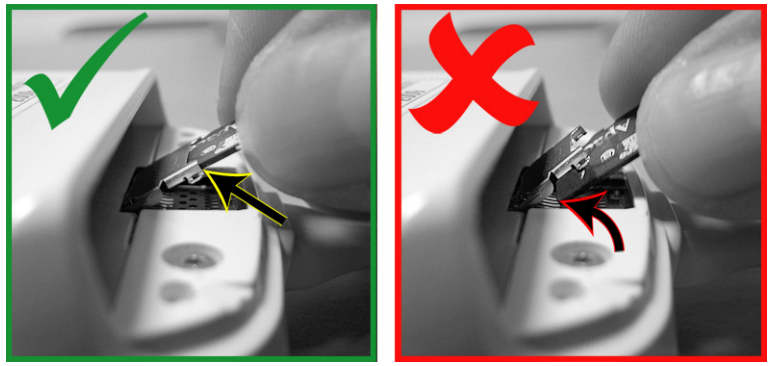
1. Remove the battery (GM-BAT) (see page 2-15).
2. Slide and raise the card slot.



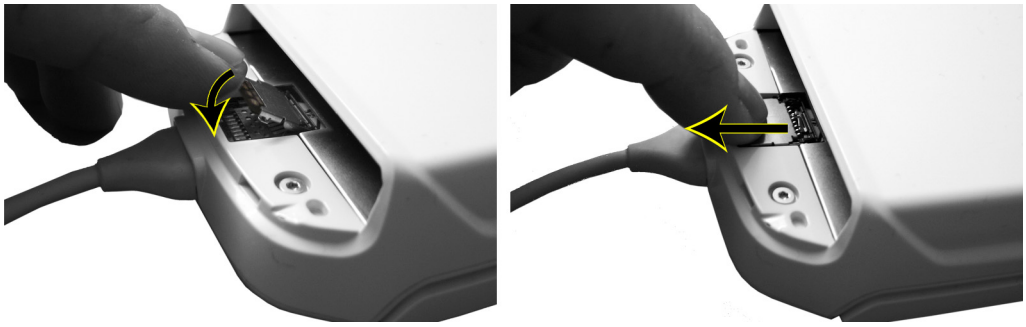
3. Insert the microSD card in the card slot.



Make sure the card is inserted in the card slot.



4. Lower and slide the slot card back in place.



5. Insert the battery (GM-BAT) in the compartment (see page 2-15).

The microSD card memory indicator

The microSD card memory indicator is displayed on the header. The following icons are displayed.

Icon	Description
	The card is empty
	The card is partially filled up
	The card is nearly full
	The card is full
	No card in the Vscan device, or card disabled from device while mounted to computer.

The microSD card handling recommendations

The microSD cards are sensitive electronic devices.

- Do not bend the microSD cards or subject them to shocks or vibrations.

First time use

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

- Install and charge the battery.
- Activate the Vscan (page 2-22).

Installing the battery

1. Insert the battery (GM-BAT) in the compartment until the lid clicks in place.

2. Make sure the battery is fully charged (see page 2-11) before activating the Vscan.

Vscan activation

Activation

There are three possible scenarios to activate the Vscan:

1. **Scenario 1** (preferred): online activation of Vscan and/or Vscan gateway:
   - Install Vscan gateway software (see ‘Installation of the Vscan gateway software’ on *page 4-5*)
   - Activate your Vscan and Vscan gateway software from the Vscan web portal on the Internet (see ‘Online activation’ on *page 4-7*).
2. **Scenario 2**: offline activation of Vscan and/or Vscan gateway:
   - Install Vscan gateway software (see ‘Installation of the Vscan gateway software’ on *page 4-5*).
   - Activate your Vscan and Vscan gateway software by contacting GE Service (see page 1-8 for phone numbers, then see ‘Offline activation’ on *page 4-12*).
3. **Scenario 3**: Vscan activation only when not installing the Vscan gateway software:
   - See ‘Activation of the Vscan without Vscan gateway software’ on *page 4-16*.

Scenario 1 is recommended if you have access to a computer with an Internet connection.

After activation the Vscan needs to be configured (see below).

Configuration

After activation the Vscan Setup wizard is started.

Language selection

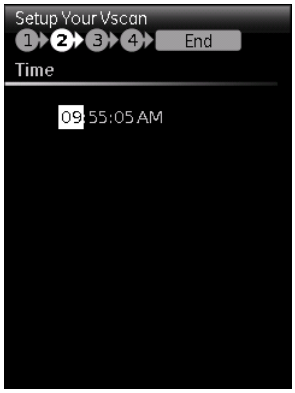
1. Use ▲ / ▼ to browse through the available languages until the desired language is highlighted.

2. Press **Select** when done.
3. Press ▶ to continue the configuration.

   The *Time* screen is displayed.

Adjust time

1. Use ◀ / ▶ to navigate between hours, minutes and seconds.
   Use ▲ / ▼ (or **Rotate**) and press **Select** to set each item.



2. Press ▶ to continue the configuration.

   The *Date* screen is displayed.

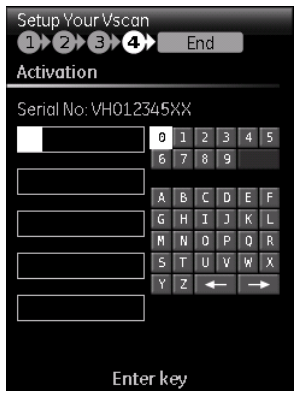
Adjust date

1. Use ◀ / ▶ to navigate between days, months and years.
   Use ▲ / ▼ (or **Rotate**) and press **Select** to set each item.

2. Press ▶ to continue.
   - If the activation key was obtained online the Vscan is then ready for use.
   - If the activation key was obtained offline the *Activation* screen is displayed.

Activation key (Scenario 3 only)

This step is only required if doing offline activation of the Vscan.

1. 

   Use ▲ / ▼ / ◀ / ▶ to highlight the digit or character to enter and press **Select**.

   The next entry in the activation key is highlighted.

2. Repeat step 1 until all 25 entries in the activation key are filled in.

NOTE: *Select ← or → on the keyboard to navigate through the activation key entries if changes need to be done.*

A message is displayed on screen to confirm that the key is accepted.

3. Press ▶ to end the configuration.

The Vscan is ready for use.

Chapter 3

Using Vscan

Contents:

Switching on/off

To switch on the Vscan

1. Open the display.
   After initialization the black and white scanning screen is displayed.

To switch off the Vscan

There are two ways to switch off the Vscan:

- Close the display
  Or
- Use the *Shutdown* menu

*NOTE: The system will delete any acquisition that is not stored when closing the display. To save the current acquisition, press **Store** before closing the display.*

Switch off using the Shutdown menu

1. Press **Menu**.
2. In the main menu, use ◀ / ▶ to browse through the menu items and highlight **Config**.
3. Use ◀ / ▶ to browse through the menu items and highlight **Shutdown**.
4. Press **Select**.

Scanning

General scanning recommendations

Before each use:

- Inspect the probe (see ‘Inspecting the probe’ on *page 6-3*).

After each use:

- Inspect the probe (see ‘Inspecting the probe’ on *page 6-3*)
- Clean the probe (see ‘Disinfection’ on *page 6-5*).
- If required disinfect the probe (see ‘Disinfection’ on *page 6-5*).

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

Use of gel

In order to assure optimal transmission of energy between the patient and the probe, a conductive gel must be applied on the probe lens.

Do not apply gel to the eyes. If there is gel contact to the eye, flush eye thoroughly with water.

Coupling gels should not contain the following ingredients as they are known to cause probe damage:

- Methanol, ethanol, isopropanol, or any other alcohol-based product
- Mineral oil
- Iodine
- Lotions
- Lanoline
- Aloe Vera
- Olive Oil
- Methyl or Ethyl Parabens (para hydroxybenzoic acid)
- Dimethylsilicone

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

	
Aquasonics 100	Parker Laboratory Inc.
Clear Image	Sonotech Inc.
Scan	Parker Laboratory Inc.
Sonogel	Sonogel Vertriebs

Other recommendations

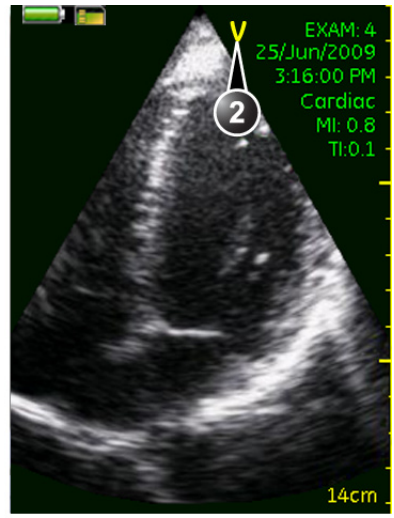
Like most high frequency computing devices, the electronic components of Vscan will generate some heat while operating normally and as intended. Vscan is equipped with safety mechanisms which will automatically reduce computing speed (frame rate), and ultimately shut down the device, before any risk of overheating occurs. Vscan is verified to comply with harmonized safety standards (see ‘Conformance Standards’ on *page i-1*), under any operating condition described in this user manual (see Environmental properties on page i-3). To help keeping the Vscan operating temperature at an optimal functional level, and to ensure longer scanning time with maximum frame rate, it is recommended to hold the Vscan so that there is good contact between the device and the hand.

Image display on Vscan is dependent of the ambient light, avoid direct sun light on the display when scanning and reviewing images.

CAUTION Do not scan on open wound.

Probe orientation

The probe is provided with an orientation marking. 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.



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

Patient examination

When scanning several patients make sure to create a new examination between each patient. To create a new examination:

1. Press **Menu**.
2. Use ◀ / ▶ to browse through the menu items and highlight **New exam** .
3. Press **Select**.

   A new examination is created. The examination number is displayed on the screen.

NOTE: A new examination is also created automatically when the system is restarted.

Presets

To ensure optimal image quality the Vscan has predefined scanning settings optimized for different applications (e.g Cardiac, Abdominal). Make sure to select the correct preset before scanning.

The current preset is displayed on the screen.

To change preset:

1. Press **Menu**.
2. Use ◀ / ▶ to browse through the menu items and highlight **Presets**  .
3. Press **Select**.

   The *Preset* menu is displayed.
4. Browse to the desired preset and press **Select**.

Icon	Preset	Optimized for
	Cardiac	Heart Aorta Thoracic/Pleural motion and fluid detection
	Abdominal	Liver Kidney Gall bladder Spleen Urology Peripheral vascular
	Obstetrics	OB/Gyn

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 is the default scanning mode.

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

1. Start scanning.

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

   - **Auto optimize**: press and hold down **Select**. A green dot is displayed on the left of the image sector indicating that the image settings have been optimized based on the current acquisition.

     To turn off Auto optimize, press and hold down **Select**.

NOTE: *If you change the probe position or adjust the Depth you may need to optimize again.*

   - **Depth** ▲ / ▼

     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.

NOTE: *The depth setting is indicated on a depth scale.*

   - **Gain** (**Rotate**)

     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.

Color imaging

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

1. Press **Color** .

   A color area is displayed on top of the black and white image.

2. Use ▲ / ▼ / ◀ / ▶ to move the color area over the region of interest.
3. The following adjustment can be done to further improve the image quality:

   - **Color gain** (**Rotate**)

     Color gain amplifies the overall strength of echoes processed in the color area. It allows control of the amount of color within a cavity.

NOTE: *Press **Color** to toggle color display on/off.*

Color aliasing

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

Aliasing will appear 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.

Auto freeze

If Vscan is idle for more than the Auto freeze time set in Config it enters in freeze mode to minimize overheating. Press **Select** to start scanning again.

AutoCycle

Vscan 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 2 sec loop.

Measurements

Taking measurements

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

To perform a measurement:

1. On a frozen image, press **Menu**.
2. In the main menu, use ◀ / ▶ to browse through the menu items and highlight **Distance**  .
3. Press **Select**.

   A red caliper is displayed.
4. Use ▲ / ▼ / ◀ / ▶ to move the caliper to the start point of the measurement.
5. Press **Select** to anchor the start point.

   A new green caliper is displayed.
6. Use ▲ / ▼ / ◀ / ▶ to move the caliper to the end point of the measurement.
7. Press **Select** to anchor the end point.

   The performed measurement is displayed with the measured value next to the end point.
8. To store the image with measurement, press **Store**  .

Voice notations

Recording Voice notations

Voice notations can be recorded at any time. The voice notations are stored in the current examination folder.

To make a voice notation:

1. Press and hold down **Store** to start recording.
2. Record your message.

   A red blinking recording symbol and a timer are displayed while recording.

NOTE: The maximum voice recording time is 10 minutes.

3. Press any button to end recording.

   The voice notation is saved to the current examination folder.

Review and storage

During live scanning, acquired images are temporarily stored on the system's memory (image buffer). When the system's memory is full, new images are replacing the oldest acquisitions. To keep images the acquisition has to be stored to the microSD card.

Reviewing acquired images

1. While scanning, press **Select** to freeze the image.
2. While in freeze, **Rotate** to scroll through the acquired images one by one.
3. Press ▶ to display the acquisition as a movie.

NOTE: *Press ▶ to play/pause the movie. To start scanning again, press **Select**.*

Storage of images

Images and voice notations for the current examination are stored to the microSD card on a dedicated examination folder. Each time the system is restarted a new examination is created. The examination number is displayed on the screen.

Pressing **Store** will store to the microSD card either of these:

- A single frame when in freeze
- A movie when in live

Single frame storage

1. While scanning, press **Select** to freeze the image and scroll (**Rotate**) to the image of interest.
2. Press **Store**.

   The image is stored to the microSD card. A confirmation message is briefly displayed on screen.

Movie storage

1. While scanning or during movie replay, press **Store** .
   The movie is stored to the microSD card. A confirmation message is briefly displayed on screen.

Recall of stored data

Images and voice notations stored on the microSD card can be recalled for review.

To recall stored data:

1. Press **Menu**.
2. In the main menu, use ◀ / ▶ to browse through the menu items and highlight **Gallery**  .
3. Press **Select**.

   The *Gallery* screen is displayed.
4. In the *Gallery* screen, use ◀ / ▶ to browse to the desired examination folder.
5. In the selected examination folder, use ▲ / ▼ to browse to the file to open.

   The files that can be opened are:

   - Single frame image with or without measurements
   - movie
   - Voice notation
6. Press **Select** to open the file.

   While reviewing a file, use ▲ / ▼ to review the other files in the examination.

*NOTE: To return to Live scanning, press and hold down **Select**.*

Deletion of data

To delete an examination

1. Press **Menu**.
2. In the main menu, use ◀ / ▶ to browse through the menu items and highlight **Gallery**  .
3. Press **Select**.

   The *Gallery* screen is displayed.
4. In the *Gallery* screen, use ◀ / ▶ to browse to the examination to delete.
5. Press **Menu**.
6. Use ◀ / ▶ until **Delete exam**  is highlighted.
7. Press **Select**.

   A confirmation dialog is displayed.
8. Press **Select** (OK) to delete the examination.

NOTE: The newest active examination cannot be deleted.

To delete a file

1. Press **Menu**.
2. In the main menu, use ◀ / ▶ to browse through the menu items and highlight **Gallery**  .
3. Press **Select**.

   The *Gallery* screen is displayed.
4. In the *Gallery* screen, use ◀ / ▶ to browse to the examination containing the file to delete.
5. In the selected examination, use ▲ / ▼ to browse to the file to delete.
6. Press **Menu**.
7. Use ◀ / ▶ until **Delete file** is highlighted.
8. Press **Select**.

   The file is deleted.

Chapter 4

Vscan gateway software

Contents:

Overview

Data acquired on Vscan can be viewed on a personal computer after installing the Vscan gateway software, a dedicated viewer for GE handheld ultrasound scanners. Vscan gateway software can read data either directly from a connected Vscan (on a Docking station) or by inserting the Vscan microSD card into a card reader (not provided) connected to the computer.

The main functionality of Vscan gateway software is:

- Read and display images and movies from the Vscan scanner
- Playback of audio recorded on Vscan
- Distance and area measurements
- Append images to an E-mail.
- Copy examinations to the computer
- Service functions for connected scanner and Vscan gateway software: software diagnostics, software updates, log function.

About the files created in Vscan

Files created on Vscan are stored into examination folders.

Each folder has a unique name consisting the Vscan serial number, the exam number followed by the date and time of storage (**<Serial No>_<Exam No>_<yyyymmdd>T<hhmmss>**).

Each file has a unique name consisting of the Vscan serial number, the exam number followed by the date and time when the exam was started (**<Serial No>_<Exam No>_<yyyymmdd>T<hhmmss>**).

The file formats are:

- Still frame: JPEG format
- Movie: MPEG-4 format
- Voice notation: WAV format.

Do not change the file or folder name. Vscan and Vscan gateway software will not be able to open a file if the file name and containing folder name do not match. This is to minimize the risk of data mix if files are moved inadvertently between examination folders or renamed in the computer.

Vscan gateway software installation

Computer requirements

The minimum requirements for the computer are listed in the table below

Item	Minimum requirements
OS	Windows XP Professional SP2 or later Windows Vista From Vscan gateway v. 1.1.1: Windows 7 32-bit and 64-bit versions are supported. Windows 7 running in VMware Virtualization Software on Mac OS X 10.6 is supported.
CPU	Pentium 4 (2.4 GHz) or Pentium M (1.6 GHz)
RAM	1 GB
Disk space	700 MB on system partition 200 MB on partition where program is installed
Graphic	DirectX 9c compatible display adapter such as: • NVIDIA GeForce 6 Series or later • AMD/ATI X1000 series or later (or Radeon R520 or later) • Intel GMA X3000 series or later Min. resolution: 1024x768
Audio	Audio output for loudspeakers or earphones
USB	At least one USB port available
Pointing device	Mouse with left and right buttons
Alphanumeric keyboard	Required
CD/DVD player	Required
Installed software	Windows Media Player version 10 Adobe Acrobat Reader 4.0 or higher (for On line Help function) Internet Explorer version 7 or higher Microsoft Outlook (for sending e-mail from Vscan gateway software)

NOTE: The computer running Vscan gateway software should have an anti virus software installed.

NOTE: Password protection should be used on the computer running Vscan gateway software, since the software is handling patient information (e.g. patient name, ID and birthdate).

CAUTION

GE has verified and validated the stability and safe operation of Vscan gateway software on a variety of personal computers complying with the minimum requirements listed above. However, be aware that any software running in parallel with Vscan gateway software may impact the performance of your computer. In the occurrence of a slow or instable computer, try to close software which are not required for clinical purpose.

Installation and activation of Vscan gateway software

Vscan gateway software needs to be installed and activated before it can be used.

CAUTION

Do NOT attempt to install the Vscan gateway software on computers running software controlling life-supporting devices.

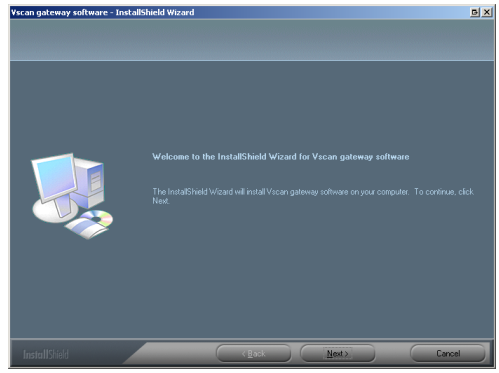
Do NOT attempt to install the Vscan gateway software on computers running software monitoring patient condition.

To be able to install the Vscan gateway software the current Windows user account must have Administrator rights.

Installation of the Vscan gateway software

1. Insert the Vscan gateway software CD into the computer's CD-ROM drive.

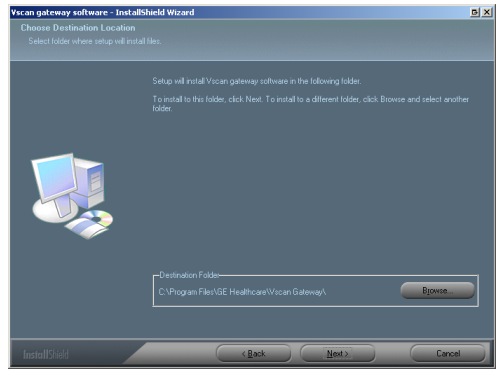
   The installation software starts automatically and a *Welcome* window is displayed.



If the CD does not start automatically, press **Start**, select **Run** and enter **X:\setup.exe** (where X is the CD drive letter) in the *Run* window.

2. Press **Next**.

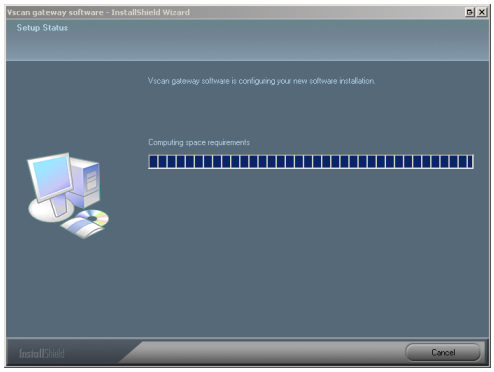
   The *Destination* window is displayed.

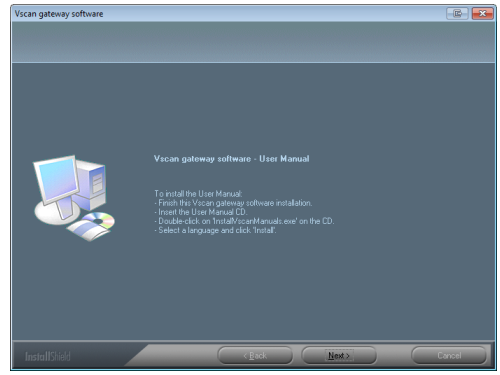


3. Press **Next** to install Vscan gateway software to the default folder or press **Browse** to install Vscan gateway software to another location.

   The files are being copied and the *User manual installation procedure* window is displayed.

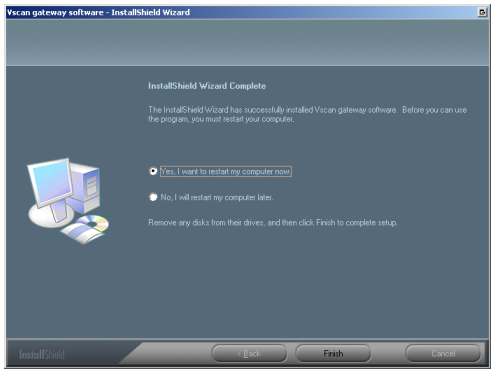
   The user manual can be installed after Vscan gateway software is installed and activated.





4. Press **Next**.

   The *Complete* window is displayed.



The computer needs to be restarted before Vscan gateway software can be used.

5. Press **Finish** to end the installation and restart the computer.

Activation of Vscan and Vscan gateway software

There are two ways to activate the Vscan and Vscan gateway software:

- Online activation: create your Vscan Activation key and Vscan gateway software System ID from the Vscan web portal on the Internet as described in ‘Online activation’ on *page 4-7*.
- Offline activation: contact the GE Service (see page 1-8 for phone numbers) to get a Vscan key and Vscan gateway System ID, see ‘Offline activation’ on *page 4-12*.

NOTE: To only activate Vscan, see ‘Activation of the Vscan without Vscan gateway software’ on page 4-16.

Online activation

Pre-requisite: a computer with Vscan gateway software installed and Internet access.

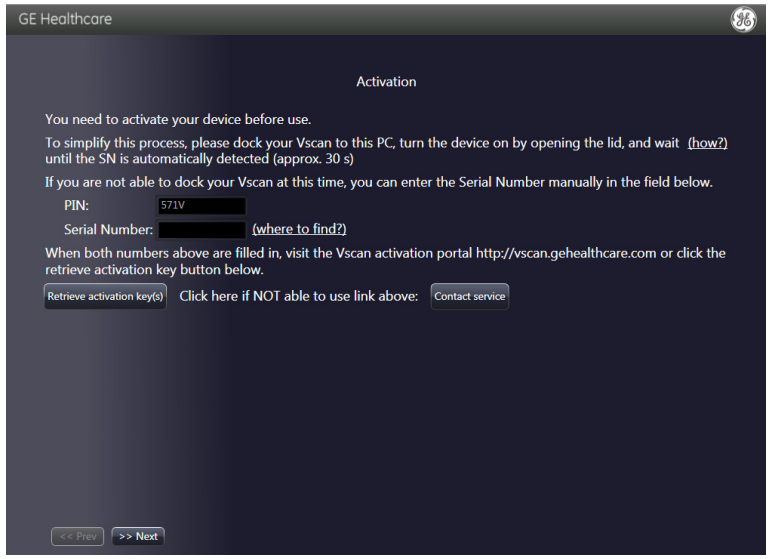
1. After installation of Vscan gateway software, double-click on the **Vscan gateway software** icon on the desktop to start the program.

*NOTE: If the icon is not on your desktop, you can typically find it by selecting **Start/Programs/GE /Vscan gateway software**.*

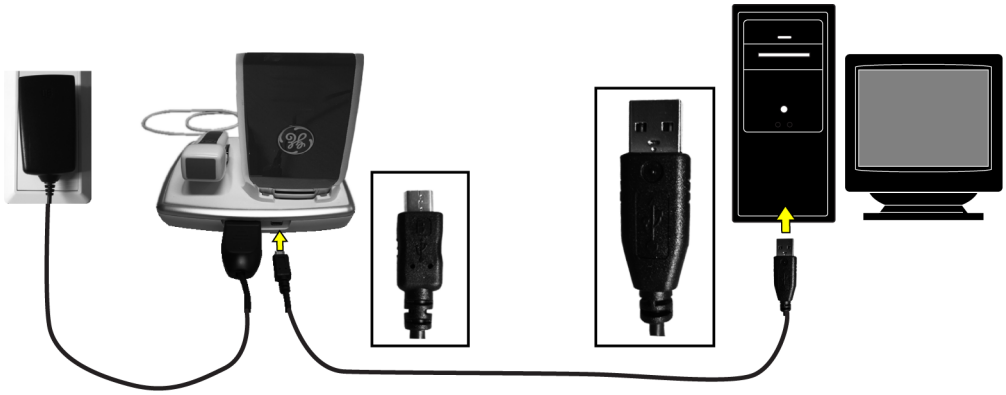
The *Language* window is displayed.

2. Select the desired language for the program and for the user manual and press **OK**.

   The *Vscan gateway software activation* window is displayed.



3. Dock your Vscan on the Docking station and open the display to start Vscan.



After approximately 30 seconds the required Serial Number of the Vscan should be automatically filled in the Activation window.

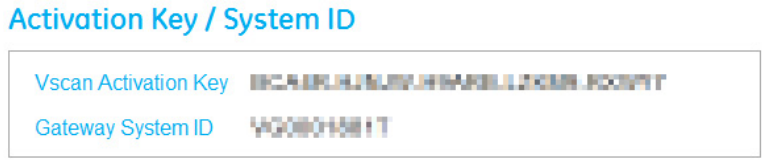
NOTE: *If you are not able to dock the Vscan, enter the Serial Number manually in the Activation window. The Serial number can be found on the label on the rear of the unit.*

4. Press **Retrieve Activation key(s)**.

   The Internet browser application is started and displays the *Vscan Product Activation* form (not shown).

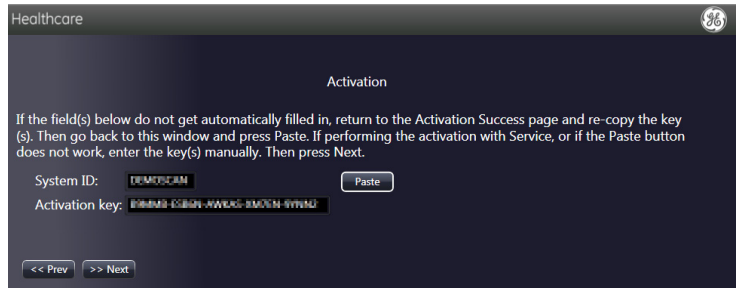
5. Fill in the form and press **Submit**.

   The *Activation Success* page is displayed showing the *Activation key* and *System ID*.



6. Highlight and copy (**Ctrl** + **c**) the Activation key and System ID (all text within the frame).
7. Return to the *Vscan gateway software activation* and press **Next**.

The *System ID* and *Activation key* fields are displayed and automatically filled in.

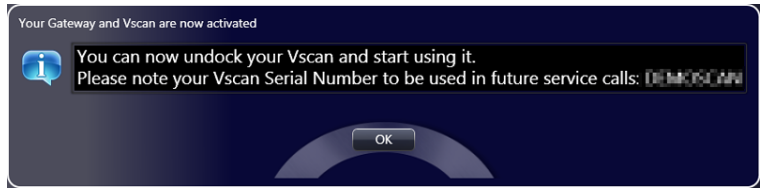


NOTE: *If the System ID and Activation key field do not get automatically filled in, return to the Activation Success page and re-copy the System ID and activation key. Then go back to the Activation window above and press* ***Paste*** *or* ***Ctrl*** *+* ***v****.*

8. Press **Next**.

   The Vscan unit is now ready for first time configuration (see ‘Configuration’ on *page 2-22*).

   Write down the Vscan Serial Number.

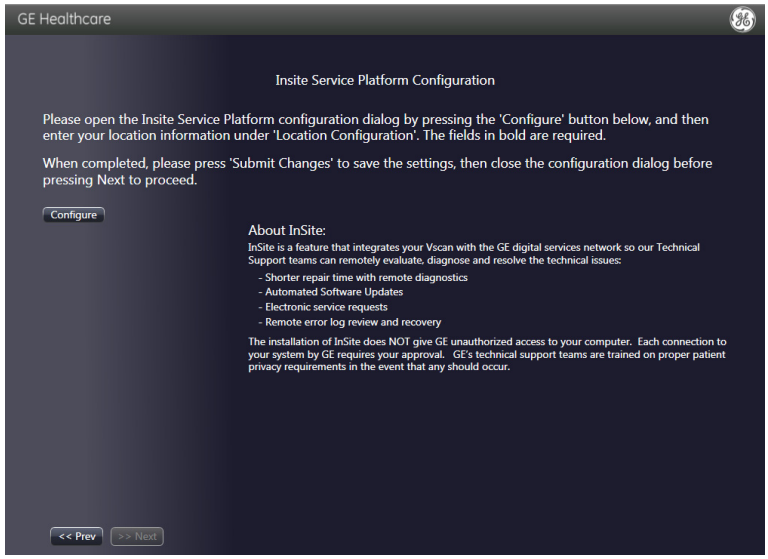


9. Press **OK**.

   The *Insite configuration* window is displayed.

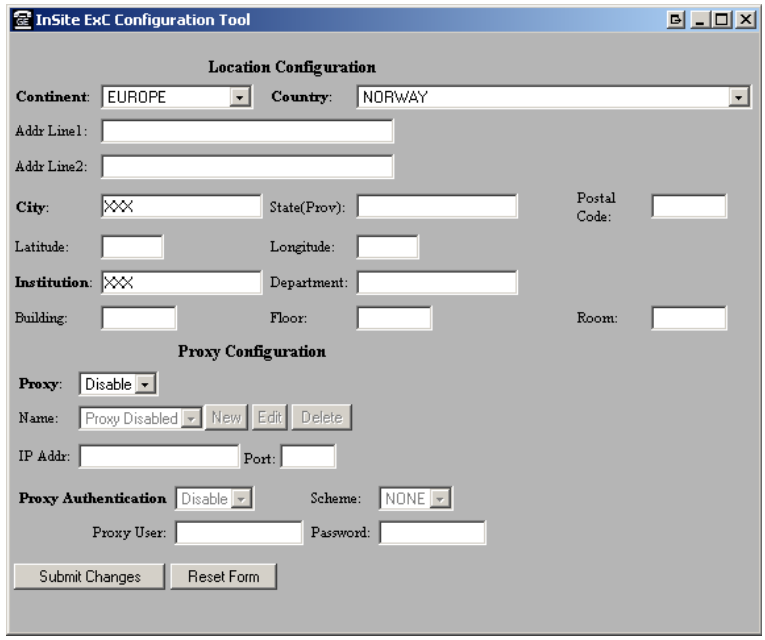
   Insite is a feature that integrates your Vscan with the GE digital services network so our technical support teams can remotely evaluate, diagnose and resolve technical issues.

NOTE: *The installation of Insite does not give GE unauthorized access to your computer. Each connection to your system by GE requires your approval. GE's technical support teams are trained on proper patient privacy requirements in the event that any should occur.*



10. Press **Configure**.

    The *Insite Configuration tool* window is displayed.



All entries in bold in the *Insite configuration* window must be filled in.
- Continent
- Country
- City
- Institution
- Proxy: Disable unless a proxy server is provided by your institution (contact the IT administrator).

Fill in the necessary information and press **Submit changes**.

Once the configuration is saved close the *Insite configuration tool* window.

11. Press **Next** and step through the next pages to check the basic software controls (e.g audio replay, image adjustment controls and movie controls).

NOTE: *Refer to 'Vscan gateway software troubleshooting' on page 6-10 if you experience any issues during the functionality check.*

The Vscan gateway software is now activated and ready for use.

Offline activation

If you do not have Internet access you can still activate Vscan and Vscan gateway software by contacting GE Service as described below.

NOTE: *For Vscan only activation when you have no computer access, see 'Activation of the Vscan without Vscan gateway software' on page 4-16.*

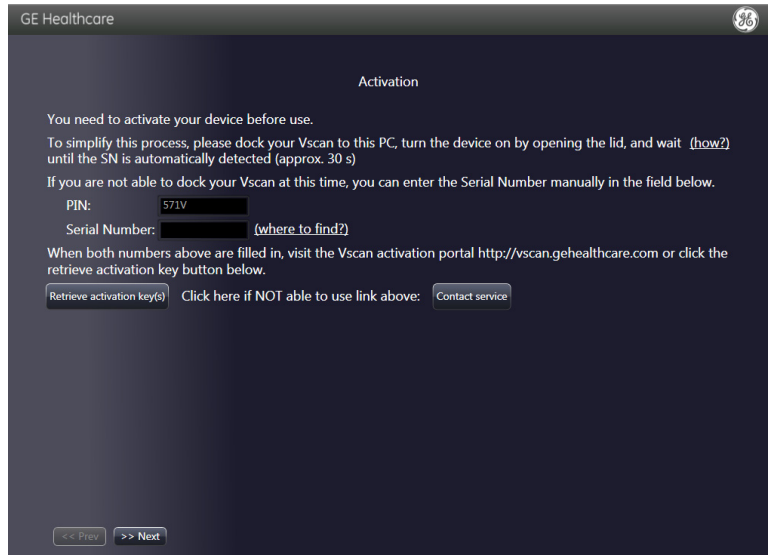
1. After installation of Vscan gateway software, double-click on the **Vscan gateway software** icon on the desktop to start the program.

NOTE: *If the icon is not on your desktop, you can typically find it by selecting **Start/Programs/GE /Vscan gateway software**.*

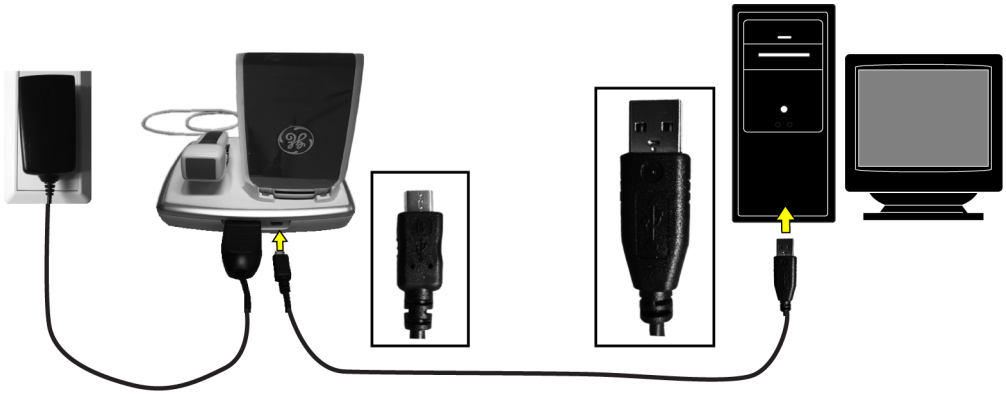
The *Language* window is displayed.

2. Select the desired language for the program and for the user manual and press **OK**.

   The *Vscan gateway software activation* window is displayed.



3. Dock your Vscan on the Docking station and open the display to start Vscan.



After approximately 30 seconds the Serial Number of the Vscan should be automatically filled in the *Activation* window.

NOTE: If you are not able to dock the Vscan, enter the Serial Number manually in the Activation window. The Serial number can be found on the label on the rear of the unit.

4. Press **Contact service** in the *Vscan gateway software activation* window.

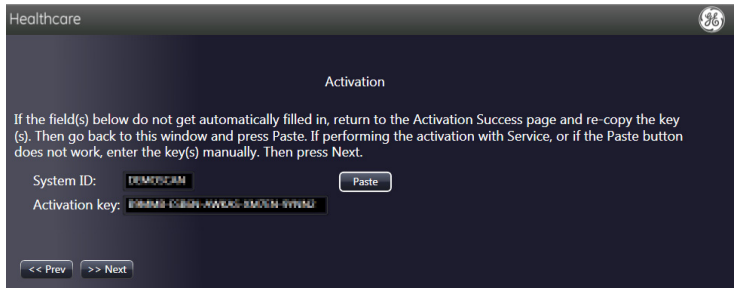
   Write down the telephone number and contact GE Service to get your Vscan key and Vscan gateway software System ID.

   The following will be required:

   - The Vscan Serial Number written on the rear label of the control unit.
   - Some user information.

5. Press **Next** in the *Vscan gateway software activation* window.

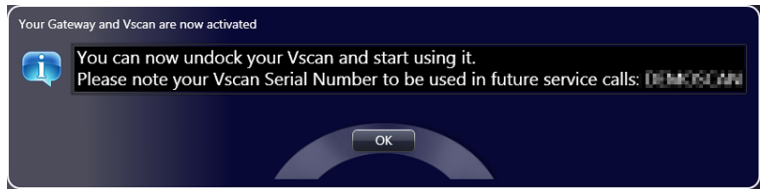
   The *System ID* and *Activation key* fields are displayed.



6. Fill in manually the *System ID* and/or *Activation key* provided by GE Service.
7. Press **Next**.

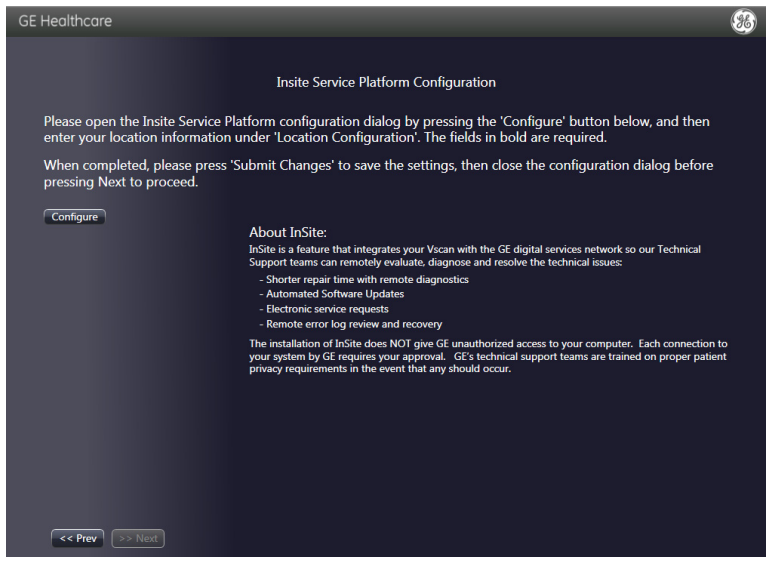
   The Vscan unit is now ready for first time configuration (see ‘Configuration’ on *page 2-22*).

   Write down the Vscan Serial Number.



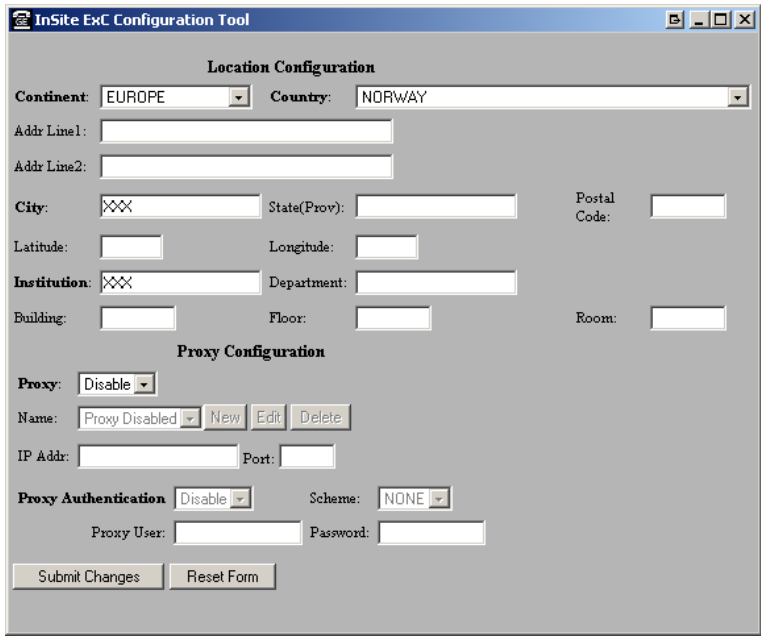
8. Press **OK**.

   The *Insite configuration* window is displayed.



9. Press **Configure**.

The *Insite Configuration tool* window is displayed.



With no Internet access there is no need to configure Insite.

10. Close the *Insite configuration tool* window and press **Next**. Step through the next pages to check the basic software controls (e.g audio replay, image adjustment controls and movie controls).

NOTE: *Refer to 'Vscan gateway software troubleshooting' on page 6-10 if you experience any issues during the functionality check.*

The Vscan gateway software is now activated and ready for use.

Activation of the Vscan without Vscan gateway software

If you do not have access to a computer to install Vscan gateway software or do not wish to install the software it is still possible to activate the Vscan unit by either contacting GE Service or by going to the Internet.

Contacting GE Service

The telephone number of your local GE Service organization can be found in 'Global ultrasound support center phone numbers' on *page 1-8*.

The following will be required:

- The Vscan Serial Number written on the rear label of the control unit.
- Some user information.

After obtaining the Activation key from GE Service the Vscan needs to be configured (see ‘Configuration’ on *page 2-22*).

Going to the Internet

1. Go to **http://vscan.gehealthcare.com**.
2. Select **Owners** from the top navigation menu.
3. Select **Activation form** and follow the instructions on screen to complete the form and retrieve your Vscan Activation key.
4. After obtaining the Activation key from the Internet the Vscan needs to be configured (see ‘Configuration’ on *page 2-22*).

Connection of Vscan to a computer

CAUTION

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC60950 for data processing equipment and IEC60601-1 for medical equipment). Furthermore all complete configurations shall comply with the valid version of the system standard IEC60601-1-1. Anybody who connects additional equipment to the signal input part or signal output part of Vscan configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of IEC60601-1-1. If in doubt consult the technical service department or your local representative for GE .

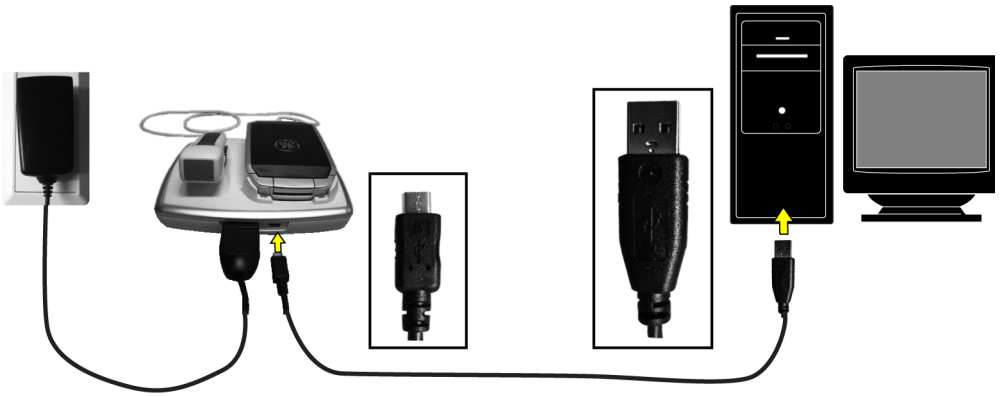


Figure 4-1. Connection setup

1. Place the Vscan on the Docking station.

NOTE: *Plug the AC/DC adapter into the electrical outlet to avoid loss of power during image viewing.*

2. Open the display to start the Vscan device.
3. Connect Docking station to the computer using the USB-2 cable.
4. Double-click the Vscan gateway software icon on the computer desktop to start the application.

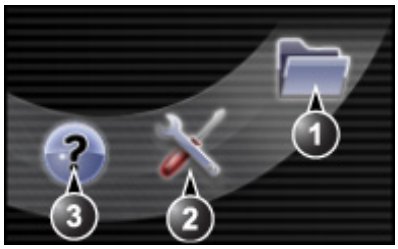
The connected Vscan is automatically detected and mounted in Vscan gateway software.

NOTE: *To disconnect Vscan safely press the **Disconnect device** button  in the Vscan gateway software Gallery screen or use the safe removal procedure from Windows.*

Using Vscan gateway software

Overview

The Vscan gateway software is organized in screens as follows:



1. Gallery screen (default screen), see page 4-21.
2. Setup screen
3. On line documentation screen: displays online documentation and access to the Vscan web portal.

Gallery screen

1. List of devices connected to the computer and local storages. Select the device to display the examinations.
2. List of examinations on the selected device. Select an examination to display the files.
3. List of files (image or voice notation) for the current examination. Select the file to display/listen to.
4. Display of the selected image file.
5. Controls for the selected file: see ‘File specific controls’ on *page 4-22*.
6. Sort examination by date, patient name or patient ID
   Examination filter: filter examinations based on a user defined filter.
7. Gallery Menu
   - **Open** : open a local storage.
   - **Save as** : save the selected examination or file to a folder.
   - **Report** : create a report in PDF format.
   - **E-mail** : send the selected file(s) by e-mail (Microsoft Outlook required).
8. Image menu
   - ◀ / ▶: navigate between the files in the current examination
   - **Dist** **/ Area** : distance and area measurement tools
   - **Annot** : annotation tool
   - **Store** : store current image with measurement and annotation
9. Disconnect the device.

Figure 4-2. Gallery screen

File specific controls

The following controls are available when selecting a file in the *Gallery* screen (Figure 4-2).

Still frame controls

Control	Description
Contrast	Control the amount of contrast.
Brightness	Control the amount of brightness.

Movie controls

Control	Description
/ Play/Pause	Start/stop the movie.
Scroll slider	Scroll through the movie by dragging the slider.
/ Backward/Forward	Scroll frame by frame through the movie.
/ Start/End	Go to start/end of the movie.
Contrast	Control the amount of contrast.
Brightness	Control the amount of brightness.

Voice notation controls

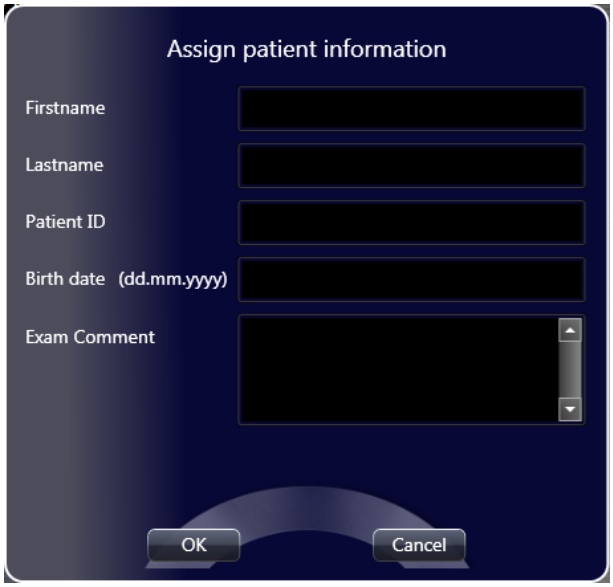
Control	Description
/ Play/Pause	Start/stop the voice notation.
Volume slider	Adjust the audio volume by dragging the slider.
Scroll slider	Scroll through the voice notation by dragging the slider.
Rewind	Rewind the voice notation to the beginning.

Patient information

Patient information can be added to an examination.

1. Right-click on the examination and select **Assign patient information** in the context menu.

   The *Assign patient information* screen is displayed.



2. Enter the information and press **OK**.

   The information entered is displayed in the examination list and is used in the report.

Measurements and annotations

Annotations, distance and area measurements can be done on still frame images, including movie when in pause.

Measurements and annotations are not automatically saved to disc. Press **Store** to keep record of the measurements and annotations.

Distance measurement

1. Select **Dist** in the *Review* pane.
2. Left-click to place the first point. Move the mouse to the end point and left-click to place the end point.

   The measurement value is displayed

Area measurement

1. Select **Area** in the *Review* pane.
2. Left-click to place the first point. Move the mouse to outline the area and left-click to place the end point.

Annotation

1. Select **Annot** in the *Review* pane.
2. Move the annotation to the desired location and left-click to place the annotation. Type the desired text and left-click to end annotation.

Deletion

Deletion of all measurements and annotations:

1. Right-click on the image and select **Delete all measurements** in the context menu.

Single deletion:

1. Place the mouse cursor over the measurement or annotation to delete.
2. Press **Delete** on the alphanumeric keyboard.

   The annotation or measurement is deleted.

*NOTE: It is also possible to right click on the measurement or annotation to delete and select **Delete highlighted measurement** in the context menu.*

Deletion of examinations and files

1. Select the examination(s) or file(s) to be deleted.

*NOTE: Press **Ctrl** or **Shift** while selecting to do multiple selection.*

2. Right-click and select **Delete** in the context menu.

   A confirmation message is displayed.
3. Select **Yes** to confirm deletion.

   The selected items are deleted.

Save examinations to the computer

To save an examination or a file from a Vscan to the computer:

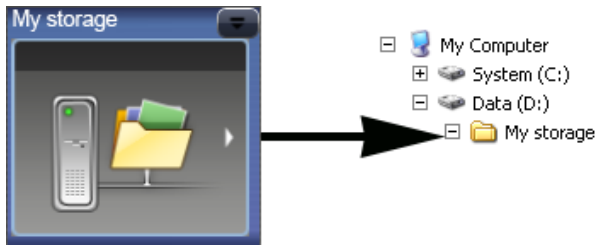
1. Select the examination or the file to save and press **Save as** .

   A *Browse* window is displayed.
2. Browse to the desired location where to store the files and press **Save**.

The local storage is automatically detected by the Vscan gateway software.

About local storage

When saving a file to the computer a folder named “Archive” is created at the selected location. The folder “Archive” contains the examinations stored in separate folders with unique names.



It is possible to disconnect the local storage to hide it from the list of devices in the Vscan gateway software.

To disconnect a local storage:

1. Press **Disconnect device** .

To reconnect the local storage to the Vscan gateway software:

1. Press **Open** .
   A *Browse* window is displayed.
2. Browse to the desired location, e.g. “My storage” folder and press **OK** in the *Browse* window.

NOTE: This folder should contain a subfolder “Archive” where the examinations are stored.

The local storage is displayed in the Device list of the Vscan gateway software.

Report

NOTE: The report function was introduced in the Vscan gateway software version 1.2.

A report containing still images, patient ID, patient information and comments can be created. The report can be printed and stored as a PDF file.

Examinations with an existing report are marked with a “R”.

The following is configurable (see ‘Report settings’ on *page 4-30*).

- The logo on the report heading
- The storage location of the reports

To create a report:

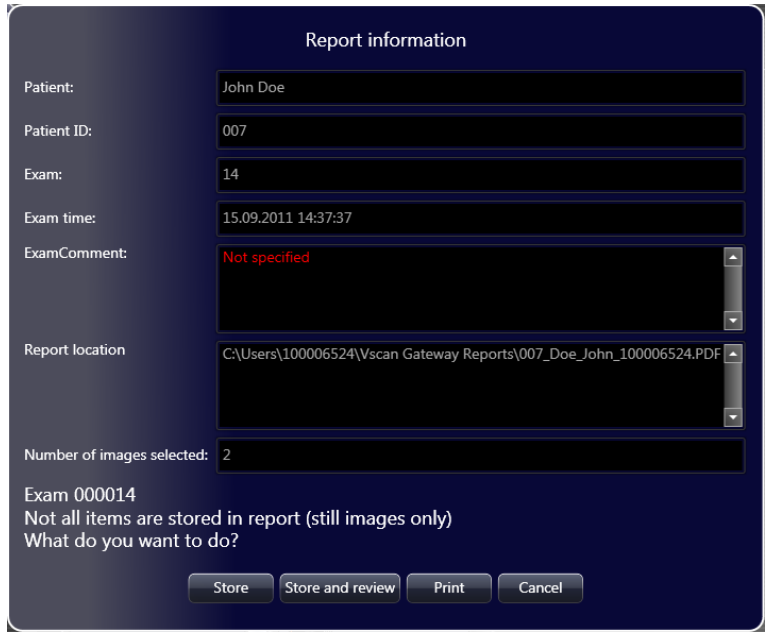
1. Select either an examination containing still images or one or several still images from an examination.
2. Press **Report** .

   If the examination has a report from before the user is asked to whether overwrite the report or not.

- Press **Yes** create a new report, the existing report will be deleted.
- Press **No** to keep the existing report. No new report is created.

NOTE: *If you wish to keep the existing report you may press **Open** and save the existing report as a new PDF with a different name and then press **Yes** to create a new report.*

The *Report information* screen is displayed.



The following information is displayed:

- **Patient name**: auto-populated from the *Assign patient information* screen. To change this information, see ‘Patient information’ on *page 4-23*.
- **Patient ID**: auto-populated from the *Assign patient information* screen. To change this information, see ‘Patient information’ on *page 4-23*.
- **Examination number**: determined by the system.
- **Examination time**: determined by the system.
- **Examination comment**: comments can be entered directly in this screen or from the *Assign patient information* screen.
- **Report location**: The storage location for the report created. To change the location see ‘Report settings’ on *page 4-30*.

3. Select one of the following:
   - **Store**: save the report.
   - **Store and review**: store the report and open it.
   - **Print**: store and print the report.
   - **Cancel**: no report is created.

E-mail

Image and voice notation files can be sent as e-mail attachment (compatible with Microsoft Outlook).

1. Select one or several files to be sent by E-mail.
2. Press **E-mail**  .

   An E-mail is created with the selected file(s) attached.

Setup screen

This screen is divided in three tabs:

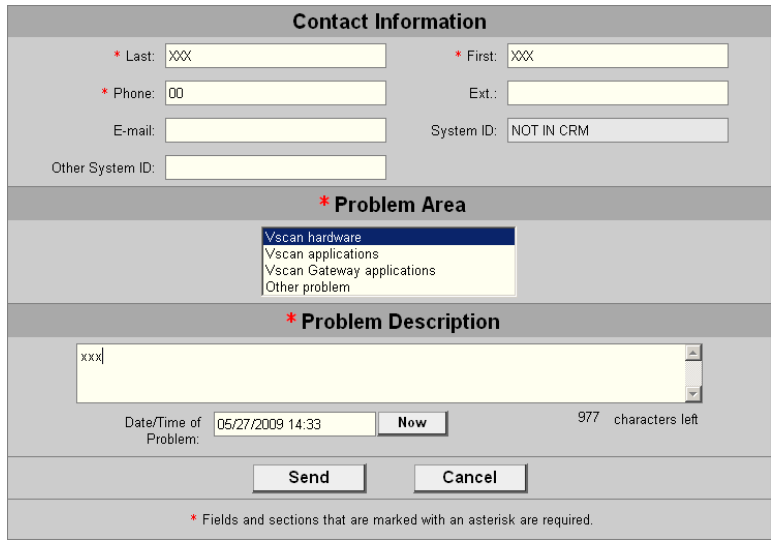
- **Home**: provide information about the Vscan gateway software and connected Vscan. From this screen the user can also:
  - Run a wizard to check basic software controls and configure the Insite service tool.
  - Change the language for the Vscan gateway software and manual.
  - Send request for service to GE (Hotline).
  - Save log file for Vscan gateway software or connected Vscan.
  - Configure the report function.
- **Diagnostics**: run diagnostic commands on the Vscan gateway software and connected Vscan.
- **Software**: install software update for the Vscan gateway software and connected Vscan.

Service request

NOTE: This feature is not available in Japan.

To send a service request to GE:

1. Press **Setup** .
2. In the Home page press **Contact hotline**.
   The *Contact GE* screen is displayed.



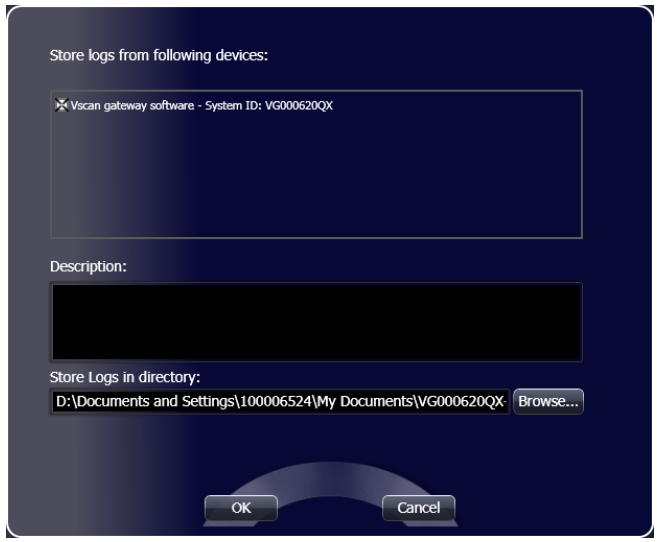
3. Fill inn the form. Fields and sections marked with an asterisk are required.
4. Press **Send**.

Generating a log file

In the event of error or system malfunction log files for the Vscan gateway and any Vscan that has been connected to the computer are available for GE service through the hotline system. If not able to send a request by using the Contact Hotline form in the *Setup* screen, the user can save log files for the Vscan gateway software or connected Vscan devices and send them to GE by other means (for instance by e-mail).

To save a log file:

1. Press **Setup** .
2. In the Home page press **Save Logs**.



3. In the *Save logs* window, enter a description of the problem. To save the log file to another location, press **Browse** and navigate to another location.
4. Press **OK**.

   A zip file is saved. The file can be sent to GE service as an attachment to an e-mail.

   The file naming convention for the log file is:

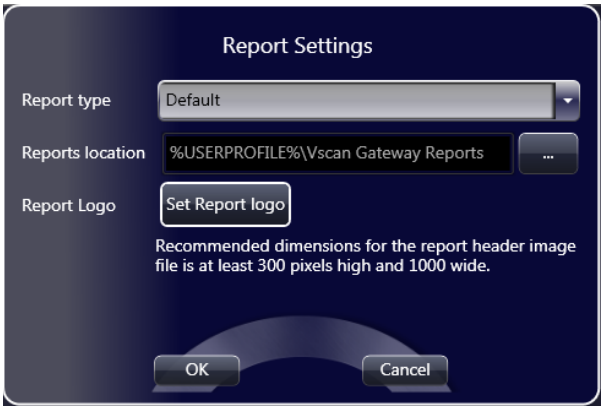
   - Vscan gateway software log file:

     <System ID>-LogFile-<yyyy-mm-dd>T<hh-mm-ss>
   - Vscan:

<Serial No>-LogFile-<yyyy-mm-dd>T<hh-mm-ss>

Report settings

1. Press **Setup** .
2. In the Home page press **Report Settings**.
   The *Report settings* window is displayed.



3. The following can be adjusted:
   - **Report type**: select a report template.
   - **Report location**: to change the storage location for the report, press the button next to the storage path, browse to the desired location and press **OK**.
   - **Report logo**: to insert a logo on the report header, press **Set report logo**, browse to the image file to insert and press **Open**.

NOTE: *Recommended image size: 1000 x 300 pixels. Image file format for the logo: bmp, jpg, png and gif.*

4. Press **OK** to close the *Report settings* window.

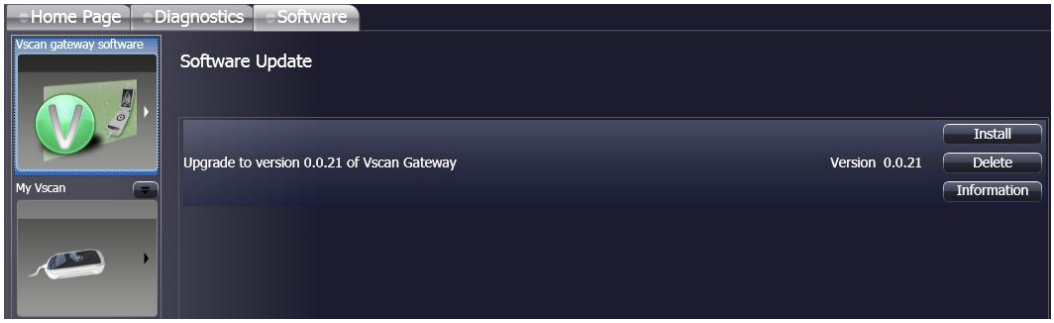
Software update

Software update for the Vscan gateway software and connected Vscan can be installed from the *Setup* screen. Available software updates are automatically detected and an **Update available** button is displayed in the upper right corner of the screen when starting Vscan gateway software.

Vscan gateway software update

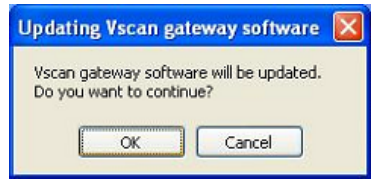
1. Press **Update available**.

The *Software* page in the *Setup* screen is displayed showing the available software update for the selected device.



2. Select the Vscan gateway software device and press **Install**.

   The Vscan gateway software is closed and a confirmation window is displayed.



3. Press **OK**.

   The installation process is started.

4. On the last screen, check the option **I would like to launch Vscan gateway software** and press **Finnish**.

   The new version of Vscan gateway software is started.

*NOTE: Press **Setup** , select the Software page and press **Delete** to remove the software upgrade that has been installed.*

NOTE: The procedure for software update installation from a CD is similar to the procedure described above.

Vscan unit software update

1. Place the Vscan on the Docking station. Open the display
2. Press **Update available**.

   The *Software* page in the *Setup* screen is displayed showing the available software update.

3. Select the Vscan device and press **Install**.

   An information window is displayed. Make sure to follow all the recommendations listed:

- Ensure that the power supply is connected to the Docking station while upgrading the software.
- DO NOT TURN OFF the Vscan unit while upgrading the software.

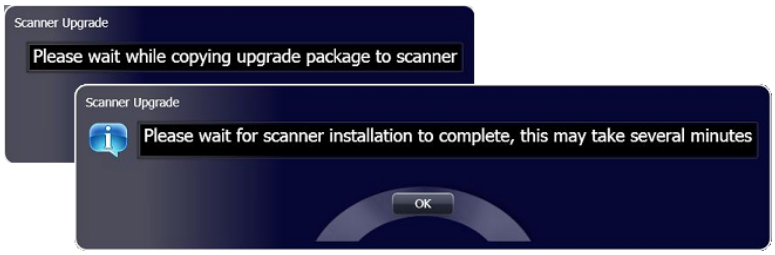
CAUTION

Do not turn off or disconnect power during the update. Doing so could cause an error requiring the device to be sent for repair.

4. Press **OK**.

   The software update files are copied and unpacked to the Vscan microSD card.
5. The Vscan is running a system test.
   - If the test failed, close the display to turn off the system and contact service.
   - If the test passed, the software update is installed. This may take several minutes.

     The following messages are displayed on screen.



     When the installation is done, the Vscan is turned off automatically. Close the display.
6. Open the display to restart the Vscan.

   The Vscan is running a system test.
   - If the test failed, close the display to turn off the system and contact service.
   - If the test passed the Vscan is ready for use.

*NOTE: The next time the Vscan is docked to the Vscan gateway software, pressing **Delete** in the Software page will remove the installed upgrade from the list.*

Vscan unit software update from a microSD card

If the software update is provided on a microSD card, proceed as follows:

1. Make sure the battery is fully charged.
2. Remove the Archive microSD card from the Vscan (see page 2-17).
3. Insert the Update microSD card in the Vscan (see page 2-18).
4. Place Vscan on the Docking station and make sure that the power supply is connected to the Docking station.
5. Open the display to start the Vscan.

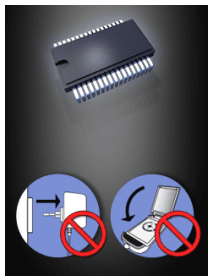
   The Vscan is running a system test.

   - If the test failed, close the display to turn off the system and contact service.
   - If the test passed the *Consult user documentation* screen is displayed.

6. Press **Store** and **Color** simultaneously to start the installation.

CAUTION

Do not turn off the Vscan during the update. Doing so could cause an error requiring the device to be sent for repair.



The unit is turned off automatically when the installation is completed. Close the display.

7. Remove the Update microSD card from the Vscan and reinsert the Archive microSD card.
8. Open the display to restart the Vscan.

The Vscan is running a system test.

- If the test failed, close the display to turn off the system and contact service.
- If the test passed the Vscan is ready for use.

Chapter 5

Vscan configuration

Contents:

Config menu

The following settings and functions are available from the *Config* menu.

	Item	Choice	Note
 Setup	Language	English, Norwegian, German, Dutch, Italian, French, Spanish, Portuguese, Russian, Greek, Danish, Swedish, Japanese and Chinese	
	Date	dd / MM / yy	Set current date
	Date format	dd / mmm / yy dd / mmm / yyyy dd / mm / yy mm / dd / yyyy mm / dd / yy mm / dd / yyyy	01 / AUG / 09 01 / AUG / 2009 01 / 08 / 09 08 / 01 / 2009 08 / 01 / 09 08 / 01 / 2009
	Time	hh:mm:ss	Set current time
	Time format	12 h 24 h	
	Auto Freeze	1, 3 or 5 min.	The Vscan enters in Freeze if idle for the time set.
	Reset exam number	OK, Cancel	The microSD card must be empty to reset the exam number to one.
	Brightness	Adjust monitor brightness. **Rotate** to adjust brightness and press **Select**.	Adjust brightness so that all the tones from the darkest to the lightest can be distinguished.
	Test	System diagnostics wizard to test the Vscan control unit and the probe.	Requires a restart of the Vscan.
	About	Displays system information (hardware and software)	This information may be required when contacting GE service.

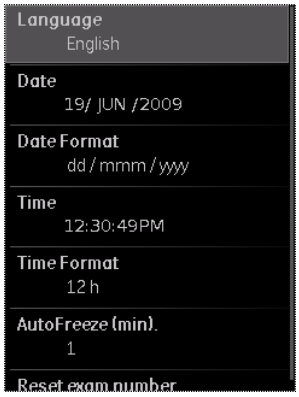
	Item	Choice	Note
	Shutdown		System shutdown procedure to use when cleaning Vscan.
	Activation	Displays the Activation key screen (see page 2-24)	

System setup adjustment

1. Press **Menu**.
2. In the main menu, use ◀ / ▶ to browse through the menu items and highlight **Config** ( ).
3. Press **Select**.

   The *Config* menu is displayed.
4. Use ◀ / ▶) to browse through the menu items and highlight **Setup** .
5. Press **Select**.

   The *Setup* screen is displayed.



6. Use ▲ / ▼ to highlight the item to adjust.
7. Press **Select** and use ▲ / ▼ to adjust the setting.
8. Press **Select** to confirm the adjustment.

NOTE: *For settings with multiple parameters (e.g. date and time), use ◀ / ▶ to navigate between the parameters.*

Chapter 6

Vscan maintenance

Contents:

System care and maintenance

CAUTION

The user must ensure that safety inspections are performed at least every 12 months according to the requirements of the patient safety standard IEC 60601-1 / UL60601-1.

Only trained persons are allowed to perform the safety inspections mentioned above.

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

To ensure that the Vscan 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

If any defects or damages are found on the control unit, the probe or its cable, DO NOT use the Vscan. 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 loose or missing hardware

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

Inspecting the probe

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

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

Cleaning the control unit, the display and the Docking station

Make sure the Docking station is disconnected from the AC adapter before cleaning.

1. Switch off the Vscan from the *Shutdown* menu (see page 3-2).
2. Moisten a soft, non-abrasive cloth with a mild, general purpose, non-abrasive soap and water solution.
3. Wipe the Vscan and the Docking station.
4. Wipe dry with a soft towel.

CAUTION Do not spray any liquid directly onto the Vscan or the Docking station.

NOTE: DO NOT scratch or press on any part of the Vscan with any sharp objects, such as pencils or pens, as this may result in damage of the Vscan.

Cleaning the probe

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

Disinfection

Recommended germicides

In order to provide users with options in choosing a germicide, GE routinely reviews new medical germicides for compatibility with the Vscan 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 transducer.

The following germicides can be used on the Vscan and its probe.

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

WARNING

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

Never use thinner, benzene, alcohol (ethanol, methanol, or isopropyl alcohol), abrasive cleaners, or other strong solvents, as these may cause damage to the control unit, the display or the probe.

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

Disinfecting the control unit

1. After cleaning, the control unit may be wiped with a tissue sprayed with a recommended germicide.

Disinfecting the probe

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

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 to achieve the desired effect.

DO NOT soak or saturate the probe with solutions containing alcohol, bleach, ammonium chloride compounds or hydrogen peroxide.

CREUTZFELD-JACOB DISEASE

Neurological use on patients with this disease must be avoided. If the Vscan becomes contaminated, there is no adequate disinfecting means.

Reinstallation of the factory software

A microSD card with the factory software is provided in a sealed envelope in case a clean re-installation of the factory software is required.

CAUTION

IMPORTANT!

Reinstallation of the factory software should only be done in agreement with service.

Procedure

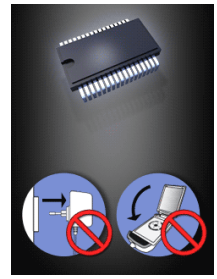
1. Make sure the battery is fully charged.
2. Remove the Archive microSD card from the Vscan (see page 2-17).
3. Insert the Factory software microSD card in the Vscan (see page 2-18).
4. Place Vscan on the Docking station and make sure that the power supply is connected to the Docking station.
5. Open the display to start the Vscan.

   After about 30 seconds, the *Consult user documentation* screen is displayed.

6. Press **Store** and **Color** simultaneously to start the installation.

CAUTION

Do not turn off the Vscan or disconnect the power supply during the installation. Doing so could cause an error requiring the device to be sent for repair.



The unit is turned off automatically when the installation is completed.

7. Remove the Factory software microSD card from the Vscan and reinsert the Archive microSD card.

   The Vscan is now reset with the factory software and needs to be activated again (see page 2-22).

Troubleshooting

Vscan troubleshooting

Problem	Possible cause	Solution
Vscan has no power.	Battery not inserted.	Insert battery (see page 2-15).
	Battery not charged	Charge the battery (see page 2-11)
	Battery defect or end of life	Contact GE Service (see page 1-7).
	Broken battery connection	Contact GE Service (see page 1-7).
Vscan is not charging.	Battery not inserted.	Insert battery (see page 2-15).
	Battery defect or end of life	Contact GE Service (see page 1-7).
	Broken battery connection	Contact GE Service (see page 1-7).
	Defect AC adapter or charger	Contact GE Service (see page 1-7).
	Mains power is down.	
	Temperature is outside the specified limits	Ensure the ambient temperature is within the specified limits (see page i-3)
When opening the display, the screen is white and nothing is happening.	Connection broken during software loading.	Contact GE Service (see page 1-7).
Parts of the image is missing when scanning.	Channels are missing	Contact GE Service (see page 1-7).
Noise when moving the probe cable	Defect probe cable	Contact GE Service (see page 1-7).
No image displayed when scanning	Defect probe	Contact GE Service (see page 1-7).

Vscan gateway software troubleshooting

Problem	Possible cause	Solution
No connection between Vscan and Vscan gateway software	Vscan is not properly docked on the docking station.	Ensure the Vscan is properly docked.
	The Docking connectors on the Vscan and the Docking station are dirty.	Verify that the docking connectors on the Vscan and on the Docking station are clean. Remove any dust or foam rests from the connectors.
	Vscan is not turned on.	Ensure that the Vscan is turned on (see page 3-2).
	The microSD card is not inserted properly, or missing.	Make sure the microSD card is properly inserted (see page 2-17).
	USB cable is not connected.	Make sure the USB cable is properly connected in both ends.
	USB port on the PC is defect.	Try another USB port on the PC.
Vscan movies are not playing in Vscan gateway software.	The display adapter requirements are not met.	See 'Computer requirements' on *page 4-4*.
	The display adapter driver is not up-to-date.	Update the display adapter driver to the latest version. New driver can be obtained from the computer or display adapter manufacturer.
	Hardware acceleration for the display adapter is turned off.	Turn on hardware acceleration for the display adapter. This can be done in the display adapter Control panel / Properties dialog • Windows Vista: Control Panel / Appearance and Personalization / Adjust Screen Resolution / Advanced Settings • Windows XP: Control Panel / Display / Settings / Advanced
	Direct 3D Acceleration is disabled.	Turn on Direct3D Acceleration. 1. Press **Start** and select **Run**. 2. Type **DxDiag** and press **OK**. 3. Select the **Display** tab and verify that the Direct3D Accelerator is turned on.
	Desktop sharing or remote desktop softwares (e. g. NetMeeting) are running.	This type of program may influence the display of Vscan movie in Vscan gateway software. Try to close this type of program when using Vscan gateway software.

Problem	Possible cause	Solution
Vscan display is flashing while scanning	Automatic reduction of the frame rate due to increase of the operating temperature after extended scanning.	Restart the Vscan to enable normal frame rate again. To help keeping the Vscan operating temperature at an optimal functional level, and to ensure longer scanning time with maximum frame rate, it is recommended to hold the Vscan so that there is good contact between the device and the hand.

Chapter 7

Safety

Contents

Introduction

This chapter describes the important safety measures which should be taken before operating the Vscan. Procedures for simple care and maintenance of the Vscan 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:

d  DANGER

Indicates that a specific hazard exists that, given inappropriate conditions or actions, will cause:

- Severe or fatal personal injury
- Substantial property damage

w  WARNING

Indicates that a specific hazard exists that, given inappropriate conditions or actions, will cause:

- Severe or fatal personal injury
- Substantial property damage

c  CAUTION

Indicates that a potential hazard may exist that, given inappropriate conditions or actions, can cause:

- Minor injury
- Property damage

Owner responsibility

It is the responsibility of the owner to ensure that anyone operating the Vscan 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 the installation, maintenance, troubleshooting, calibration and repair of the equipment.

The owner of the Vscan 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 the Vscan 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.

CAUTION

For USA only:

Federal law restricts this device to use by, or on the orders of, a physician.

CAUTION

This Vscan 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

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 the Vscan, 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

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. It is recommended to use voice notation to identify the patient. Identification errors could result in an incorrect diagnosis.

If the Vscan needs to be sent for repair, ensure that any patient information is erased from the microSD card, or that the microSD card is removed from the Vscan before shipping. In case that any patient information is still residing on the Vscan, GE will contact the customer and request for urgent collection of that patient information. GE will keep this patient information in a secure environment for a maximum period of one month. All patient information will be permanently deleted at that point.

Be certain to ensure privacy data of patient information.

Diagnostic information

The images and calculations provided by the system are intended for use by competent users, as a diagnostic tool. They are explicitly not to be 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 utility 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 in order to optimize its performance and to recognize possible malfunctions. Application training is available through the sales representative.

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

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 infection. 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 live pads. 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 ‘Vscan maintenance’ on *page 6-1*.

Personnel and equipment safety

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, 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, or to unplug it.
- If flammable substances are detected, evacuate and ventilate the area before turning off the Vscan.

Electrical hazard

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's protective covers. No user-serviceable parts are inside. If servicing is required, contact GE service.
- Do not spray or place liquids on or above the Vscan. 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

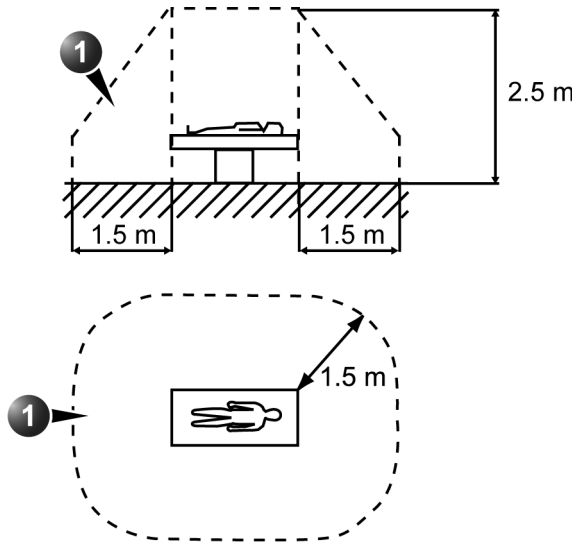
The Vscan is an internally powered device, type BF.

The AC/DC adapter is Class II.

External Connection

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

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



1. Patient environment

Figure 7-1. 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 health-care 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 60601-1-2 (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 page 7-15).

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.

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 page 7-15 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 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 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.

Electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emission CISPR 11 EN55011	Group 1	The ultrasound unit 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 CISPR 11 EN55011	Class B	The ultrasound unit 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 IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 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 transients / bursts IEC 61000-4-4	±2 kV for power-supply lines ±1 kV for input/output lines	±2 kV ±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (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 sec.	Compliance for all test levels. Controlled shutdown with return to pre-disturbance condition after operator's intervention. (Power-on switch)	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 IEC 61000-4-8	3 A/m	3 A/m 50 and 60 Hz	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.			

Guidance and manufacturer's declaration – electromagnetic immunity			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance[c]**
Conducted RF IEC 61000-4-6 Conducted RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms [V1] 3 V/m [E1]	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 $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ 800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$ 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).[b] 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 is affected by absorption and reflection from structures, objects and people.			
[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. [c] See examples of calculated separation distances in next table.			

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.			
	Separation distance according to frequency of transmitter m		
Rated maximum output of transmitter W	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 is:

- The ability to display physiological images as input for diagnosis by trained physician.
- The ability to display quantified data as input for diagnosis by trained physician.
- The display of ultrasound indexes as aid for safe use of the Vscan.

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
- 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 510(k) guidance of September 9, 2008.

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 510(k) guidance of September 9, 2008.

Acoustic output and display on the Vscan

MI and TI values are displayed on the scanning screen. For all imaging modes of Vscan, TIS equals TIB and is displayed as TI.

The Vscan chooses the correct category based on mode of operation and chosen application, and presents only one TI to the operator. It is therefore important that the operator chooses the right application.

The maximum possible MI and Ispta on the Vscan is within the limits set in Track 3 in the FDA 510(k) guide of September 9, 2008, 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.

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 page 8-1). 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.
- Better image quality yields faster clinical results, making it possible to complete the relevant ultrasound examination more rapidly. Therefore, any control that improves the quality of the examination can help to reduce patient exposure, even though it may not directly affect acoustic output.

Application selection

Selecting the application appropriate to a particular ultrasound examination automatically provides acoustic output limits within FDA guidelines 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. The choice of mode (black and white or color imaging) determines whether the ultrasound beam is stationary or in motion. This greatly affects the energy absorbed by the tissue (see ‘Acoustic Output Reporting Tables’ on *page 8-2* 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 **A**s **R**easonably **A**chievable (ALARA) while acquiring clinical information.

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 an optimal image is achieved, the need for increasing acoustic output or prolonging the exposure cannot be justified. It is recommended that all users receive proper training in applications before performing them in a clinical setting. Contact the GE sales representative for training assistance.

Track 3 ALARA Educational Program

The user should be familiar with the document “Medical Ultrasound Safety”, published by AIUM (American Institute of Ultrasound in Medicine), see page 8-8. This document is acceptable to FDA as meeting the content of the ALARA educational program. In addition to the AIUM document, the sections ‘Acoustic output and display on the Vscan’ on *page 7-16* and ‘System controls affecting acoustic output’ on *page 7-17* should be studied carefully in order to implement ALARA.

Environmental protection

System disposal

The device must not be destroyed by incineration. Please return the device to your local GE representative for disposal.

Probe overview

Probe	Mode	Technical data
G3S	Black and white Color	Frequency: 1.7–3.8 MHz Foot print: 13 x 19 mm

Maximum probe temperature

Probe	Max Temp (Simulated use)	Max Temp (Still air)
G3S	40.0	34.5

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

1. Thermocouple was placed at the geometric center of the lens.
2. a: Thermal phantom at 37 °C for non-external probes.
   b: 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 IEC 60601-2-37.

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

Device labels and symbols

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

Label	Purpose	Location
CE 0470	CE mark	Vscan control unit
	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 control unit Vscan AC adapter Vscan battery (GM-BAT)
	Follow instructions for use. Read and understand all instructions in the User's Manual before attempting to use the ultrasound unit.	Vscan control unit
	TÜV NRTL mark	Vscan control unit
	Equipment Class II for products not relying protective earth such as products having double or reinforced insulation.	Vscan AC adapter
	Type BF Applied Part symbol (see page i-3).	Vscan control unit
	Direct Current	Vscan control unit Vscan AC adapter
	Alternating current	Vscan AC adapter
	Output, use only on Vscan device.	Vscan Docking station Vscan battery charging compartment Vscan charger (GM-CHA)
	Input, use only Vscan charger (GM-CHA).	Vscan control unit

Label	Purpose	Location
	Rechargeable, use only Vscan battery (GM-BAT).	Vscan control unit Vscan Docking station
	AC adapter and charger	Plastic bag containing the Vscan AC adapter and charger
	Manufacturer address	Vscan control unit Vscan battery (GM-BAT)
	Manufacturing date (month/year)	Vscan control unit
MFD	Manufacturing date (yymmdd)	Vscan AC adapter
	Part number	Vscan control unit
	Serial number	Vscan control unit
	Batch number	Vscan Docking station Vscan battery charging compartment Vscan charger (GM-CHA)
	For indoor use only	Vscan AC adapter
	Do not expose the battery to direct flame.	Vscan battery (GM-BAT)
	Do not attempt to disassemble the battery.	Vscan battery (GM-BAT)

Chapter 8

Appendix

Contents:

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:

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
P_1	W_{o1}	*Bounded Output Power* / Power emitted from the central 1cm of aperture

IEC	FDA	Meaning—IEC 60601-2-37 / FDA & NEMA UD2, UD3
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.
- c: This formulation for TIS is less than that for an alternate formulation in this mode.

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 transducer/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/IEC 60601-2-37

Transducer Model: G3S

Operating Mode: black and white

Index Label				MI	TIS			TIB	TIC
					scan	non-scan		non-scan	
						Aaprt≤1	Aaprt>1		
Global Maximum: Index Value				1,48	0,21	a	a	a	b
	IEC	FDA	Units						
Associated Acoustic Parameter	p_{ra}	$p_{r.3}$	(MPa)	2,03					
	P	W_o	(mW)		32				
	min of [$P_\alpha(z_s)$, $I_{ta,\alpha}(z_s)$] [($W_{3(z1)}$,$I_{TA.3}(z1)$)]								
	z_s	z_1	(cm)						
	z_{bp}	z_{bp}	(cm)						
	z_b	z_{sp}							
	z *at max.* Ipi,α	z_{sp}	(cm)	4,18					
	$d_{eq}(z_b)$	$d_{eq}(z_{sp})$	(cm)						
	f_{awf}	f_c	(MHz)	1,88	1,88				
	Dim of A_{aprt}	X	(cm)		1,39				
		Y	(cm)		1,15				
Other Information	t_d	PD	(us)	2,11					
	prr	PRF	(Hz)	35					
	p_r *at max.* I_{pi}	p_r@PII$_{max}$	(MPa)	2,66					
	d_{eq} *at max.* I_{pi}	d_{eq}@PII$_{max}$	(cm)						
	Focal Length	FL_X	(cm)		0,30				
		FL_Y	(cm)		0,36				
	$I_{pa,\alpha}$ *at max. MI*	$I_{PA.3}$@MI$_{max}$	(W/cm^2)	101					
Operating Control Conditions	Image Depth (cm)			6	6				
	Application			Ob	Ob				

a), b) see ‘Explanation of Footnotes’ on *page 8-3*.

Transducer Model: G3S

Operating Mode: color

Index Label				MI	TIS			TIB	TIC
					scan	non-scan		non-scan	
						Aaprt≤1	Aaprt>1		
Global Maximum: Index Value				1,23	0,77	a	a	a	b
	IEC	FDA	Units						
Associated Acoustic Parameter	p_{ra}	$p_{r.3}$	(MPa)	1,61					
	P	W_o	(mW)		94				
	min of [$P_\alpha(z_s)$, $I_{ta,\alpha}(z_s)$] [($W_{.3(Z1)}$,$I_{TA.3}$(z1))]								
	z_s	z_1	(cm)						
	z_{bp}	z_{bp}	(cm)						
	z_b	z_{sp}							
	z *at max.* Ipi,α	z_{sp}	(cm)	4,28					
	$d_{eq}(z_b)$	$d_{eq}(z_{sp})$	(cm)						
	f_{awf}	f_c (2D) (CFM)	(MHz)	1,88	1,75 2,45				
	Dim of A_{aprt}	X	(cm)		1,39				
		Y	(cm)		1,15				
Other Information	t_d	PD	(us)	0,73					
	prr	PRF	(Hz)	68					
	p_r *at max.* I_{pi}	p_r@PII$_{max}$	(MPa)	2,13					
	d_{eq} *at max.* I_{pi}	d_{eq}@PII$_{max}$	(cm)						
	Focal Length	FL_X (cm) (2D) (CFM)			0,39 0,21				
		FL_Y (cm) (2D) (CFM)			0,36 0,30				
	$I_{pa,\alpha}$*at max. MI*	$I_{PA.3}$@MI$_{max}$	(W/cm^2)	207					
Operating Control Conditions	Image Depth (cm)			6	8				
	Application			Ob	Cardiac				

a), b) see ‘Explanation of Footnotes’ on *page 8-3*.

Measurement accuracy

The measurement accuracy of the system is validated on images of an ultrasound phantom with speed of sound of 1540 +/-10 m/s. For in-vivo ultrasound images the accuracy may be slightly reduced due to variations of the speed of sound in different kinds of tissue.

Distance measurement

The distance measurement accuracy is 7% of the measured distance, for distances >1 cm.

Area measurement

The area measurement accuracy is 10% of the measured area for areas larger than 1 cm^2.

Medical Ultrasound Safety

The user should be familiar with the enclosed document “Medical Ultrasound Safety”, published by AIUM (American Institute of Ultrasound in Medicine). This document is acceptable to FDA as meeting the content of the ALARA educational program. ALARA is an acronym for the principle of prudent use of diagnostic ultrasound by obtaining the diagnostic information at an output that is As Low As Reasonably Achievable.

NOTE: *This document is only available in English.*

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