GE Healthcare

Technical Publications

Vscan

Version 1

CE 0470

User Manual

GM092207 — English

Rev. 01

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.

GE Healthcare

Manual status:
GM092207-01
3 November 2011

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 Healthcare 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:


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.


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.


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 Healthcare 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

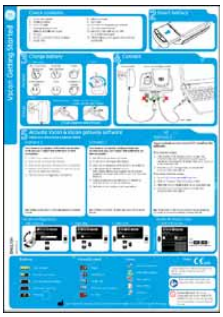
Preparing the Vscan for use

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

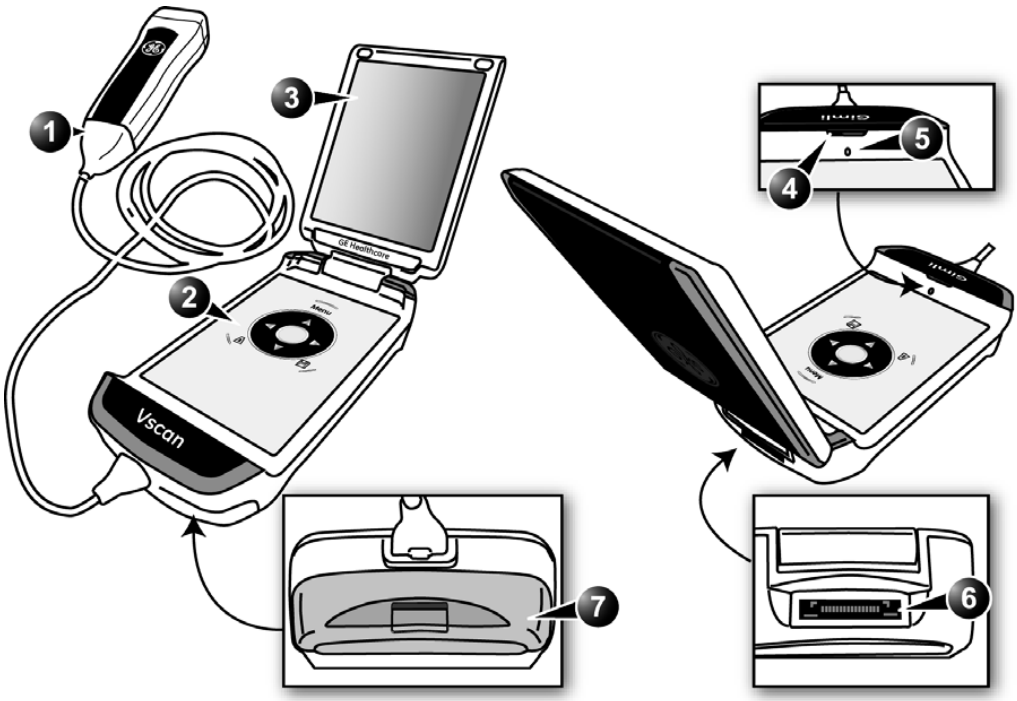
	Quick card
 	CD-ROM Vscan gateway software CD-ROM user manual
	Service contact information
	microSD card with factory SW (In a sealed envelope – only to be used in agreement with service organization)

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

System description

System overview

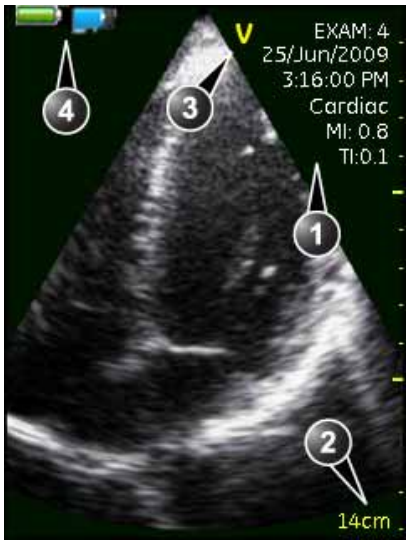
The Vscan device



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

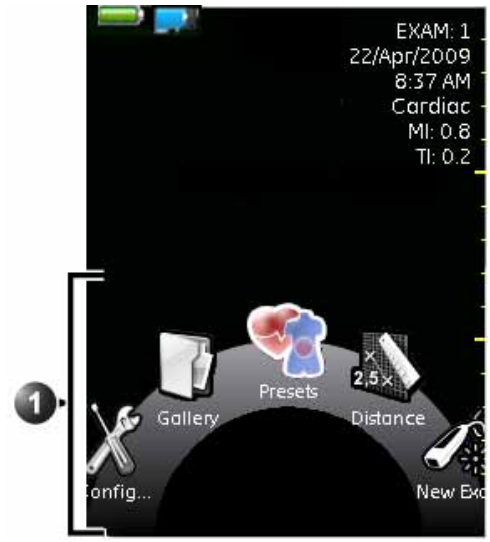
Figure 2-1. The Vscan device

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

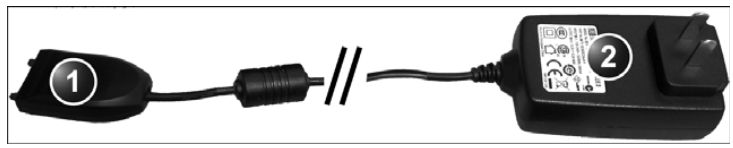
Figure 2-4. External battery charging compartment

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.

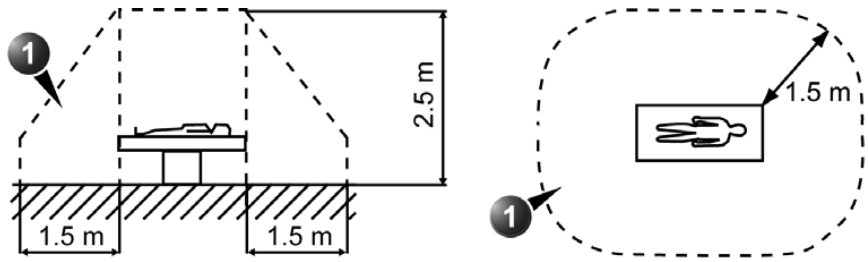


1. Charger (GM-CHA)
2. AC/DC adapter

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

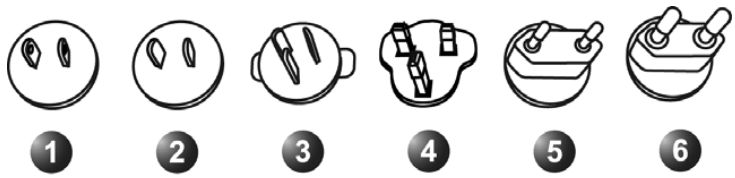
Figure 2-6. Patient environment

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)

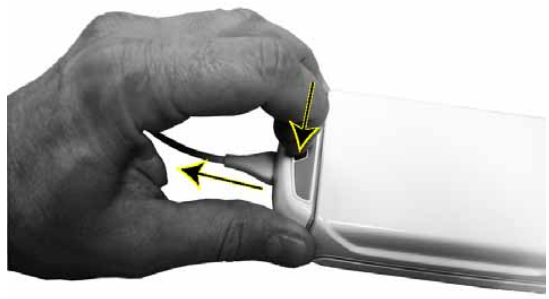
To remove the battery

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

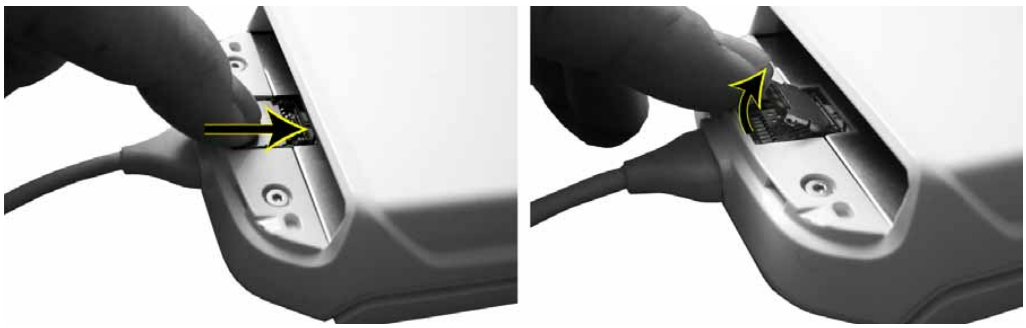
Image acquisitions and voice notation recordings are stored to a microSD card (MicroSD or MicroSDHC, speed grade 6 or lower).

The microSD card is located under the battery.

Removing / inserting the microSD card

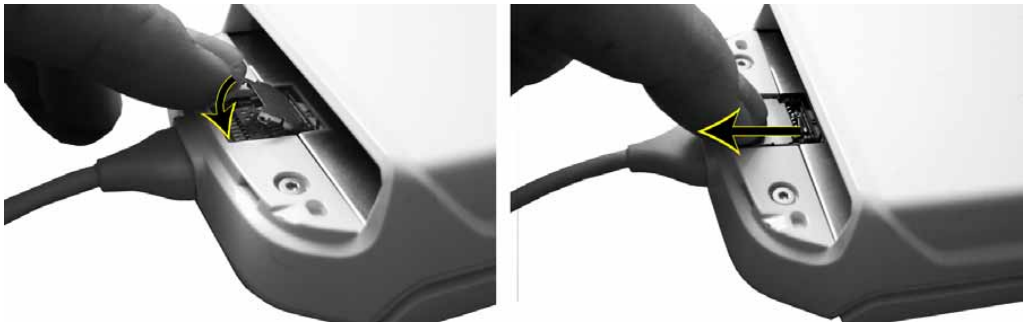
To remove the microSD card

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



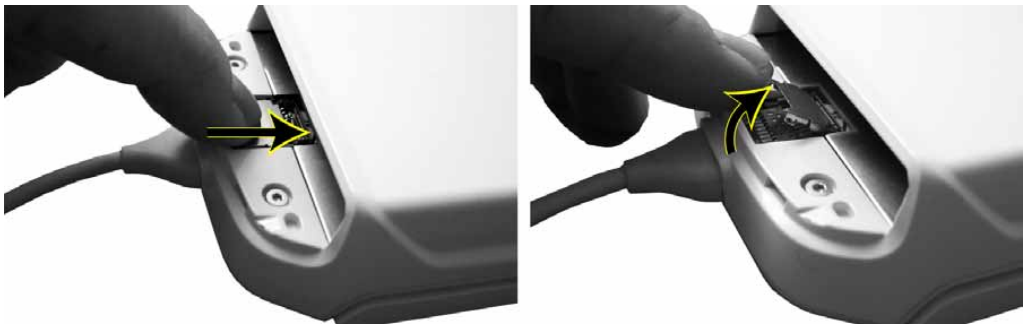
3. Remove the microSD card from the card slot.

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

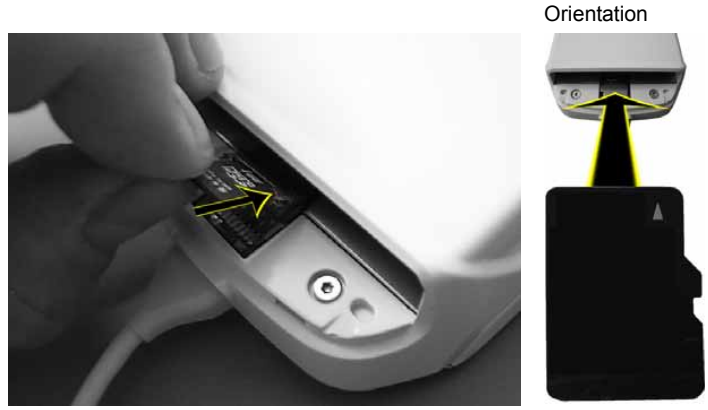


To insert the microSD card

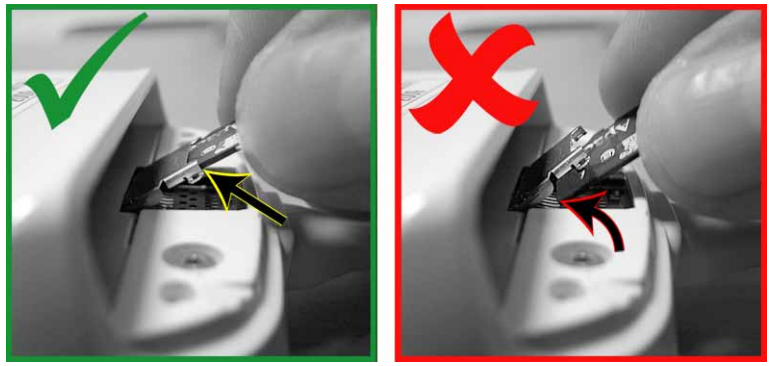
1. Remove the battery (GM-BAT) (see page 2-15).
2. Slide and raise the card slot.



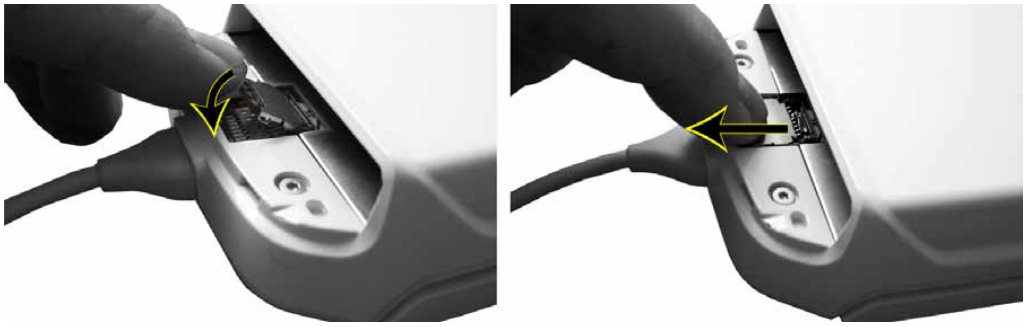
3. Insert the microSD card in the card slot.



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 4-8*).
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

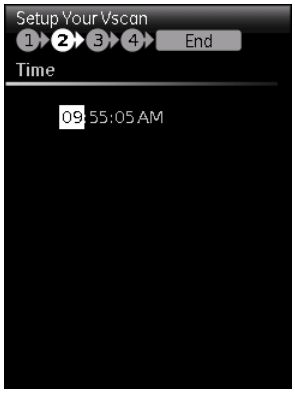
1. Use ▲ / ▼ to browse through the available languages until the desired language is highlighted.

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

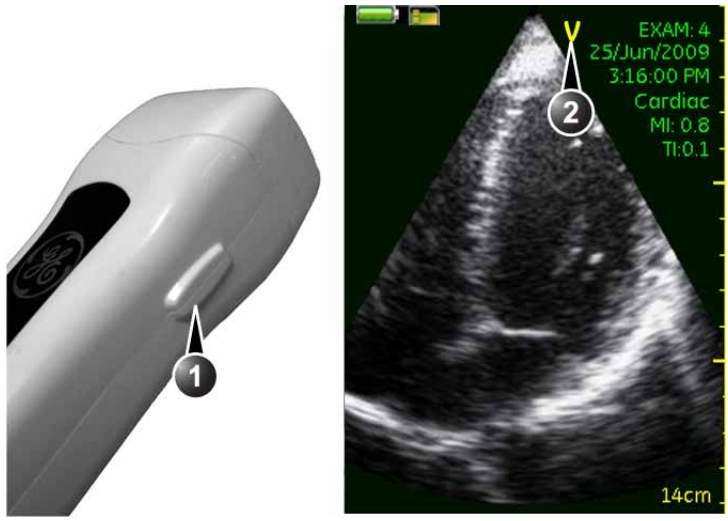
Like most high frequency computing devices, the electronic components of Vscan will generate some heat while operating normally and as intended. Vscan is equipped with safety mechanisms which will automatically reduce computing speed (frame rate), and ultimately shut down the device, before any risk 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).

GE Healthcare 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.

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

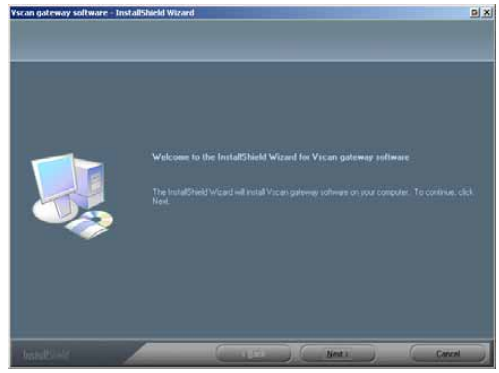
Do NOT attempt to install the Vscan gateway software on computers running software monitoring patient condition.

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.

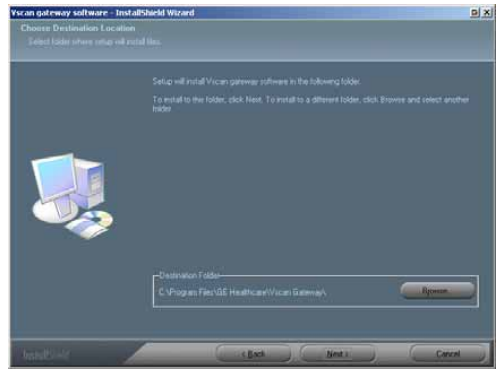
   The installation software starts automatically and a *Welcome* window is displayed.



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**.

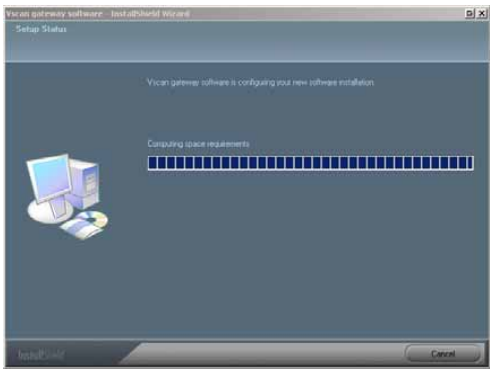
   The *Destination* window is displayed.

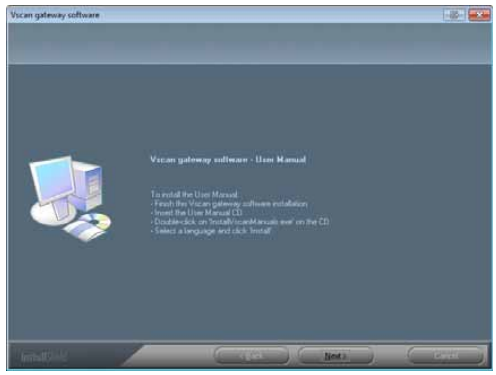


3. Press **Next** to install Vscan gateway software to the default folder or press **Browse** to install Vscan gateway software to another location.

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

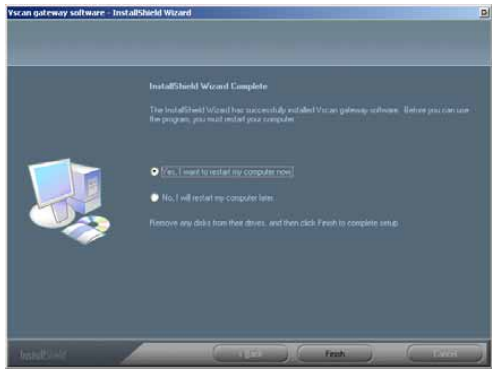
The user manual can be installed after Vscan gateway software is installed and activated.





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 4-8*.
- 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.

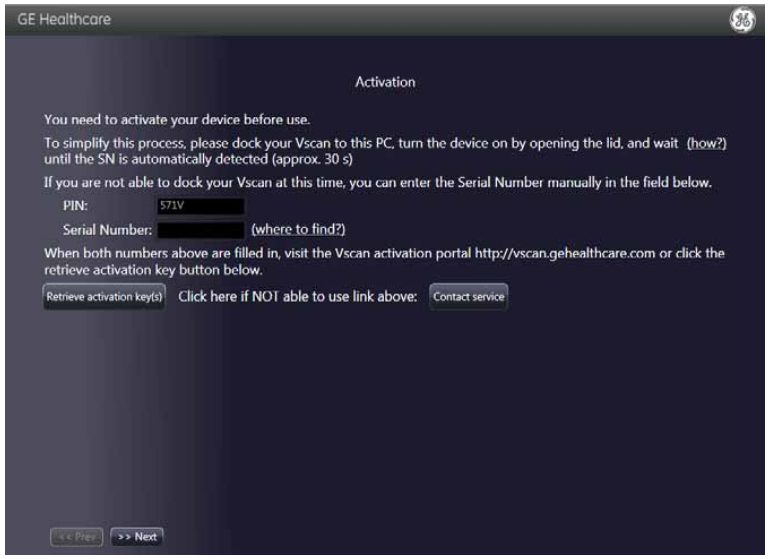
1. After installation of Vscan gateway software, double-click on the **Vscan gateway software** icon on the desktop to start the program.

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

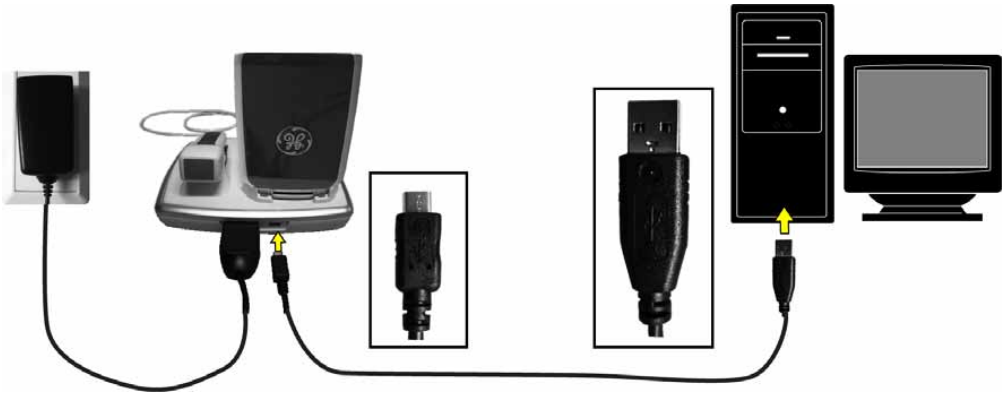
The *Language* window is displayed.

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*).

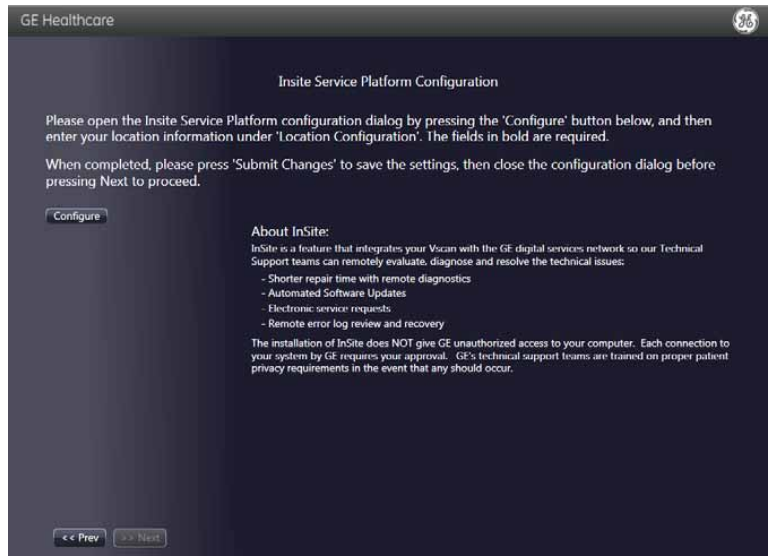
   Write down the Vscan Serial Number.

9. Press **OK**.

   The *Insite configuration* window is displayed.

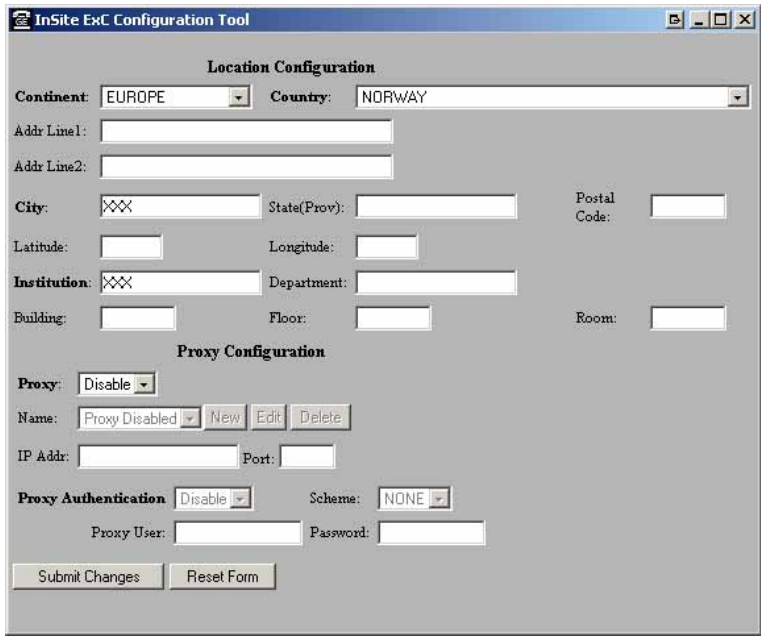
   Insite is a feature that integrates your Vscan with the GE digital services network so our technical support teams can remotely evaluate, diagnose and resolve technical issues.

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.

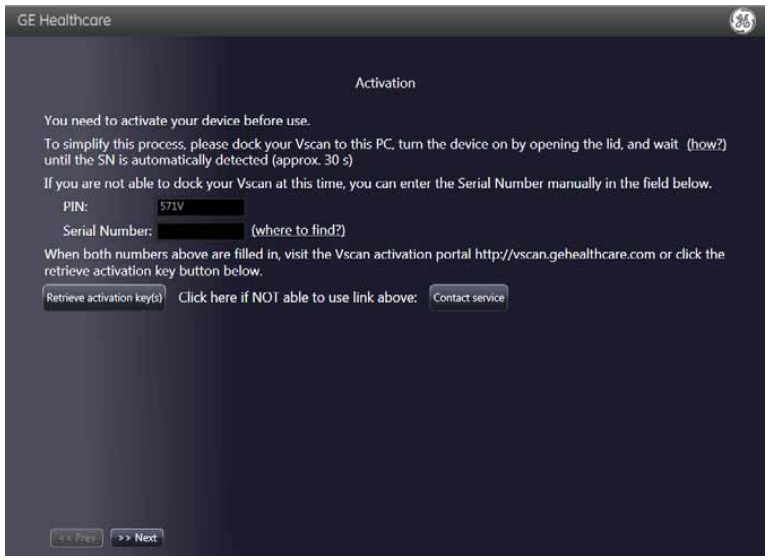
1. After installation of Vscan gateway software, double-click on the **Vscan gateway software** icon on the desktop to start the program.

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

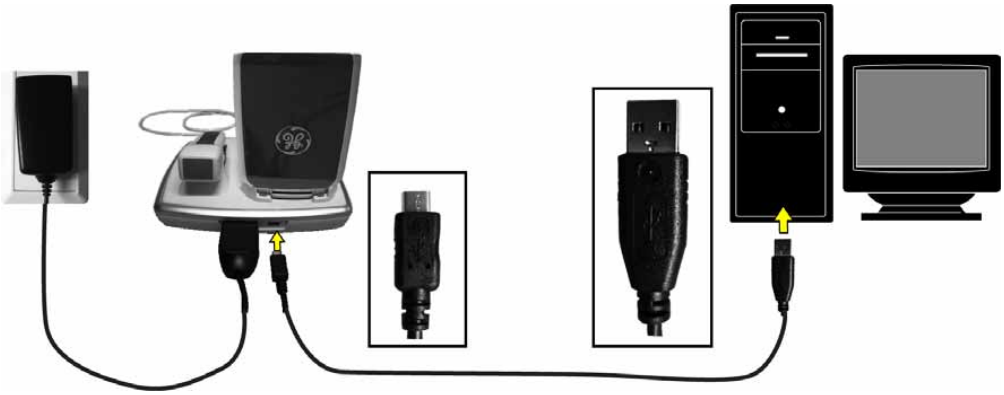
The *Language* window is displayed.

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.

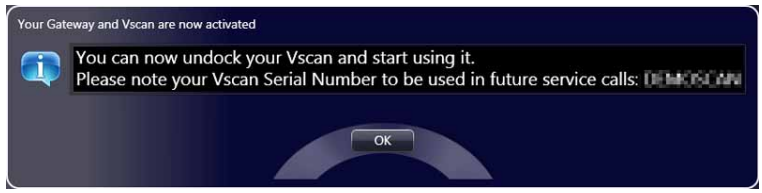
5. Press **Next** in the *Vscan gateway software activation* window.

   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**.

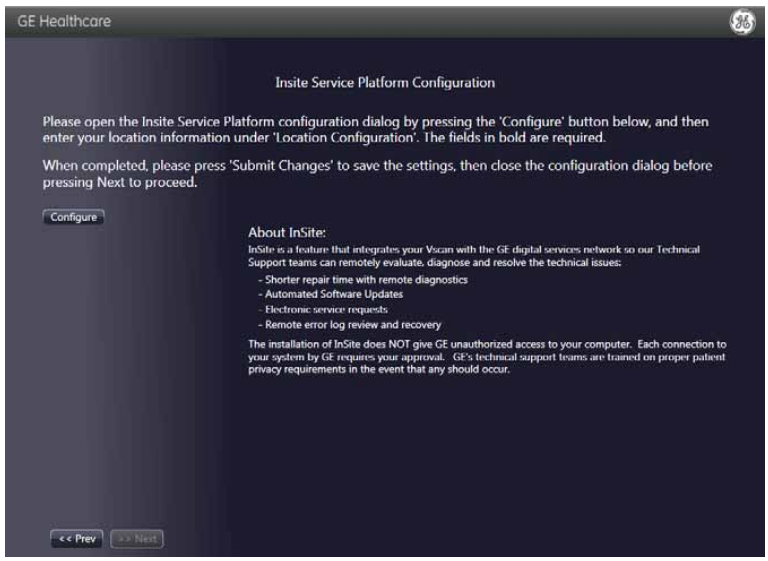
   The Vscan unit is now ready for first time configuration (see ‘Configuration’ on *page 2-22*).

   Write down the Vscan Serial Number.



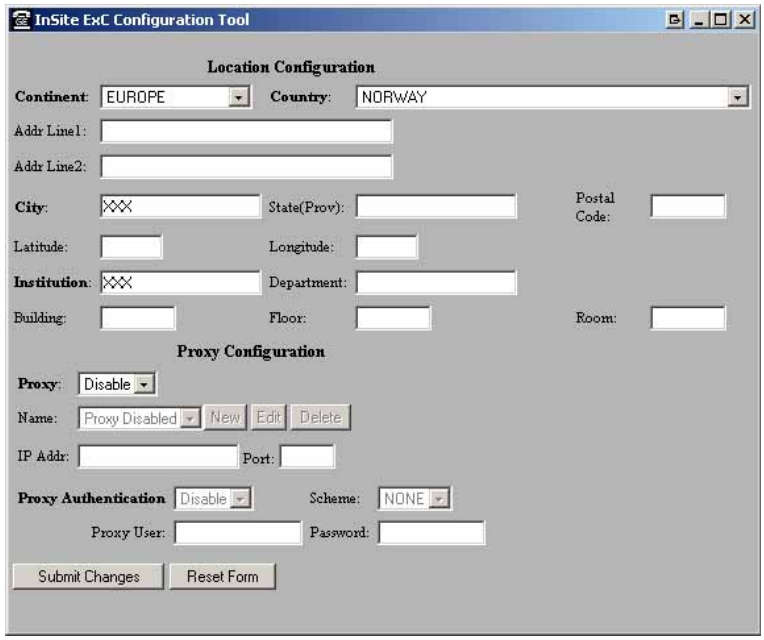
8. Press **OK**.

   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 Healthcare.

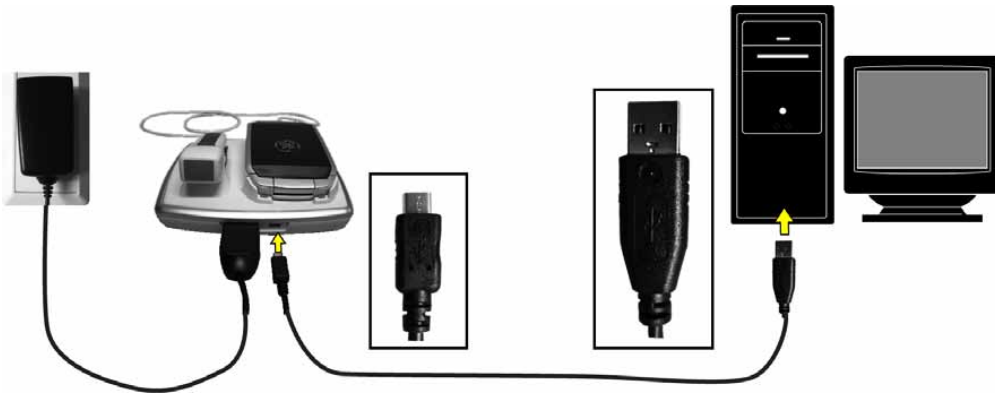


Figure 4-1. Connection setup

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.

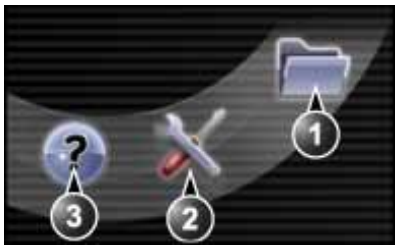
The connected Vscan is automatically detected and mounted in Vscan gateway software.

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:

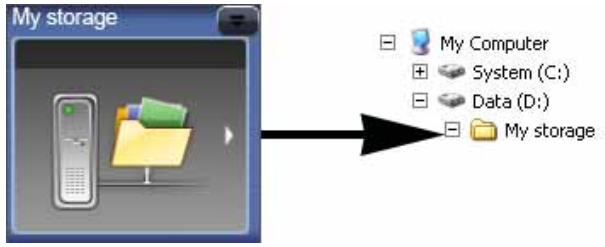
1. Select the examination or the file to save and press **Save as** .

   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:

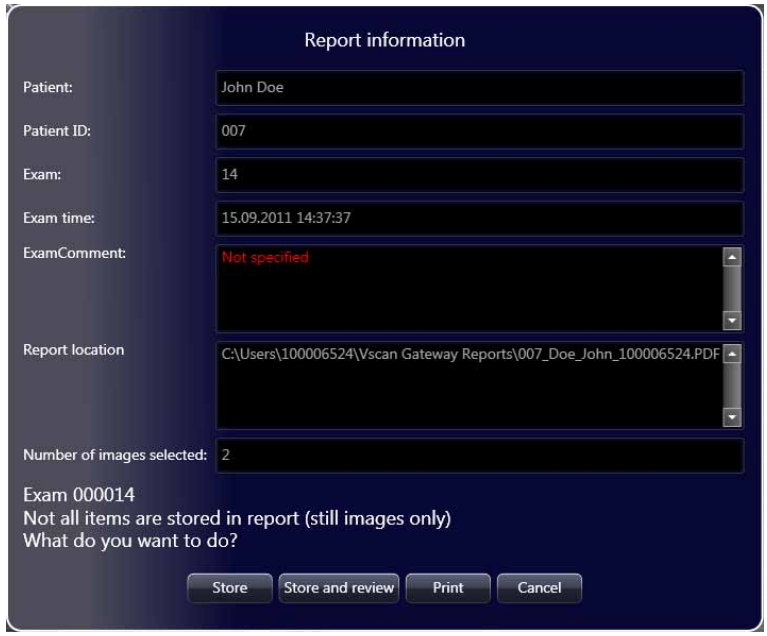
1. Select either an examination containing still images or one or several still images from an examination.
2. Press **Report** .

   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:

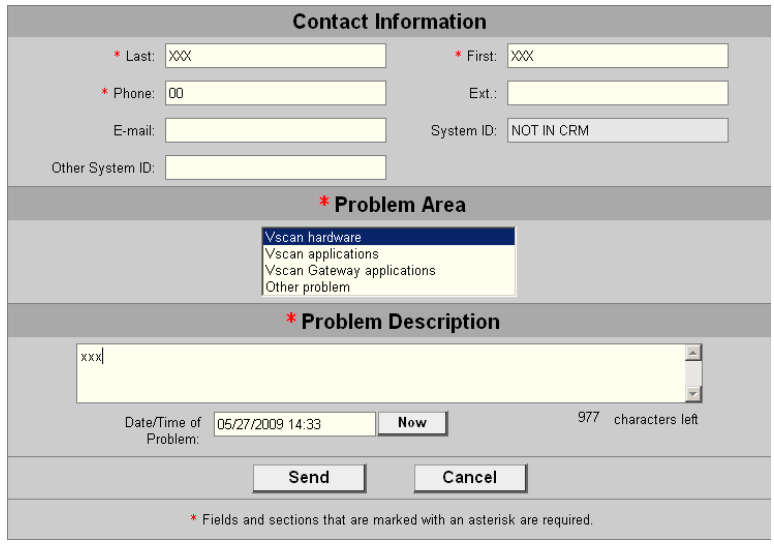
- **Home**: provide information about the Vscan gateway software and connected Vscan. From this screen the user can also:
  - Run a wizard to check basic software controls and configure the Insite service tool.
  - Change the language for the Vscan gateway software and manual.
  - Send request for service 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.



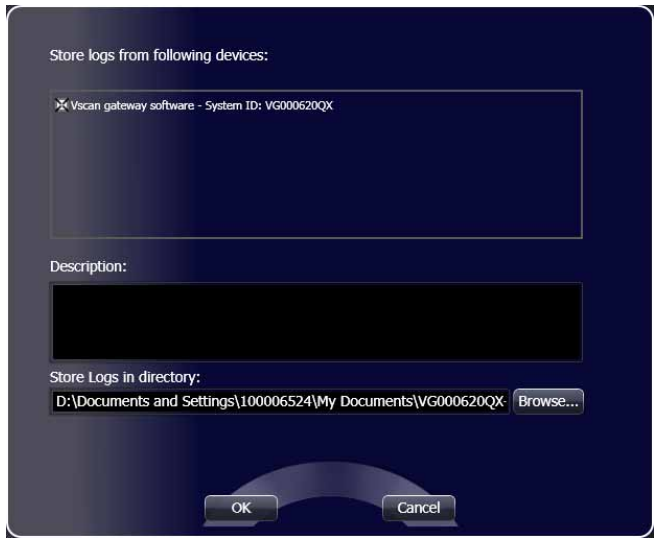
3. Fill inn the form. Fields and sections marked with an asterisk are required.
4. Press **Send**.

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.

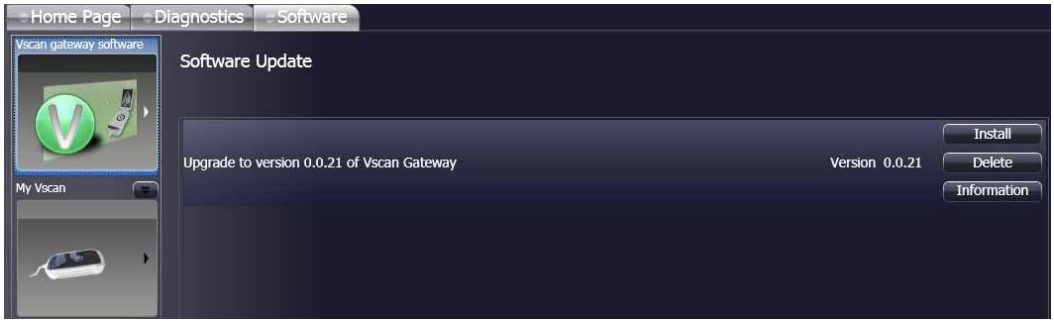
Software update

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.

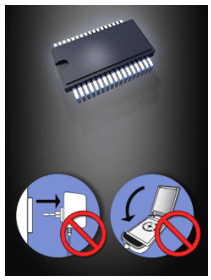
   The Vscan is running a system test.

   - 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.

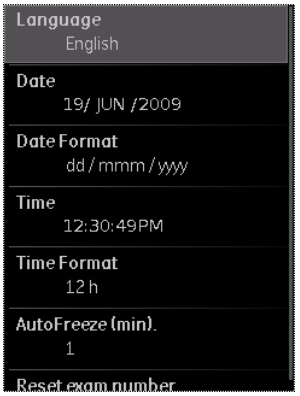
	Item	Choice	Note
	Shutdown		System shutdown procedure to use when cleaning Vscan.
	Activation	Displays the Activation key screen (see page 2-24)	

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 Healthcare 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.

WARNING

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

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

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

WARNING

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

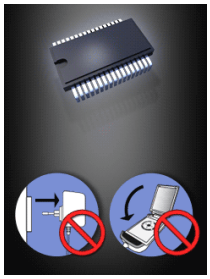
1. Make sure the battery is fully charged.
2. Remove the Archive microSD card from the Vscan (see page 2-17).
3. Insert the Factory software microSD card in the Vscan (see page 2-18).
4. Place Vscan on the Docking station and make sure that the power supply is connected to the Docking station.
5. Open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

DANGER

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

- Severe or fatal personal injury
- Substantial property damage

WARNING

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

- Severe or fatal personal injury
- Substantial property damage

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


WARNING

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

Always include proper identification with all patient data. 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

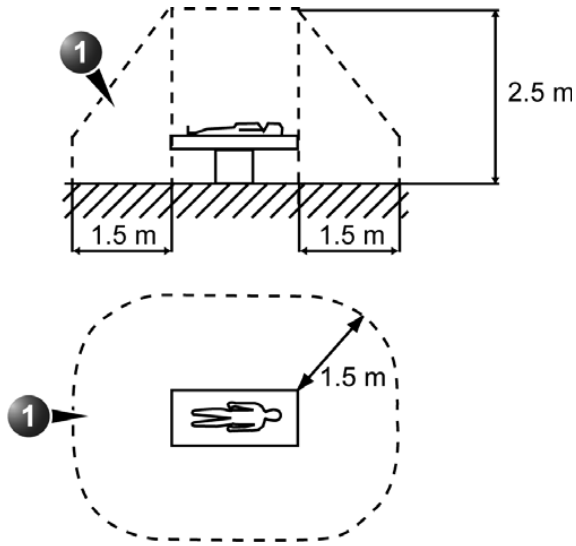
The Vscan is an internally powered device, type BF.

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 Healthcare 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 Healthcare 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).

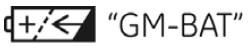
NOTE: Thermal phantom made with tissue-mimicking material as referenced in IEC 60601-2-37.

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.*

To contact the AIUM concerning their publications:

American Institute of Ultrasound in Medicine Laurel, Maryland 20707-590

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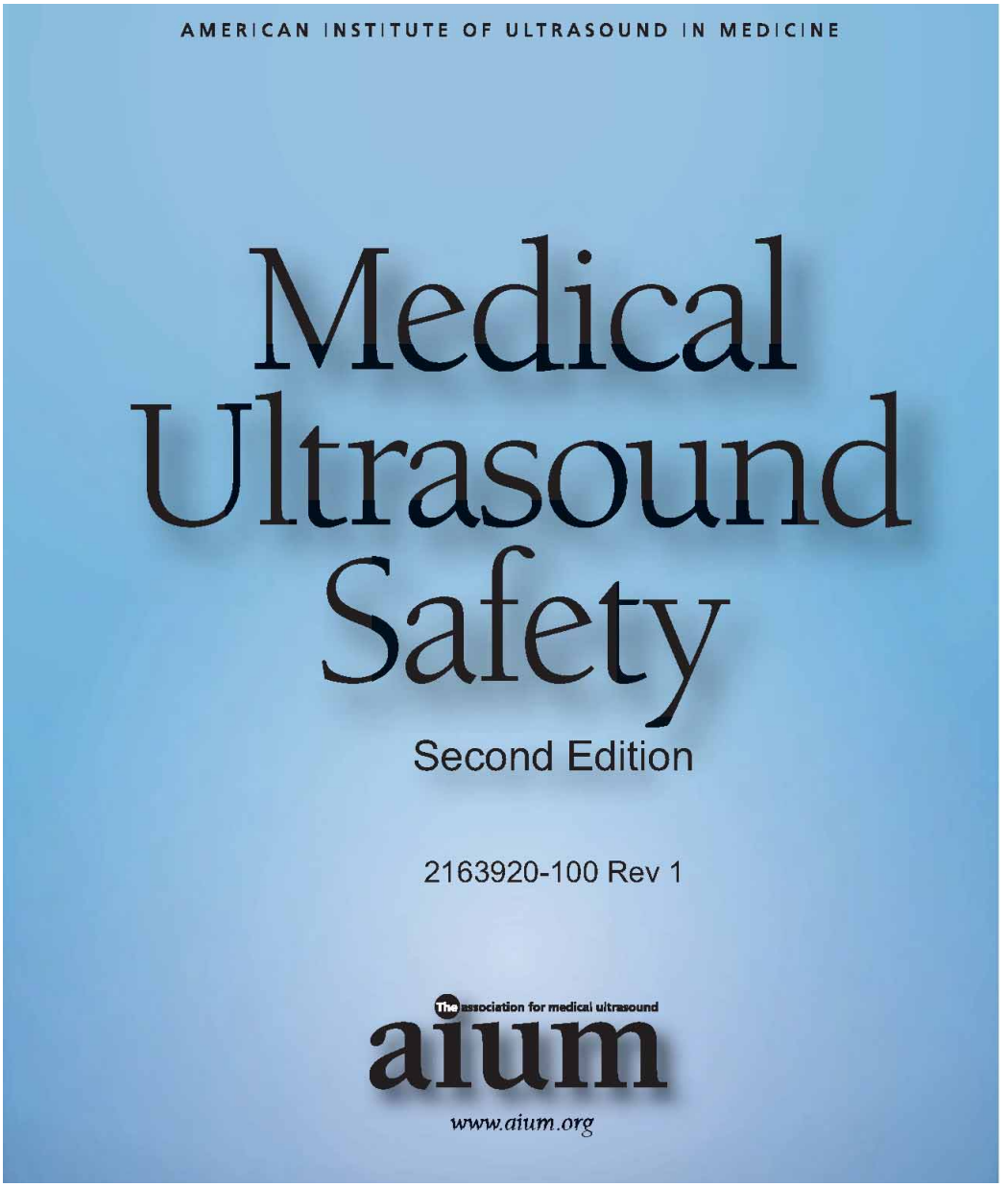
Medical Ultrasound Safety



AMERICAN INSTITUTE OF ULTRASOUND IN MEDICINE

Medical Ultrasound Safety

Second Edition

Part 1: Bioeffects and Biophysics
Part 2: Prudent Use
Part 3: Implementing ALARA

www.aium.org

The AIUM Executive Office is located at 14750 Sweitzer Ln, Suite 100, Laurel, MD 20707-5906.

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Table of Contents

Preface to the First Edition

With the availability of an output display in some present and in future diagnostic ultrasound equipment and the potential for higher output capabilities within these devices, it is incumbent on the user to be knowledgeable of the uses of this equipment and the potential for ultrasound-induced bioeffects. The responsibility for patient safety is falling more heavily on the ultrasound equipment user's shoulders, and the need for an educational background in these uses and bioeffects is evident. In other words, there is a shift in responsibility for patient safety from the manufacturer to the user. In this regard, this tripartite brochure has been generated to provide the user with a working background and general principles that will provide for the understanding of the purpose and use of the Output Display Standard and how this display can be used to obtain diagnostic information with ultrasound exposure as low as reasonably achievable. The user education requirement represents a new level of responsibility that will permit increased ultrasound diagnostic capabilities within the context of user controlled ultrasound exposure. Information regarding ALARA and possible ultrasound bioeffects described in this brochure also applies to equipment without an output display.

—Michael S. Tenner, MD
AIUM Past President

Preface to the Second Edition

Many technological advances in ultrasonic scanning have occurred since the publication of the first edition. The improved instrumentation has fostered an ever-increasing range of clinical applications. Ultrasound imaging has become an integral part of virtually all areas of medicine. The number of ultrasound examinations has continually increased and is now in the millions each year. Along with this increased use there is a significant benefit to more patients, but at the same time more individuals are exposed to greater amounts of ultrasound energy. Furthermore, some new techniques, such as the introduction of contrast agents, significantly increase the risk of possible harmful effects from ultrasound examinations. Health care professionals need to be concerned that patients are not exposed to any unnecessary risk. The purpose of this manual is to help the health professional be aware of the potential harmful effects of ultrasound and how to minimize their occurrence.

—Marvin C. Ziskin, MD
Chairman, Revision Task Force

Introduction

A new feature, called the output display, is now available on current and future diagnostic ultrasound equipment. The output display provides the user with an indication of the potential for bioeffects that might be caused by the ultrasound energy being emitted. With this information, users can better control the diagnostic ultrasound equipment and examination to ensure that needed diagnostic information is obtained with a minimum of risk to the patient.

To get the most benefit from the output display, the user should have a basic understanding of the nature of ultrasound-induced bioeffects, how to conduct an examination that minimizes the potential for bioeffects, and how to operate the controls of the equipment used in the examination.

This publication is divided into 3 parts. Part 1 describes ultrasound-induced bioeffects and why we should be concerned about them. Part 2 describes the risks and benefits of conducting diagnostic examinations and introduces the concept of ALARA, ie, ultrasound exposure that is as low as reasonably achievable. Using ALARA, we can obtain needed diagnostic information with minimum risk to the patient. Part 3 describes how to implement ALARA on equipment with and without an output display. With an output display, we have the best information about the potential for bioeffects and can make the best decisions.

Each manufacturer's equipment has somewhat different control features. This manual can only provide general principles about ALARA and diagnostic ultrasound equipment. Please refer to the user documentation for your particular equipment to learn the details of its particular controls and output displays.

Acknowledgments

First Edition

Since 1991, the development of this ultrasound education publication has gone through a number of style and format changes and involved dedicated professionals from a number of organizations. Initially, 3 videotapes were planned, with the creation of 3 scripts. What finally emerged is this publication. There are many individuals to thank. Without their assistance, this publication would not have been possible.

Contributors to the First Edition (1994) included:

American College of Cardiology
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- Jannet Lewis, MD

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US Food and Drug Administration
Mel Greberman, MD
Jerry Harris, PhD
Hector Lopez, PhD
Robert Phillips, PhD
Robert Sibley
Melvin Stratmeyer, PhD

Special recognition is given to Chas Burr for his extensive revisions to the final content of the First Edition and to the coeditors: William D. O'Brien, Jr, PhD, and Terrence J. Sweeney.

Second Edition

The Second Edition was prepared by a special task force of the AIUM Bioeffects Committee. The members of the task force were:

John G. Abbott, PhD
Jacques S. Abramowicz, MD
Charles C. Church, PhD
Gerald R. Harris, PhD
Marvin C. Ziskin, MD, Chair

Valuable suggestions were made by other members of the AIUM Bioeffects Committee, especially Timothy A. Bigelow, PhD, J. Brian Fowlkes, PhD, and Michael L. Oelze, PhD.

The Second Edition was approved by the AIUM Bioeffects Committee on November 9, 2008, and then by the AIUM Board of Directors on November 10, 2008.

Part 1

Bioeffects and Biophysics

Chapter 1
Is It Safe?

Issues Addressed:
- Why it is important to know ultrasound physics
- What dose-effect studies tell us
- Mechanisms of ultrasound-induced biological effects
- History of ultrasound
- Prudent use

Everyone thinks ultrasound is safe.

Everyone thinks ultrasound is safe

Q. Everyone thinks that ultrasound is safe. We keep hearing "no known instance of human injury as a result of exposure to diagnostic ultrasound." So why do we have to learn about biophysics and bioeffects?

There is a potential risk.

There is a potential risk

A. When ultrasound propagates through human tissue, there is a potential for tissue damage. There has been much research aimed at understanding and evaluating the potential for ultrasound to cause tissue injury. Through these studies, we are trying to determine the exact mechanisms responsible for ultrasound-induced bioeffects and apply that information to diagnostic ultrasound. Many studies are dose-effect studies. These laboratory studies give us 2 things: First, they provide an opportunity to use much higher exposure levels than those currently used in a diagnostic ultrasound examination to thoroughly test the safety of ultrasound, and second, they permit a detailed study of mechanisms thought to be responsible for ultrasound-induced bioeffects.

Part 1

Dose-effect studies

Dose-effect studies

Q. So dose-effect studies are performed at higher intensities than diagnostic ultrasound?

A. Much higher levels. In fact, virtually all ultrasound-induced adverse biological effects have occurred at these higher intensity levels.

Q. What's been learned from the dose-effect studies?

Thermal and nonthermal mechanisms

Thermal and nonthermal mechanisms

A. So far, we've deduced that 2 mechanisms are known to alter biological systems. One, called the "thermal mechanism," refers to heating of soft tissue and bone. The other, the "nonthermal mechanism," involves mechanical phenomena such as cavitation, although nonthermal mechanisms include more than cavitation alone. You can think of cavitation as the interaction of ultrasound with tiny bubbles in tissue and liquids.

History of ultrasound

History of ultrasound

Q. How long have we known of the potential hazards of ultrasound?

A. In 1880, two French scientists, Jacques and Pierre Curie, discovered piezoelectricity, the basis for ultrasonic transducers. About 35 years later, another French scientist named Paul Langevin developed one of the first uses of ultrasound, underwater sound ranging of submerged objects, known today as sonar. In the process, he discovered and reported that very high-intensity ultrasonic levels could have a detrimental effect on small aquatic animals.

Ten years later, scientists Wood and Loomis conducted experiments that substantiated Langevin's observation. Then, in 1930, Harvey published a paper about the physical, chemical, and biological effects of ultrasound, reporting that alterations were produced in a variety of organisms, cells, tissue, and organs. Long before anyone even thought of using ultrasound to produce images of the human body, it was already known that high levels of ultrasound were hazardous. The pioneering engineers

and clinicians who designed the first ultrasound imaging devices knew about the potential for disrupting biological tissue.

Thus, there has been concern about potential harmful effects throughout the entire period of diagnostic instrumentation development.

If there's a potential for bioeffects . . .

If there's a potential for bioeffects . . .

Q. If there's a potential for bioeffects, why do we use ultrasound?

A. Ultrasound is widely used because it provides many clinical benefits to the patient and has an outstanding safety record. Furthermore, in the absence of contrast agents, there has never been a documented instance of a patient being injured from this diagnostic modality.

No patient injury has ever been reported from diagnostic ultrasound

Q. If there is a potential for ultrasound-induced bioeffects, why has there been such a good safety record?

Diagnostic ultrasound equipment is regulated by the Food and Drug Administration

Diagnostic ultrasound equipment is regulated by the Food and Drug Administration

A. As the uses of medical devices have grown and more application areas and equipment have been developed, regulations have been enacted to provide for patient safety concurrent with equipment development. In 1976, the Medical Device Amendments to the Food, Drug, and Cosmetic Act were enacted requiring the US Food and Drug Administration (FDA) to regulate all medical devices, including diagnostic ultrasound equipment. The FDA has required manufacturers of diagnostic ultrasound equipment to keep acoustic output below that of machines on the market before 1976, the year the amendments were enacted. Manufacturers bringing new products to market must compare the various performance characteristics of ultrasound equipment, including acoustic output, to devices previously approved for marketing.

Within these "limits," ultrasound has shown itself to be a safe and effective diagnostic tool for medical application. But it is important to remember that the pre-1976 output levels are based in history, not on scientific safety evaluations.

Part 1

In June 2005, the American Institute of Ultrasound in Medicine (AIUM) approved the Official Statement *Conclusions Regarding Epidemiology for Obstetric Ultrasound*:

There is insufficient justification to warrant conclusion of a causal relationship between diagnostic ultrasound and recognized adverse effects in humans

"Based on the epidemiologic data available and on current knowledge of interactive mechanisms, there is insufficient justification to warrant conclusion of a causal relationship between diagnostic ultrasound and recognized adverse effects in humans. Some studies have reported effects of exposure to diagnostic ultrasound during pregnancy, such as low birth weight, delayed speech, dyslexia, and non–right-handedness. Other studies have not demonstrated such effects. The epidemiologic evidence is based on exposure conditions prior to 1992, the year in which acoustic limits of ultrasound machines were substantially increased for fetal/obstetric applications."

History of ultrasound in medicine

History of ultrasound in medicine

Q. Why is there more discussion of ultrasound safety now than in the past?

Higher outputs bring potentially greater risk

Higher outputs bring potentially greater risk

A. The question of safety is being discussed more because more and more applications are being found, and the industry is producing technically sophisticated devices that provide more diagnostic information. Dialogue among the medical community, manufacturers, and the FDA has resulted in a standard that allows higher outputs for greater diagnostic capability. This will improve some imaging and Doppler situations but with greater risk and greater operator responsibility.

Prudent use

Prudent use

Just because we haven't detected bioeffects on humans at diagnostic levels doesn't mean that they don't exist. We know the potential for risk exists. It's important for ultrasound users to know about biophysics and bioeffects so they can make informed decisions about the use of ultrasound and can reduce the chances of bioeffects occurring. In the future, more and more decisions about the use of ultrasound output levels will be made by equipment operators.

The use of ultrasound in medicine began in the 1950s. At that time, the number of applications was limited. The uses for ultrasound grew in the 1950s, adding applications such as cardiology, obstetrics, gynecology, vascular ultrasound, ophthalmology, and the imaging of regions of the body, such as the female breast and male pelvis. By the early 1960s, most of the basic ultrasound applications used today had been attempted, although with much less diagnostic content than today. Clinical use continued to grow during the 1970s with the introduction of real-time scanning.

Originally, the efficacy of diagnostic ultrasound depended entirely on the natural acoustic properties of body tissue. Most applications continue to do so, but the late 1980s saw the production of stabilized gas-filled microbubbles for use as ultrasound contrast agents. Similar in effect to magnetic resonance or computed tomographic contrast, ultrasound contrast agents improve the diagnostic information available to the clinician from standard imaging modalities. Significantly, they have also allowed the development of entirely new imaging techniques. However, because these microbubbles can respond to ultrasound much more strongly than tissue alone, thus increasing the likelihood of an adverse effect, they must be used with care and only by qualified operators.

Early examinations were conducted entirely through the skin surface, but intracavitary and intraoperative applications have undergone a recent surge as manufacturers and clinicians seek to expand the diagnostic potential of ultrasound. Today, the clinical uses for ultrasound are many and varied, and diagnostic ultrasound is one of the fastest growing imaging techniques in medicine. Surveys in the United States indicate that a very high percentage of pregnant women are scanned to obtain fetal health information. Currently, there are hundreds of thousands of medical ultrasound scanners in use worldwide. This equipment handles millions of examinations each year. And the number continues to grow.

Notes

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Part 1

Bioeffects and Biophysics

Chapter 2

Thermal Bioeffects

Issues Addressed:

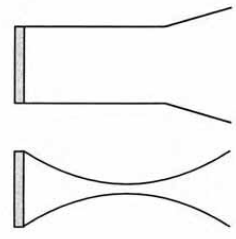
- Focused and unfocused ultrasound fields
- Spatial and temporal considerations
- Attenuation, absorption, and scattering
- Soft tissue, layered, and fetal bone models
- Soft tissue, layered, and fetal bone heating
- Axial temperature increase profiles

Q. If ultrasound causes tissue temperature to rise, where is the largest temperature rise found?

A. The highest temperatures tend to occur in tissue in the region between where the ultrasound beam enters tissue and the focal region.

Because the temperature elevation is related to both ultrasonic power and the volume of exposed tissue, we need to keep in mind whether the beam is scanned or unscanned, in other words, whether the equipment moves the beam or keeps it stationary. Scanned modes, such as B-mode imaging and color flow Doppler, distribute the energy over a large volume. In scanned modes, the highest temperature is frequently at the surface where the ultrasound enters the body.

Unscanned modes, such as spectral Doppler and M-mode, concentrate the power along a single line in the patient and deposit energy along the stationary ultrasound beam. Energy is distributed over a much smaller volume of tissue than in the scanned case. In unscanned modes, the highest temperature increase is found between the surface and the focus. In other words, the hottest point is along the center axis of the beam and proximal to the focal point but not at the focal point. The exact loca-



Focused and unfocused ultrasound fields

Part 1

tion depends on the tissue attenuation and absorption properties and the beam's focal length. For long focal lengths, the location of the maximum temperature elevation may lie closer to the surface, but for short focal lengths, it is generally closer to the focus.

Spatial considerations

$$Intensity = \frac{power}{area}$$

Q. Focusing the ultrasound beam increases the temperature?

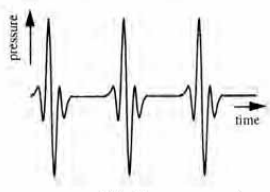
A. Focusing concentrates the power in the beam onto a small area, thereby improving image lateral resolution but also causing higher intensities and the potential for higher temperatures.

Q. What other aspects of the ultrasound beam affect the temperature?

Temporal considerations

A. An important aspect is time.

Ultrasonic waves can be emitted in pulsed wave form. There's a burst of energy, and then there's a period of silence. Then, there's another pulse and more silence, and on and on. During the pulse, the acoustic intensity is high, but during the silence, the intensity is zero.

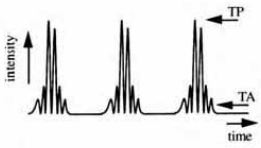


Pulsed pressure waveform

If we take the entire repeating time period, both the pulse and the silence, and average the intensity of the ultrasound over time, we come up with a temporal-average intensity that may be a thousand times smaller than the instantaneous or temporal-peak intensity that occurs during the pulse. Bioeffects resulting from temperature increases depend, in part, on the temporal-average intensity.

Pulsed intensity waveform

The intensity at the location of the greatest temporal-average intensity is referred to as the spatial-peak temporal-average intensity (SPTA). The SPTA is often used as a specification of ultrasound output.



Temporal-average (TA) and temporal-peak (TP) intensities

In addition to time averaging, there's another time concept that affects temperature increase: the duration of the ultrasound exposure, or how long one location is imaged during an examination. It takes time for tissue temperature to rise, and the longer the exposure duration, the greater the possibility of a biological effect.

Ultrasound exposure duration

Q. What causes the temperature rise in tissue during ultrasonic exposure?

A. The absorption of energy. During an examination, much of the ultrasound energy is absorbed by body tissue. If the rate of energy deposition in a particular region exceeds the body's ability to dissipate the heat, the local temperature will rise.

Absorption and attenuation are often confused. Attenuation is the loss of energy from the propagated ultrasound wave. There are 2 causes for attenuation: absorption and scattering. Absorption is the conversion of ultrasonic energy into heat, whereas scattering is the redirection of the ultrasound away from the direction it was originally traveling.

Attenuation
1. *Absorption = energy converted to heat*
2. *Scattering = redirection of ultrasound*

Absorption of acoustic energy by tissue results in the generation of heat in the tissue. This is what is referred to as the thermal mechanism. There are a number of physical and physiologic variables that play a role in absorption and the generation of temperature increases. Some, of course, are the operating characteristics of the equipment. For now, let's concentrate on physical parameters.

Q. What are some of the physical parameters that affect absorption?

A. The ultrasound energy is absorbed by tissue, at least to some extent. The extent depends on the tissue, on what we call tissue absorption characteristics.

The attenuation coefficient and absorption coefficient have the same units: dB/cm or dB/cm-MHz

A specific way in which tissue absorption characteristics are quantified is with the absorption coefficient. The absorption coefficient is expressed in decibels per centimeter (dB/cm). Because the absorption coefficient is directly proportional to the ultrasonic frequency, the coefficient is often normalized to the frequency and represented as decibels per centimeter per megahertz (dB/cm-MHz). Absorption coefficients are very dependent on the organ or tissue type that is being imaged.

Increasing attenuation coefficient:
- *Water*
- *Biological fluids*
- *Soft tissues*
- *Skin and cartilage*
- *Fetal bone*
- *Adult bone*

Part 1

Q. Let's get some examples. What's the absorption coefficient of, say, fluids, such as amniotic fluid, blood, and urine?

A. Almost zero. These fluids absorb very little ultrasonic energy. That means the ultrasound goes through the fluid with very little decrease. And there's little temperature elevation in the fluid.

Q. Which body tissue absorbs the most energy?

A. Bone. Its absorption coefficient is very high. Dense bone absorbs the energy very quickly and causes the temperature to rise rapidly. Adult bone absorbs nearly all of the acoustic energy impinging on it. Fetal bone absorption coefficients vary greatly depending on the degree of ossification.

Homogeneous soft tissue model

Q. Now what's between fluid and bone?

A. Soft tissue. Tissues vary in density depending on the particular organ, but the density doesn't vary much within an organ. We call it soft to distinguish it from hard tissue such as bone. It's also true that the tissue density within a particular organ is not always the same. But for our purposes, we assume that attenuation and absorption are uniform throughout the organ. We call this a homogeneous soft tissue model.

Q. How does frequency affect absorption?

A. The higher the frequency, the higher the absorption. What that means to operators is that a higher-frequency transducer will not allow us to "see" as far into the body.

Higher frequency = increased absorption, reduced penetration, possible near surface heating

Q. Does that mean that higher-frequency transducers create more heat?

A. Not necessarily. There are many factors that contribute to creating heat. However, if all other factors are equal, the ultrasound energy of higher-frequency transducers is absorbed more rapidly than that of lower-frequency transducers, thereby causing reduced penetration. In some cases, this may introduce increased heating near the skin surface.

However, because of the rapid absorption of higher-frequency ultrasound, there's another indirect effect that might occur. If we're not getting deep enough, we might choose to increase the output, and the increased intensity could also increase temperature.

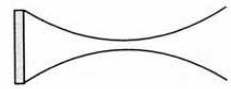
Q. Now let's talk about what all this means in practical terms. What is the situation of greatest interest?

A. The situation of greatest interest involves a fetus with ossified bone (second and third trimesters) and a mother with a thin abdominal wall. Because there would be little absorption of energy between the transducer and the fetus, nearly all of the energy would be absorbed by a fetal bone if the beam were focused on or close to it.

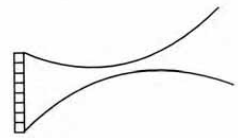
Q. What can we as operators do to minimize the temperature rise?

A. First, temperature increases depend on intensity, the duration of exposure at the same location, the transducer focal point size and location, and absorption of the energy by the tissue. In general, intensity is alterable and depends on the particular equipment we're using. As the operators, we can also control the duration or exposure time. The transducer is typically moved frequently during the examination, which will naturally reduce the exposure duration at a specific tissue location.

Let's look at the other 2 factors: transmit focal point and absorption. A highly focused beam whose focal point is in the amniotic fluid will not cause significant heating of the fluid because its absorption coefficient is low. If the focus is in tissue, all things being the same, the temperature rise will be a little higher. In addition, the same beam will cause an even higher temperature rise if its focus is placed on bone, which has a much higher absorption coefficient. Be aware that there are fixed focused transducers whose focus can't be changed and multielement array transducers whose focus can be changed by the operator during an examination.



Fixed focus transducer



Multielement array transducer

Part 1

The other important determinant of the local temperature rise is absorption of ultrasound energy in tissue layers in front of the point of interest. Increased absorption in these layers decreases the ultrasound energy available at the point of interest. For example, an obstetric examination of a patient with a thick abdominal wall is less likely to cause a significant temperature increase in the fetus than an examination through a thin abdominal wall.

Q. What are some examples of temperature increase calculations?

A. We have computer models that predict the relationship between the transducer focus and changes in the temperature curve.

Computer Tissue Models

- Homogeneous soft tissue model
- Layered tissue (fluid-filled bladder) model
- Fetal bone model

Assumptions

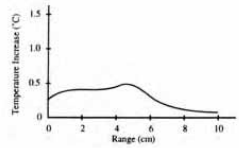
- Speed of sound is uniform throughout
- Attenuation is uniform throughout each type of tissue
- Absorption is uniform throughout each type of tissue
- Absorption equals attenuation (scattering is negligible)

Modeling various tissue layers is difficult because there are so many variables to consider. We focused on 2 simplified models. In the first, ultrasound travels through homogeneous soft tissue. In the second, ultrasound travels through a fluid-filled bladder. We assumed that the speed of sound, acoustic impedance, attenuation, and absorption are uniform throughout the volume of interest.

Transducer

- 3 MHz
- 19-mm diameter
- 6-cm transmit focal length
- 100-mW output ultrasonic power

We also selected a 3-MHz, 19-mm-diameter transducer with a 6-cm transmit focal length. For convenience, we have used an ultrasonic output of 100 mW for our example. This is a relatively high output level for today's diagnostic equipment, only found in some Doppler and color Doppler modes. Keep in mind that these models are for educational purposes and may not reflect actual clinical situations.

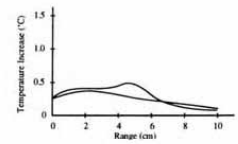


Homogeneous soft tissue model: axial temperature increase profile for a transmit focal length of 6 cm

Homogeneous Tissue Model: Abdominal Examination

First, let's look at the homogeneous tissue model. This model is similar to the situation in an abdominal examination involving soft tissue only. The temperature increase in degrees Celsius goes up the left side of the figure. The range in centimeters goes across the bottom of the figure.

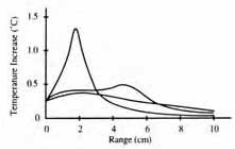
We'll see that the temperature increase exhibits a maximum at about 5 cm.



Homogeneous soft tissue model: axial temperature increase profile for transmit focal lengths of 6 and 10 cm

For the next scenario, all we'll change is the focal point location. We just saw the 6-cm focal length. Now, let's see what the same transducer does in the same tissue with a 10-cm focal length. It flattens out quite a bit, doesn't it?

But look at what happens if the focal length is 2 cm. The temperature goes way up to about 1.3°C at a range of about 2 cm. What does that mean? It means that a significant increase in temperature near the beam's focus is more likely with shorter focal lengths because less overall attenuation of the beam has occurred.



Homogeneous soft tissue model: axial temperature increase profile for transmit focal lengths of 2, 6, and 10 cm

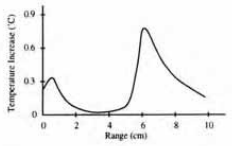
Now, let's look at this in a situation similar to an obstetric examination.

Layered Tissue Model: Obstetric Scan

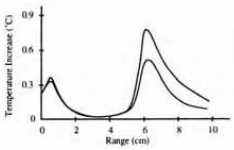
- Abdominal wall thickness = 1 cm
- Bladder fluid path = 5 cm

For this situation, we have a layered tissue model on the basis of an obstetric scan through the abdominal wall and through the fluid-filled bladder to the fetus. For the sce-

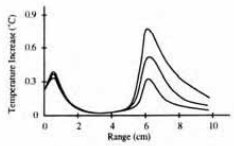
Part 1



Layered tissue model: axial temperature increase profile for a transmit focal length of 6 cm



Layered tissue model: axial temperature increase profile for transmit focal lengths of 6 and 10 cm



Layered tissue model: axial temperature increase profile for transmit focal lengths of 4, 6, and 10 cm

nario, we assumed a patient with a thin abdominal wall of 1 cm and a fluid path of 5 cm. The transducer and its ultrasonic power are the same as those used in the homogeneous tissue cases. The transmit focal length of 6 cm is at the location of the far side of the bladder, and note that the temperature goes up to about 0.8°C at this range. Also note that the increase in temperature in the abdominal wall is about 0.4°C. There's almost no absorption of ultrasound in the bladder fluid, so little heat is produced there.

Now here's the axial temperature increase profile in the layered tissue model for a longer focal length of 10 cm. The temperature rise at the far side of the bladder is about 0.5°C, a drop from when the ultrasound beam was focused at that location.

Let's look at a situation in which the beam focuses in front of the far side of the bladder, at a 4-cm transmit focal length. The temperature rise at the far side of the bladder is about 0.3°C, also a drop from when the ultrasound beam is focused at that location. Note that the increase in temperature in the abdominal wall is about 0.4°C for all 3 focal length conditions.

That means that if the transmit focus location occurs before the target, then the temperature rise at the far side of the bladder, at a range of 6 cm for this layered tissue model, is less than if the focus is at or beyond the target, where the temperature elevation at the target is higher.

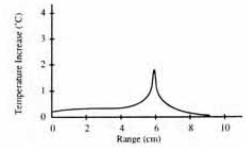
Fetal Bone Model

- Homogeneous soft tissue parameters
- Bone location at 6 cm in range
- 100-mW output ultrasonic power

Let's see what happens when we focus near bone. For this model, we'll use the homogeneous soft tissue parameters for the tissues through which the beam passes, but our reflective surface is bone that is perpendicular to the beam at a range of 6 cm. We'll also use the same output ultra-

sonic power of 100 mW. When the transmit focal range is beyond the location of bone, focal range of 10 cm, there is a peak in the temperature increase to about 1.9°C at the bone location.

Here's what happens with a transmit focal length of 6 cm, ie, the ultrasound beam is focused on the bone surface: a theoretical temperature rise of about 4.2°C.

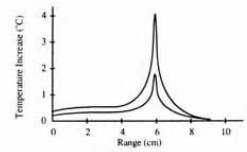


Fetal bone model: axial temperature increase profile for a transmit focal length of 10 cm

Q. How does all this apply to actually scanning a patient? Is this dangerous?

A. Potentially dangerous. The examples we looked at are for educational purposes and do not necessarily occur in clinical situations. For example, the output power used for the calculation would not be commonly used, but it is within the capability of many systems.

The temperature rise during an actual examination depends on many factors. For example, very few patients have as thin an abdominal wall as we assumed in this model. In addition, the exposure to bone must be continuous over time for local temperatures to rise. That seldom happens in actual examinations. Plus, some heating is lost because of the cooling effect of local blood flow. To date, there is no evidence of any harm in humans from thermal effects at the output levels of current ultrasonic devices.



Fetal bone model: axial temperature increase profile for transmit focal lengths of 6 and 10 cm

Abdominal wall thickness, focal length and location, exposure duration, bone attenuation, tissue attenuation, bone absorption, and tissue absorption

Q. But if it's potentially dangerous, why hasn't there been an incident due to thermal effects?

A. The combined conditions required to produce these heating effects are unlikely to occur. In addition, the control parameters on current equipment are designed to limit the temporal-average intensity. By minimizing the temporal-average intensity, significant thermal effects in the body are not likely to occur. However, it is unclear what output levels will be used in future applications and equipment.

Part 1

The goal is to get an image that provides necessary diagnostic information

The goal is to get an image that provides *necessary* diagnostic information. If we are overly cautious, we may end up with poor image quality or inadequate Doppler signals. For operators to minimize the risk, we need to understand the factors that contribute to the temperature rise, eg, the thickness of the mother's abdominal wall, the beam focal length and location, the exposure duration, and the attenuation and absorption characteristics of tissue and bone.

Part 1

Bioeffects and Biophysics

Chapter 3

Nonthermal Bioeffects

Issues Addressed:

- Onset of cavitation
- Peak compressional pressure
- Peak rarefactional pressure
- Stable and transient cavitation
- Microstreaming
- Nucleation site
- Threshold phenomenon

Q. Nonthermal bioeffects means bioeffects not caused by a temperature rise. That tells us what they are not. Exactly what are nonthermal bioeffects?

A. Nonthermal bioeffects are not as well understood as thermal effects. They are sometimes referred to as mechanical bioeffects because they seem to be caused by the motion of tissue induced when ultrasound pressure waves pass through or near regions with gas or air pockets. Most of the nonthermal interactions deal with the generation, growth, vibration, and possible collapse of microbubbles within the tissue. This behavior is referred to as cavitation.

Cavitation was first discovered around the turn of the century, not in tissues but at the surface of a ship's propellers. Researchers found that the low-pressure region immediately behind a ship's propellers caused bubbles to be produced in the water and grow to a very large size. The bubbles then collapsed violently, damaging the propellers. Cavitation bubbles can produce damage when they undergo rapid collapse by absorbing energy from the ultrasound field and concentrating it in a very small region.

Part 1

Cavitation

What is cavitation?

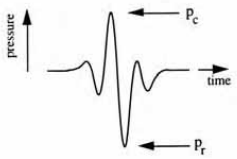
Q. What is cavitation?

A. With diagnostic ultrasound, cavitation refers to ultrasonically induced activity occurring in tissues or body liquids that contain bubbles or pockets containing gas or vapor. These bubbles originate within materials at locations termed *nucleation sites*, the exact nature and source of which are not well understood in a complex medium such as tissue or blood.

Positive pressure = compressional pressure

Negative pressure = raefactional pressure

A sound wave has alternating positive pressure and negative pressure. Positive pressure is also called compressional pressure; negative pressure is also called rarefactional pressure. If the rarefactional pressure is sufficiently large, microbubbles may be produced, or existing microbubbles may be enlarged. Because ultrasound contrast agents contain billions of microbubbles, they generally should be used with lower output levels than are suitable for noncontrast imaging unless otherwise necessary to obtain the desired diagnostic information.



Peak compressional pressure (p_C) and peak rarefactional pressure (p_Y)

Q. In a noncontrast examination, when does cavitation occur?

A. The occurrence of cavitation and its behavior depend on many factors, including the ultrasonic pressure and frequency, the focused or unfocused and pulsed or continuous ultrasonic field, the degree of standing waves, and the nature and state of the material and its boundaries.

Q. Is cavitation activity related to the SPTA?

Cavitation depends on:
- *Frequency*
- *Pressure*
- *Focused/unfocused beams*
- *Pulsed/continuous ultrasound*
- *Degree of standing waves*
- *Nature and state of material*
- *Boundaries*

A. No. The correlation is not with temporal-average intensities but rather with pressure. Cavitation is most closely related to peak negative pressure, or peak rarefactional pressure, during the pulse. For this reason, the mechanical index (MI) displayed on diagnostic machines is proportional to the peak rarefactional pressure.

Peak negative pressure is roughly related to the pulse-average intensity. So, the spatial-peak pulse-average intensity (SPPA), is loosely related to cavitation.

Q. Are there different types of cavitation?

A. Cavitation can be discussed in terms of 2 categories: stable cavitation and inertial (or transient) cavitation.

Cavitation is related to the peak rarefactional pressure

Stable cavitation is associated with vibrating gas bodies. In stable cavitation, a gas body oscillates or pulsates continuously around its equilibrium size. As the oscillations become established, the liquidlike medium around the gas body begins to flow or stream; we call this *microstreaming*. Microstreaming has been shown to produce stress sufficient to disrupt cell membranes.

Types of cavitation
1. Stable
2. Inertial (or transient)

During inertial cavitation, preexisting bubbles or cavitation nuclei expand because of the rarefactional pressure of the ultrasonic field and then collapse in a violent implosion. The whole process takes place in a time span on the order of microseconds. The implosion can produce huge local temperature rises that may be thousands of degrees Celsius and pressures equal to hundreds of atmospheres, all in a volume of less than 1 μm^3. The implosion can damage cells and tissue, ultimately leading to cell death. In addition, bubble implosion can generate highly reactive chemical species. All of these effects, microstreaming, implosion, and generation of reactive chemicals, occur in a very small space around the bubble, affecting only a few cells.

Oscillating bubble and microstreaming

Q. Is it really possible for cavitation to occur at the amplitudes and frequencies used for diagnostic ultrasound?

A. Yes, if nucleation sites are available. There is ample theoretical and some experimental evidence to support this conclusion and that biological alterations can occur. We are fortunate to have this evidence because it documents the levels above which cavitation is thought to occur, and because there is a lot of scientific evidence to suggest that the onset of transient cavitation is a threshold phenomenon.

There's a combination of rarefactional pressure values, ultrasonic frequency, and cavitation nuclei that are required for inertial cavitation to occur. If, as evidence suggests, in-

ertial cavitation is a threshold phenomenon, then exposure to pressure levels below the threshold will never induce such events, no matter how long the exposure lasts.

Can cavitation be produced by diagnostic ultrasound equipment?

Can cavitation be produced by diagnostic ultrasound equipment?

Q. Do we know of any incidence of cavitation occurring in human tissue or fluids resulting from diagnostic ultrasonic exposure?

A. Currently, there is no evidence that diagnostic ultrasound exposure has caused cavitation in humans in the absence of gas bodies or bubbles. However, because cavitation could be limited in a small region probably affecting only a single cell or a few cells, it is extremely difficult to detect an adverse biological effect, unless the cavitation events are widespread among a large volume of tissue.

In addition, the control parameters on current equipment limit the peak output. However, limits may be raised or eliminated in future equipment.

Can cavitation be produced by ultrasound contrast agents?

Q. What happens in the presence of a contrast agent?

A. Ultrasound contrast agents are typically suspensions of stabilized microbubbles, each of which can undergo cavitation under the right exposure conditions. Because the materials used to stabilize the bubbles are different for different agents, some agents will cavitate at lower output levels than others, but all can cavitate below an MI equal to 1.9, the upper limit established by the FDA.

If there's a potential for cavitation . . .

Q. If there's a potential for cavitation, why would we use contrast agents?

Contrast agents provide additional diagnostic information

A. Ultrasound contrast agents are used to improve the diagnostic information available to the clinician from standard imaging modalities or to perform imaging studies that are not possible without contrast. Because using ultrasound contrast may involve an increased risk to the patient, it is very important for the user to follow the manufacturer's recommendations for safe use of the agent.

In November 2007, the AIUM approved its Official Statement *Bioeffects of Diagnostic Ultrasound with Gas Body Contrast Agents*:

"Induction of premature ventricular contractions, microvascular leakage with petechiae, glomerular capillary hemorrhage, and local cell killing in mammalian tissue in vivo have been reported and independently confirmed for diagnostic ultrasound exposure with a mechanical index (MI) above about 0.4 and a gas body contrast agent present in the circulation.

"Although the medical significance of such microscale bioeffects is uncertain, minimizing the potential for such effects represents prudent use of diagnostic ultrasound. In general, for imaging with contrast agents at MI > 0.4, practitioners should use the minimal agent dose, MI, and examination time consistent with efficacious acquisition of diagnostic information. In addition, the echocardiogram should be monitored during high-MI contrast cardiac-gated perfusion echocardiography, particularly in patients with a history of myocardial infarction or unstable cardiovascular disease. Furthermore, physicians and sonographers should follow all guidance provided in the package inserts of these drugs, including precautions, warnings, and contraindications."

Follow all guidance provided in the package inserts of contrast agents

If bubbles are not present, are effects possible?

Q. So bubbles are needed to produce effects?

Lung

A. No. There is also a large body of evidence that exposure of the lung can produce small, localized hemorrhages under some conditions in laboratory animals. Apparently these lesions resolve naturally and are without lasting effects in normal subjects, but their possible significance in compromised individuals has not been studied.

Q. How can the likelihood of effects on the lung be minimized?

A. The threshold rarefactional pressure for this effect is higher at higher frequencies, but it is lower for longer pulse durations and exposure times. As always, consis-

tent application of the ALARA principle is the simplest and most effective way to ensure the patient receives a safe and efficacious diagnostic examination.

Intestine

Q. Are other organs similar to lung in this way?

A. Yes. Some studies have shown that these small hemorrhages may also occur in the intestine. However, the threshold appears to be higher than for the lung.

The bottom line

Q. Could you summarize these findings?

Exposure of gas bodies is the greatest risk of nonthermal effects

A. Yes. Exposure of gas bodies of any size to diagnostic ultrasound represents the greatest risk of nonthermal effects. To minimize the chances of an adverse effect, keep the output as low as possible, and keep the examination time as short as possible while still obtaining the necessary diagnostic information. In mammalian tissues that do not contain well-defined gas bodies, no independently confirmed, biologically significant adverse nonthermal effects have been reported for diagnostically relevant exposures, ie, MI ≤ 1.9.

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Target Audience

These educational activities are designed to meet the needs of those who perform and interpret diagnostic ultrasound studies. They are also designed for practicing ultrasound professionals as a review of the latest safety information in the ultrasound field.

Educational Objective

The goal of this educational activity is to provide medical ultrasound professionals with the most up-to-date and practical information they need to increase their knowledge and skills in the field. After completing this activity, participants should be able to identify potential risks and benefits of ultrasound imaging and describe how to use output display indices and system control features to implement the ALARA (as low as reasonably achievable) principle. Through this educational activity, we strive to improve the practice of medical ultrasound and increase the quality and safety of patient care.

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One credit will be awarded for successful completion of each test with a grade of 70% or higher (ie, at least 7 correct answers). Participants will be sent a CME certificate certifying receipt of credits earned. This credit is available from March 2009 through March 2012. Forms received after March 30, 2012, will not be processed. Allow 4 to 6 weeks for processing.

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3. If not taking the test online, send the completed form(s) (photocopies accepted) with the appropriate payment, in US dollars (see Payment section of form), to: *Medical Ultrasound Safety, Second Edition* CME Test, AIUM, PO Box 79862, Baltimore, MD 21279-0862 USA.

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CME Test 1

CME Test 1 Questions

The following questions are based on "Medical Ultrasound Safety, Second Edition, Part 1: Bioeffects and Biophysics." Both true-or-false and multiple-choice questions are included. Each question has only 1 correct answer. Photocopy the CME Test and Evaluation Form, and send along with the applicable nonrefundable fee to Medical Ultrasound Safety, Second Edition *CME Test, AIUM, PO Box 79862, Baltimore, MD 21279-0862 USA. This test may also be taken online at www.aium.org. Online participants can print their CME certificates instantly with a passing grade of 70% or higher. All tests must be received by March 30, 2012.*

Objectives: After completing this activity, the participant should be able to describe ultrasound-induced bioeffects and discuss why we should be concerned about them.

1. Dose-effect studies permit a detailed study of:
   A. Mechanisms of ultrasonic bioeffects.
   B. Maximum safe output levels.
   C. Human injury statistics.
   D. Diagnostic accuracy statistics.

2. There has been concern about potential harmful effects of ultrasound throughout the entire period of diagnostic instrumentation development.
   True or False

3. The 1976 output levels set by the US Food and Drug Administration are based on history, not scientific safety evaluations.
   True or False

4. There is evidence of a causal relationship between diagnostic ultrasound and recognized adverse effects in humans.
   True or False

5. Why is there increased discussion about the safety of ultrasound?
   A. Higher output of today's more sophisticated diagnostic ultrasound devices.
   B. Surge of intracavitary and intraoperative applications.
   C. Introduction of contrast agents.
   D. All of the above.

(continued)

CME Test 1

CME Test 1 Questions

The following questions are based on "Medical Ultrasound Safety, Second Edition, Part 1: Bioeffects and Biophysics."

6. Increasing technical sophistication of ultrasound devices means decreasing operator responsibility for output levels.
   True or False

7. The longer the exposure duration, the greater the possibility of a temperature-related bioeffect.
   True or False

8. It is important for ultrasound users to know about biophysics and bioeffects so that they can:
   A. Make informed decisions about output power levels.
   B. Practice prudent use.
   C. Reduce the chances of bioeffects.
   D. All of the above.

9. Generally, ultrasound contrast agents should be used with lower output levels than are suitable for noncontrast imaging unless otherwise necessary to obtain the desired diagnostic information.
   True or False

10. Which body tissue absorbs the most ultrasonic energy?
    A. Amniotic fluid.
    B. Blood.
    C. Bone.
    D. Urine.

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"Medical Ultrasound Safety, Second Edition, Part 1: Bioeffects and Biophysics." All tests must be received by March 30, 2012.

Please print. This section must be completed in order to receive CME credit.

Name _____

Degree _____

Street Address _____

Institutional Affiliation _____

City, State, ZIP Code _____

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Profession

Professional organizations in which you hold membership:

_____

_____

Primary Profession

☐ Physician ☐ Scientist ☐ Sonographer or Technologist ☐ Other

Your Primary Employer is a(n)

☐ Academic Institution ☐ Hospital ☐ Private Practice ☐ Combination ☐ Other

Certifications (Please check all that apply):

ARDMS Certifications

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☐ Adult Echocardiography
☐ Breast
☐ Neurosonology
☐ Obstetrics/Gynecology
☐ Ophthalmic Biometry
☐ Ophthalmology
☐ Pediatric Echocardiography
☐ Vascular Technology
☐ Fetal Echocardiography

Medical Board General and Subspecialty Certifications

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  ☐ Neuroradiology ☐ Pediatric Radiology ☐ Vascular and Interventional Radiology
☐ Emergency Medicine
☐ Family Practice
☐ Internal Medicine
  ☐ Cardiovascular Disease ☐ Endocrinology ☐ Gastroenterology ☐ Nephrology
☐ Neurology
☐ Nuclear Medicine
☐ Obstetrics and Gynecology
  ☐ Maternal and Fetal Medicine ☐ Reproductive Endocrinology ☐ Urogynecology
☐ Ophthalmology
☐ Pediatrics
☐ Podiatry
☐ Surgery
  ☐ Breast Surgery ☐ General Vascular Surgery
☐ Urology
☐ Other

I attest to having completed this CME activity.

Signature: _____

(continued)

CME Test and Evaluation Form

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Please check the appropriate fee. This section must be completed in order to receive CME credit. Fees subject to change.

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Test 1

Please circle the appropriate answer. This section must be completed in order to receive CME credit.

1. A. B. C. D.
2. True or False
3. True or False
4. True or False
5. A. B. C. D.
6. True or False
7. True or False
8. A. B. C. D.
9. True or False
10. A. B. C. D.

Evaluation

Please rate the overall educational effectiveness of this CME activity (rating of 5 = superior, rating of 1 = poor).

1. Quality of "Part 1: Bioeffects and Biophysics" CME activity. 5 4 3 2 1

2. Appropriateness of the test questions. 5 4 3 2 1

3. The extent to which the stated educational objectives (at the top of the CME test page) were reached. 5 4 3 2 1

4. Choose "Yes" or "No."

This activity will influence how I practice ultrasound.	☐ Yes	☐ No
I learned something new from reading this section.	☐ Yes	☐ No
Did this presentation appear to be influenced by an unreported conflict of interest?	☐ Yes	☐ No

If yes, please explain:_____

5. As a result of this CME activity, which of the following best describes a change that you would consider making in how you practice ultrasound?
   - ☐ A. I will slightly modify what I currently do.
   - ☐ B. I will make a major change in what I currently do.
   - ☐ C. I will implement a technique/technology that is completely new to me.
   - ☐ D. I will implement a technique/technology that I currently use but for a different purpose.
   - ☐ E. None of the above, but with some change to my practice.
   - ☐ F. I am not currently considering any changes in the way I use ultrasound after completing this CME activity.

6. Please describe any change(s), if any, that you plan to make in the way you practice ultrasound as a result of this CME activity.

_____

_____

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Part 2

Prudent Use

Chapter 4
Benefits and Risks

Issues Addressed:
- Risks versus benefits
- Diagnostic ultrasound benefits
- Risk of not performing the study
- Prudent use
- New technology and applications
- High output, potentially greater risk
- High output, potentially greater diagnostic capability
- Shifting responsibility

Risks versus benefits

Q. Risks versus benefits. What do we mean by that in terms of ultrasound?

There has not been a reported incident of adverse bioeffects on humans at diagnostic ultrasound levels in the absence of contrast agents

Contrast agents can increase the risk of cavitation

A. The risks are the potential for adverse bioeffects caused by heating or cavitation (as explained in Chapters 2 and 3). Although there has not been a reported incident of adverse bioeffects on humans at diagnostic ultrasound levels in the absence of contrast agents, we do know from animal studies that heating of the tissue may occur with ultrasound, and we also know that an elevated intrauterine temperature (regardless of cause) can be teratogenic (causing birth defects in fetuses). The use of contrast agents can lead to improved diagnosis in many conditions, but the bubble-based contrast agents can increase the risk of cavitation and thereby the risk of harm.

The benefit is the diagnostic information ultrasound provides. And ultrasound imaging provides very good data, data that allow physicians to make clinical decisions. With information from an ultrasound examination, physicians can weigh alternative courses of action and select the best method for helping the patient.

Part 2

Ultrasound imaging is popular first and foremost because it's a superb diagnostic modality. It provides tremendous diagnostic information with great sensitivity and specificity. But it's also a favorite imaging technique because it appears safe, is widely accepted by patients, is portable, provides immediate results, and is relatively low in cost compared to other diagnostic imaging modalities. Physicians must weigh the expected benefit from a diagnostic ultrasound procedure against the potential risks of that procedure.

Example of benefits from diagnostic ultrasound: cardiac studies

Q. What are some examples of the benefits of diagnostic ultrasound?

A. Let's look at ultrasound in cardiac studies. The use of diagnostic ultrasound for cardiac applications has increased dramatically over the past 10 years. From M-mode scans to transesophageal echocardiography, ultrasound gives us the ability to image the structure and function of the heart and great vessels in exquisite detail. Ultrasound also has the ability to follow the normal and abnormal course of blood flow within the heart.

Q. How about potential bioeffects with some of the new cardiac applications?

A. Diagnostic ultrasound has an excellent safety record over the years that it's been used to study the heart. The nature of many cardiac ultrasound techniques, the variety of imaging windows, and the fact that the heart is filled with moving blood means that the duration of the exposure of any one area of the heart is reduced.

It's a real risk not to perform the study

Newer applications of ultrasound through the esophagus and within the vascular space may result in bioeffects we've not previously known about. We need more research before we can define all of the risks. But remember, the physician should weigh potential bioeffects against the real risks of not doing the study and missing important timely diagnostic information.

Q. What other medical specialties benefit from ultrasound?

A. Ultrasound has had a huge impact on the area of obstetrics. The use of ultrasound examinations during pregnancy has increased dramatically since the 1970s. The use of ultrasound in obstetrics is a principal area of concern for potential bioeffects. Ongoing studies may provide accurate information related to potential effects of ultrasound on the embryo/fetus. In fact, the combination of the increase in use and the concern for safety led to the National Institutes of Health consensus development conference in the early 1980s. The conference discussed the use of diagnostic ultrasound in pregnancy. The committee did not recommend routine ultrasound examinations during pregnancy, but they did suggest a number of appropriate clinical indications for the use of ultrasound imaging during pregnancy. Surprisingly, in the United States, ultrasound is still not recommended as a routine examination in pregnancy but only when a medical indication exists. In reality, more than 70% to 80% of women who come to prenatal care receive at least 1 ultrasound examination, not always with a clear medical indication but as a means of reassurance for the patient and the caregiver.

Example of benefits from diagnostic ultrasound: obstetric ultrasound

Q. How do you balance the benefits and risks?

Balancing benefits and risks

A. Ultrasound imaging during pregnancy is important because it provides a considerable amount of information (such as accurate gestational age, number of fetuses, fetal growth, and, in specialized hands, fetal anatomy). On the one hand, ultrasound offers lots of diagnostic uses, may be used to replace some procedures, can be used in conjunction with other procedures, is cost-effective, is accepted by patients, and provides a great deal of high-quality clinical information.

Ultrasound benefits:
- *Many diagnostic uses*
- *Replaces or used with other procedures*
- *Cost-effective*
- *Patient acceptance*
- *High-quality information*

On the other hand, we have the risks: thermal and nonthermal bioeffects. But there's another risk that must be considered: the risk of not performing the ultrasound examination and either not having the information or having to get it in a less desirable or invasive way. As the AIUM statement says, "*. . . the benefits to patients of the prudent use of diagnostic ultrasound outweigh the risks, if any, that may be present.*"

Prudent use

Part 2

New technology and applications

Q. What about the benefits of new ultrasound technology and applications?

A. There has been a virtual explosion of technology and applications over the past few years: new manufacturers, new products, new medical specialties, and more and more medical applications. Now we have everything from small handheld Doppler systems that follow blood flow in peripheral vessels to more general imaging systems that display nearly all of the body's soft tissues in detail.

Users assume more responsibility

But it's more than technology; it's what that technology gives us: eg, better-quality images and more diagnostic information. Still, all of the operating modes and the varying output levels mean that more responsibility must be assumed by the users. This is a point that is very often neglected: many assume that if an instrument is "FDA approved," then there is no risk of bioeffects. This is not accurate because changing the mode of operation or manipulating controls has the potential to cause major changes in output and hence in exposure (see Chapter 6).

Diagnostic ultrasound is widely accepted because it is a superb diagnostic tool with an excellent history of safety. We want to keep it that way. But with more and different types of equipment, larger numbers of patients, and all of the new applications, such as Doppler, 3-dimensional (3D), and 4-dimensional (4D) ultrasound, there's increased concern about potential bioeffects.

Q. Now that we understand the potential for ultrasound-induced bioeffects, should we change how we use the equipment?

A. We must learn to balance the risks and benefits. We have learned about bioeffects: thermal effects or tissue heating and mechanical effects such as cavitation. We learned how intensity, exposure time, focal properties, frequency, and pressure are associated with the risk of bioeffects. Using too much intensity can increase the risks, but using too little intensity for the clinical situation can lead to poor images and the loss of essential information.

When we use ultrasonic devices, we should remember the safety concerns. Ultrasound should neither be used as a "toy" to only obtain "souvenir" pictures (also known as "entertainment ultrasound") or without clinical need, nor should it be considered as "perfectly safe." We know and have known for more than 75 years that ultrasound, at certain levels, can alter biological systems. There will always be a need for continued awareness of future research findings. But we also know that one should not hesitate to have a diagnostic ultrasound examination when there is clinical benefit to be derived.

Future benefit versus risk

Q. In the future, might there be increased risk as well as increased benefit?

A. The future may be quite different. If existing acoustic output limits were removed, the primary responsibility for the safety of acoustic output would shift even more from design restrictions, as on current diagnostic ultrasound devices, to the judgment of the users. In return for potentially enhanced diagnostic capabilities, we will have to balance the clinical need against the risk of an adverse bioeffect. We will need to improve knowledge of the thermal and mechanical mechanisms, the bioeffects of ultrasound, the ultrasound output levels being used, and the relationship of output level to image quality. Unfortunately, research has shown that, for now, the level of knowledge of ultrasound end users regarding bioeffects and the influence of the instrument controls on output is limited.

Notes

Part 2

Prudent Use

Chapter 5
ALARA

Issues Addressed:
- The ALARA principle
- Controlling ultrasound energy
- Controlling exposure time
- System capability and ALARA
- Operating mode and ALARA
- Transducer capability and ALARA
- System setup and ALARA
- Scanning techniques and ALARA

Q. Knowing that ultrasound energy is related to potential bioeffects, how can we reduce the risks?

ALARA, or as low as reasonably achievable

A. We have a simple principle that we can apply to the use of ultrasound energy. It's called ALARA, which stands for "as low as reasonably achievable." Following the ALARA principle means that we keep total ultrasound exposure as low as reasonably achievable while optimizing diagnostic information.

Users control the total exposure to the patient

With new ultrasound equipment, the on-screen output display (thermal index [TI] and MI) lets us determine the exposure level in terms of the potential for bioeffects. For equipment that does not have an output display, we depend on whatever output information, such as intensity, decibels, or the percentage of power, that the system provides.

Because the threshold, if one exists, for diagnostic ultrasound bioeffects is undetermined, it becomes our responsibility to control the total exposure to the patient. Controlling the total exposure depends on the output

level and exposure time. The output level required for an examination depends on the patient and the clinical need. Not all diagnostic examinations can be performed at very low levels. In fact, using too low a level may result in poor data and the need to repeat the examination. Using too high a level may not necessarily increase the quality of the information, but it will expose the patient to unneeded ultrasound energy. The use of ALARA is a way of implementing safety assurance.

What determines exposure time?

Q. If the output level depends on the patient and the clinical need, what determines the exposure time?

A. Ultimately, the exposure time depends on the person conducting the examination. Primarily, it's our training, education, and experience that determine how quickly we can obtain a useful image and thus the length of the examination and the amount of exposure. So, the question is, "How much time do we need to obtain the desired diagnostic information?"

System capabilities:
Operating mode •
Transducer capabilites •
System setup •
Scanning techniques •
Knowledge and experience •

But there are also some other factors that might affect the length of time that any particular tissue is exposed. One is the mode, whether it's a moving or a stationary beam; and another is the choice of transducer. Other factors include the patient's body characteristics, the operator's understanding of the controls on the system and how they affect output levels, and, particularly, whether continuous wave or pulsed Doppler or color flow Doppler is used. To achieve ALARA, we need thorough knowledge of the imaging mode, transducer capabilities, system setup, and operator scanning techniques.

Operating mode:
B-mode •
M-mode •
Doppler •
Color flow Doppler •

System capabilities include the following: mode, transducer capabilities, system setup, and scanning techniques. Let's talk about each. First, the mode we select, such as M-mode, B-mode, or Doppler, depends on what we're looking for. B-mode imaging gives anatomic information, while Doppler and color flow Doppler modes give information about blood flow through vessels. M-mode gives information about how anatomic structures move in time. If one wishes to use 3D/4D ultrasound, one needs to remember that the 3D/4D image sets consist of series of

B-mode 2-dimensional (2D) acquisitions, which are then constructed by the computer into 3D/4D representations. Hence, whatever the settings are for B-mode 2D imaging will be what determines the output. Time will be the most important variable because, on the one hand, a 2D sweep will be fast and time limited, but prolonged exposure may result from attempting to obtain the "best" set of images.

Second, transducer capabilities relate to the penetration depth of ultrasound in tissue at the frequency chosen, resolution, and field of view that we can obtain with the selected transducer.

Transducer capabilities:
- *Frequency*
- *Penetration*
- *Resolution*
- *Field of view*

Third, system setup and control settings depend on where we start on the output scale and on our knowledge of which combination of controls gets the best results.

System setup:
- *Starting output power*
- *Starting intensity outputs*
- *Scanning results*

Fourth, the scanning technique we use is based on our knowledge of anatomy and pathology, of ultrasound physics, and of the equipment's signal-processing features plus our experience with a given scanning modality, such as sector, linear, and so forth. A system's recording and playback features let us reduce the exposure time to just the time necessary to obtain a useful image. Analysis and diagnosis can be performed with recorded images rather than lengthy live imaging sessions. The same can be said about 3D volumes, obtained by an examiner and analyzed by this examiner or someone else, with no exposure to the patient, at the bedside, the reading room, the other side of town, or another country.

Scanning techniques:
- *Anatomy and pathology*
- *Ultrasound physics*
- *Signal-processing features*
- *Recording and playback features*

ALARA is a simple concept and easy to understand. Implementing ALARA well, however, requires all of our knowledge and skills as diagnostic ultrasound users. In Part 3, we will learn how many of the controls found on diagnostic ultrasound equipment can affect ultrasound output. Without an output display standard, we must rely on that knowledge to estimate a patient's ultrasound exposure. With an output display standard, we have a real-time indication of the exposure in terms of the potential for bioeffects. Either way, we implement ALARA by minimizing the exposure level and duration while being sure to obtain the necessary diagnostic information.

Notes

CME Test 2

CME Test 2 Questions

The following questions are based on "Medical Ultrasound Safety, Second Edition, Part 2: Prudent Use." Both true-or-false and multiple-choice questions are included. Each question has only 1 correct answer. Photocopy the CME Test and Evaluation Form, and send along with the applicable nonrefundable fee to Medical Ultrasound Safety, Second Edition *CME Test, AIUM, PO Box 79862, Baltimore, MD 21279-0862 USA. This test may also be taken online at www.aium.org. Online participants can print their CME certificates instantly with a passing grade of 70% or higher. All tests must be received by March 30, 2012.* *For complete CME Test Information, see page 23.*

Objectives: After completing this activity, the participant should be able to identify potential risks and benefits of ultrasound imaging and discuss increasing end-user responsibility for prudent use.

1. Ultrasound benefits include:
   A. Superb diagnostic information.
   B. Portability.
   C. Cost-effectiveness.
   D. All of the above.

2. Known risks of ultrasound include tissue heating and cavitation.
   True or False

3. Bubble-based contrast agents can increase the risk of cavitation and thereby the risk of harm.
   True or False

4. An elevated intrauterine temperature can be teratogenic.
   True or False

5. When we use ultrasonic devices, we should remember that ultrasound:
   A. Is perfectly safe.
   B. Can alter biological systems.
   C. Causes birth defects.
   D. Has a well-defined threshold for bioeffects.

(continued)

CME Test 2

CME Test 2 Questions

The following questions are based on "Medical Ultrasound Safety, Second Edition, Part 2: Prudent Use."

6. In the United States, ultrasound is recommended in pregnancy only when a medical indication exists.
   True or False

7. If an instrument is approved by the US Food and Drug Administration, then there is no risk of bioeffects.
   True or False

8. Which output information lets us determine the exposure level in terms of the potential for bioeffects?
   A. Decibels.
   B. Intensity.
   C. Output display index.
   D. Percentage of power.

9. The ALARA (as low as reasonably achievable) principle means always keeping output at very low levels.
   True or False

10. Following the ALARA principle means that we:
    A. Control the output level.
    B. Control the exposure time.
    C. Optimize diagnostic information.
    D. All of the above.

Send your completed forms along with the applicable nonrefundable fee to *Medical Ultrasound Safety, Second Edition* CME Test, AIUM, PO Box 79862, Baltimore, MD 21279-0862 USA, or submit tests online at www.aium.org.

CME Test and Evaluation Form

"Medical Ultrasound Safety, Second Edition, Part 2: Prudent Use."
All tests must be received by March 30, 2012.

Please print. This section must be completed in order to receive CME credit.

Name _____

Degree _____

Street Address _____

Institutional Affiliation _____

City, State, ZIP Code _____

Telephone _____

Profession
Professional organizations in which you hold membership:

_____

_____

Primary Profession
☐ Physician ☐ Scientist ☐ Sonographer or Technologist ☐ Other

Your Primary Employer is a(n)
☐ Academic Institution ☐ Hospital ☐ Private Practice ☐ Combination ☐ Other

Certifications (Please check all that apply):

ARDMS Certifications
☐ Abdomen
☐ Adult Echocardiography
☐ Breast
☐ Neurosonology
☐ Obstetrics/Gynecology
☐ Ophthalmic Biometry
☐ Ophthalmology
☐ Pediatric Echocardiography
☐ Vascular Technology
☐ Fetal Echocardiography

Medical Board General and Subspecialty Certifications
☐ Diagnostic Radiology
  ☐ Neuroradiology ☐ Pediatric Radiology ☐ Vascular and Interventional Radiology
☐ Emergency Medicine
☐ Family Practice
☐ Internal Medicine
  ☐ Cardiovascular Disease ☐ Endocrinology ☐ Gastroenterology ☐ Nephrology
☐ Neurology
☐ Nuclear Medicine
☐ Obstetrics and Gynecology
  ☐ Maternal and Fetal Medicine ☐ Reproductive Endocrinology ☐ Urogynecology
☐ Ophthalmology
☐ Pediatrics
☐ Podiatry
☐ Surgery
  ☐ Breast Surgery ☐ General Vascular Surgery
☐ Urology
☐ Other

I attest to having completed this CME activity.

Signature: _____

(continued)

CME Test and Evaluation Form

Payment

Please check the appropriate fee. This section must be completed in order to receive CME credit. Fees subject to change.

Physicians	☐ Member	$20	(AIUM ID # _____)
	☐ Nonmember	$40	
Sonographers	☐ Member	$10	(AIUM ID # _____)
	☐ Nonmember	$20	

☐ I have enclosed a check made payable to the AIUM, in US dollars, in the amount of $_____.

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Test 2

Please circle the appropriate answer. This section must be completed in order to receive CME credit.

1. A. B. C. D.
2. True or False
3. True or False
4. True or False
5. A. B. C. D.
6. True or False
7. True or False
8. A. B. C. D.
9. True or False
10. A. B. C. D.

Evaluation

Please rate the overall educational effectiveness of this CME activity (rating of 5 = superior, rating of 1 = poor).

1. Quality of "Part 2: Prudent Use" CME activity. 5 4 3 2 1

2. Appropriateness of the test questions. 5 4 3 2 1

3. The extent to which the stated educational objectives (at the top of the CME test page) were reached. 5 4 3 2 1

4. Choose "Yes" or "No."

This activity will influence how I practice ultrasound.	☐ Yes	☐ No
I learned something new from reading this section.	☐ Yes	☐ No
Did this presentation appear to be influenced by an unreported conflict of interest?	☐ Yes	☐ No

If yes, please explain:_____

5. As a result of this CME activity, which of the following best describes a change that you would consider making in how you practice ultrasound?
   - ☐ A. I will slightly modify what I currently do.
   - ☐ B. I will make a major change in what I currently do.
   - ☐ C. I will implement a technique/technology that is completely new to me.
   - ☐ D. I will implement a technique/technology that I currently use but for a different purpose.
   - ☐ E. None of the above, but with some change to my practice.
   - ☐ F. I am not currently considering any changes in the way I use ultrasound after completing this CME activity.

6. Please describe any change(s), if any, that you plan to make in the way you practice ultrasound as a result of this CME activity.

_____

_____

_____

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Implementing ALARA

Chapter 6
Knobology

Issues Addressed:
- Basis of knobology
- Tradeoff between in situ intensity and image depth
- Operator controls and ALARA
- Prudent use
- An example of implementing ALARA

Q. What should we know about equipment control features, otherwise known as "knobology," to implement ALARA?

A. Whether a diagnostic ultrasound system has an output display, the same types of controls are used to obtain the needed diagnostic images. We should understand how these controls affect acoustic output levels so we can use them to get the best image with the least exposure. In this chapter, we will learn about types of controls that are available on most ultrasound imaging equipment.

Q. How can the operator control ultrasound output?

Operator controls and ALARA

A. There are several external system controls the operator can adjust to improve the quality of the image and to minimize the output intensity. To understand how these controls are related to ALARA, let's divide them into 3 broad categories: First, controls that directly affect intensity. Second, controls that indirectly affect intensity. These are controls such as mode, pulse repetition frequency, and others. When you change the setting for one of these controls, you may also be changing the intensity. Third, controls that do not affect intensity. We can think of the third category as "receiver controls." These are controls that affect the processing of ultrasonic echoes returned from the body.

These aren't "official" categories, but they help us understand how the knobs affect ALARA. In fact, each equipment manufacturer provides somewhat different sets of controls. By reviewing the user's guide for the equipment, we can determine the particular controls that perform the functions described here.

Controls directly affecting intensity:
Application selection •
Output intensity •

Let's look at controls that directly affect intensity. They are application selection and output intensity.

Application selection

With application selection, we may choose from applications such as peripheral vessel, cardiac, ophthalmic, fetal imaging, and others. There may be different "ranges" of intensity output based on these applications. Selecting the right application range is the first thing you can do. For example, cardiac intensity levels are not generally recommended for performing a fetal scan. Some systems automatically select the proper range for a particular application, whereas others require a manual selection.

For equipment that does not have an output display, the maximum intensity for each application is regulated by the FDA. The FDA regulation is meant to limit ultrasonic output levels to ranges historically used for each application. But users have some choice in the matter; we are responsible for the proper selection of an application range.

For equipment with an output display, the FDA currently regulates only the maximum output for the system. Manufacturers establish intensity ranges appropriate for typical patient examinations. However, within the system limits, users may override the application-specific limits. We are responsible for being aware of the output level that is being used. We know the output level from the system's real-time output display.

Output intensity or power

Another control that has a direct effect on intensity is, of course, output intensity. This control also may be called transmit, power, or output. Once the appropriate application range has been selected, the transmit intensity control increases or decreases the output intensity within the range. Most equipment allows you to select intensity levels less than maximum, say 25% or 50%. ALARA implies

that you select the lowest output intensity that is consistent with good image quality.

Q. Which controls indirectly affect intensity?

Controls indirectly affecting intensity:
- *System mode*
- *Pulse repetition frequency*
- *Focusing depth*
- *Pulse length*
- *Transducer choice*

A. The second group of controls is intended to change aspects of the transmitted ultrasonic field other than the intensity. However, because they change the field, the intensity is affected. Whether the intensity increases or decreases and by how much is difficult to predict.

System mode

The choice of B-mode, M-mode, or Doppler, for example, determines whether the ultrasound beam is stationary or in motion, which greatly affects the energy absorbed by the tissue. If the beam is moving, then each targeted tissue volume experiences the beam only for a fraction of the time, except near the transducer for sector scans. If the beam is stationary, then the time a targeted tissue volume in the beam receives ultrasound is increased.

Q. What about the pulse repetition frequency?

Pulse repetition frequency

A. The number of ultrasound pulses in 1 second is referred to as the pulse repetition frequency (PRF). The higher the PRF, the more output pulses per second, increasing the temporal-average intensity. There are several controls that have an effect on the PRF. For example, with some diagnostic ultrasound systems, if we decrease the scan depth, then the system may automatically increase the PRF.

Q. Next on the list is focusing. How would focusing affect the intensity?

Focusing depth

A. In focusing, the beam is narrowed to get a better lateral resolution, increasing the spatial average intensity. Most systems adjust their output to offset the effects of focusing, so they tend to maintain the same intensities. As operators, we need to set the transducer focus at the depth of the structure we're examining. Different examinations require different focal depths. Setting the transducer focus at the proper depth improves the resolution of that structure, and we don't need to increase intensity to see it better.

Part 3

Pulse length

Q. What about the pulse length?

A. Pulse length, sometimes called burst length or pulse duration, is the time the pulse is on. In general, the longer the pulse, the greater the temporal-average intensity value, which both raises the temperature in the tissue and slightly increases the likelihood for cavitation. In pulsed Doppler imaging, increasing the Doppler sample volume length usually increases the pulse length.

Transducer choice

Q. Transducer choice is another factor that indirectly affects intensity. How?

A. Tissue attenuation increases with the transducer frequency. The higher the frequency, the higher the attenuation. That is, a higher-frequency transducer requires more output intensity to "see" at a greater depth. To scan deeper at the same output intensity, a lower-frequency transducer must be used. So, for deeper structures, if we find ourselves maximizing the output and gain without obtaining good image quality, we may have to switch to a lower frequency.

*Receiver controls that affect the **image only**:*
Receiver gain •
Time-gain compensation •
Video dynamic range •
Postprocessing •

Q. We are calling the third category receiver controls. We use these to improve image quality. They have no effect on output; they only affect how the ultrasound echo is received and processed. The controls include gain, time-gain compensation (TGC), video dynamic range, and postprocessing. Let's just look at one of these: system gain. How can we use the receiver gain to implement ALARA?

Always increase the receiver gain first

A. The receiver gain controls amplification of the return echo signal. To obtain good diagnostic information, a high return signal amplitude is needed. This can be attained either by higher output, similar to talking louder, or by higher receiver gain, similar to a hearing aid with a volume control. The need for gain is determined by tissue attenuation, ie, how much of the ultrasound is lost as it passes to the anatomic structure being imaged and back to the transducer. In some cases, we control the receiver gain by setting the gain control or TGC. But in other cases, gain is automatically adjusted by the system when the user adjusts the output control. If the equipment has a

receiver gain control, and we're searching for a weak signal, we should always increase the system's receiver gain first, and then increase the power output. That way, we reduce the output required and make it less likely to use high acoustic intensities in the patient's body tissue. Remember, low receiver gain may necessitate using a higher output or may result in suboptimal image quality.

Q. What is an example of the use of ALARA in a clinical examination?

A. Imagine we are getting ready to do a liver scan. It will involve the use of B-mode, color, and Doppler ultrasound. Let's see how we would follow the ALARA principle to set up and conduct the examination.

The first thing we need to do is select the appropriate transducer frequency. Next, we adjust the output intensity (or power) transmit setting. We check to make sure that it is positioned at the lowest possible setting to produce an image. We adjust the focus to the area of interest and then increase the receiver gain to produce a uniform representation of the tissue. If we can obtain a good image by increasing the gain, we can lower the output and continue to increase the gain. Only after making these adjustments and if tissue penetration or echo amplitude levels are inadequate should we increase the output to the next higher level.

- *Select transducer*
- *Check output transmit setting*
- *Adjust focus*
- *Increase receiver gain*
- *Adjust output transmit again*

After we have achieved a good B-mode image, then we can use color to localize the blood flow so we can position the Doppler sample volume. This allows us to locate the vessel of interest faster, and that minimizes exposure time. Now that we have an image of the vessel, we position the range gate (or sample volume gate) over the vessel.

Minimize exposure time

Now we check the Doppler trace. We adjust the power setting by setting the Doppler transmit intensity at the lowest possible level to produce a clear signal. We will make a few more adjustments, eg, adjusting the velocity scale. Now we increase the receiver gain to get a diagnostic signal. If maximum gain adjustments are inadequate, then we raise the output to the next higher level.

Adjust output transmit setting again

That basically is how we implement ALARA. Select the right transducer, start with a low output level, and obtain the best image possible by using focusing, receiver gain, and other imaging controls. If that is not adequate for diagnostic purposes, then increase the output level.

We can further implement ALARA by reducing the total ultrasonic exposure time. That is, using our skill, experience, and knowledge of the patient, we can structure the examination to find and obtain useful images quickly. Recording and playing back parts or all of the examination for later measurement and analysis can further minimize the duration of the exposure.

Q. There are many different types of ultrasound systems with different controls and displays. Does ALARA change from system to system?

Some systems do not have an output control; different systems have different controls and displays

A. ALARA remains the same: keep ultrasound output as low as reasonably achievable. How we do that will change somewhat from system to system. For example, virtually all medical diagnostic ultrasound equipment has some type of acoustic output control. However, we may occasionally see a single-purpose device that doesn't have an output adjustment. In this case, we practice ALARA by minimizing the exposure time.

Acoustic output control:
Percentage (dB) •
Direct unit (mW/cm² or mW) •
Thermal index •
Mechanical index •

If the machine has an output control, we use it and the other controls to achieve ALARA. But remember, there are a variety of different types of intensity settings on ultrasound equipment, depending on the manufacturer's design. For example, some equipment may have a separate control on the keyboard or console that has discrete increments. Other equipment may have the intensity level adjustment accessed through the system presets. And output settings may be displayed in a variety of different ways. For example, acoustic output may be expressed as a percentage of total power, in decibels, in intensity units of milliwatts per square centimeter, or in thermal and mechanical indices.

In addition to the technical aspect of ALARA, there's the philosophical aspect. This includes minimizing the scan time, performing only required scans, and never compromising quality by rushing through an examination.

Q. We're responsible for patient care, and we must use diagnostic ultrasound prudently. What's the rule for prudent use?

A. We want the best diagnostic information with minimal exposure to the patient. And because the threshold at which ultrasound energy causes bioeffects for each individual patient is not known, our goal must be to adjust the output intensity of the equipment to get the most information at the lowest possible output level.

That's what we mean by ALARA. Using settings that are as low as reasonably achievable allows for the best quality ultrasound data for diagnosis.

Notes

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Part 3

Implementing ALARA

Chapter 7

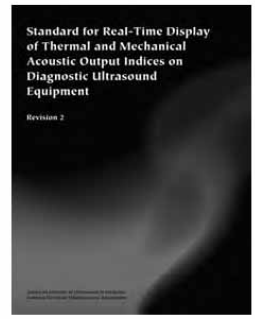
The Output Display Standard

Issues Addressed:

- Purpose of the output display standard
- Mechanical index
- Thermal index
- Soft tissue thermal index
- Cranial bone thermal index
- Bone thermal index
- What the indices mean
- How to implement ALARA by using the indices

Q. What is the output display standard?

A. Most diagnostic ultrasound systems now on the market implement output display indices that relate to the potential for ultrasound bioeffects. These indices and how they are to be displayed were originally specified in a standard developed in a cooperative effort by the National Electrical Manufacturers Association, the FDA, the AIUM, and many other medical and basic science societies. The full name of this standard is *Standard for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, Revision 2*. It is referred to colloquially as the output display standard (ODS). The content of this standard has now been adopted internationally by the International Electrotechnical Commission.



Q. What is displayed?

A. Two types of indices may be displayed: TI, which provides an indication of the risk of harm due to thermal mechanisms; and MI, which provides an indication of the risk due to mechanical or nonthermal mechanisms, such as cavitation.

Output display:
- *Thermal index*
- *Mechanical index*

Part 3

Q. What is the purpose of the ODS?

A. The goal of the ODS is to make users aware of the actual output of their ultrasound equipment as it is being used. The TI and MI provide real-time information about the potential for bioeffects that can be used to help implement ALARA easily and efficiently. As users, we can quickly learn how different control settings change the indices. We implement ALARA by obtaining needed information while keeping the indices, the potential for bioeffects, as low as reasonably achievable.

The MI is a relative indicator of the potential for mechanical effects

Q. What is the MI?

A. Scientific evidence suggests that mechanical or nonthermal bioeffects, such as cavitation, are threshold phenomena, occurring only when a certain level of output is exceeded. However, the threshold level varies depending on the tissue. The potential for mechanical effects is thought to increase as the peak pressure increases but to decrease as the ultrasound frequency increases. The MI automatically accounts for both the pressure and frequency. When interpreting the MI, remember that it is intended to estimate the potential for mechanical bioeffects. The higher the index reading, the greater the potential. However, neither MI = 1 nor any other level indicates that a bioeffect is actually occurring. We should not be alarmed by the reading, but we should use it to implement the ALARA principle.

	Scanned Mode	Unscanned Mode
Soft Tissue	TIS at Surface	TIS Small Aperture Large Aperture
Bone at Focus	TIS at Surface	TIB
Bone at Surface	TIC	TIC

Three thermal indices:
Soft tissue thermal index •
Cranial bone thermal index •
Bone thermal index •

Q. What is the TI?

A. Actually, there are 3 TIs that are used for different combinations of soft tissue and bone in the area to be examined. The purpose of the TIs is to keep us aware of conditions that cause increased temperature elevations, whether at the surface, within the tissues, or at the point where the ultrasound is focusing on bone.

The soft tissue TI (TIS) provides information on whether a change in an instrument setting will lead to an increase or decrease in temperature within soft homogeneous tissue. The cranial bone TI (TIC) provides information on

increases or decreases in temperature in bone at or near the surface, such as may occur during a cranial examination. The bone TI (TIB) provides information on temperature changes in bone at or near the focus after the beam has passed through soft tissue. For example, the TIB is appropriate when focusing near fetal bone during a second- or third-trimester examination.

The TI is a relative indicator of the temperature rise. Thus, a TI reading of 2 represents a higher temperature rise than a TI reading of 1. Because the TI is not an accurate measure of the temperature rise in vivo, a TI of 1 should not be taken literally to mean an actual increase in temperature of 1°C, nor should a TI of 2 be taken to mean an increase of 2°C. Any actual in vivo increase in the risk of bioeffects due to thermal mechanisms in the patient is influenced by a number of factors, such as the tissue type, blood perfusion, mode of operation, and exposure time. Those who developed the standard deliberately chose the term *index* to avoid a literal association between the TI reading and the actual temperature increase. The TI does, however, provide important information to the user: it indicates that the possibility for an increase in the risk of potential bioeffects due to thermal mechanisms exists, and it provides a relative magnitude that can be used to implement ALARA.

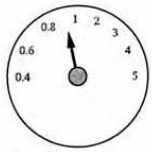
The TI is a relative indicator of the temperature increase

Q. How and when are the output indices displayed?

A. The output display must be located to be easily seen by the operator during an examination. An output display is not required if the transducer and system are not capable of exceeding an MI or a TI of 1. However, if the transducer and system are capable of exceeding an MI or a TI of 1, then it must display values as low as 0.4 to help the user implement ALARA.

No display of any index value is required if the transducer and system are not capable of exceeding an MI or a TI of 1

The standard requires, in instruments where the indices are required to be displayed, that both indices be displayed at all times.



A display of an index value as low as 0.4 is required if the transducer and system are capable of exceeding an MI or a TI of 1

Part 3

Q. Are there other system features required by the ODS?

Manufacturers are required to provide default settings

A. The ODS requires manufacturers to provide default settings on their equipment. These settings establish the output level that will be used automatically at power-up, entry of new patient information, and a change from non-fetal to fetal application presets. Once the examination is under way, the user should adjust the output level as needed to achieve clinically adequate images while keeping the output index as low as possible.

Q. Is it really that simple? All we need to know is the output index value?

A. Yes and no. A high index value does not always mean high risk, nor does it mean that bioeffects are actually occurring. There may be modifying factors that the index cannot take into account. But high readings should always be taken seriously. Attempts should be made to reduce index values but not to the point that diagnostic quality is reduced.

Minimizing exposure time will help reduce risk

The indices do not take time into account. The exposure time is an important factor users must keep in mind, especially if the index is in a range that might be considered high. The exposure time is the ultrasound exposure time at a particular tissue region. In all cases, minimizing the ultrasound exposure time will help reduce risk.

Every patient is different. The tissue characteristics assumed in the formulas for the output display indices may differ significantly from the characteristics of the patient or examination type. Important characteristics we should consider include:

- Body size;
- Blood flow (or perfusion);
- The distance the organ of interest is from the surface;
- Where the bone is in relation to the beam axis and focal point; and
- Factors, such as the presence or absence of fluid, that affect the attenuation of ultrasound.

Q. Tell us in more detail how to use the output display to help implement ALARA.

A. Let's look at the basic principles to follow. To begin, we determine which TI is being displayed. The displayed TI is mode specific, so the index selection is automatic. However, some equipment may allow us to override or add to the system's choice. When displaying a TI, we should ask 4 questions:

Thermal Index	*Tissues*	*Typical Examinations*
TIS	Soft tissue	Cardiac, first-trimester fetal
TIB	Bone near focus	Second- and third-trimester fetal
TIC	Bone near surface	Transcranial

First, which TI is appropriate for the study we are performing: TIS, TIC, or TIB? The TIS is appropriate when imaging soft tissue and is used, eg, during first-trimester fetal examinations or in cardiac color flow imaging examinations. The TIC is used during transcranial examinations. The TIB is used when the focus is at or near bone and may be appropriate for second- and third-trimester fetal examinations or certain neonatal cephalic examinations.

Second, are there modifying factors that might create either an artificially high or low reading? These modifying factors include the location of fluid or bone and blood flow. For example, is there a low attenuation path so that the actual risk for local thermal bioeffects is greater than that suggested by the TI display? This could be caused by an unusually long distance of amniotic or other fluid through which the ultrasound must travel. Another example is that a highly perfused tissue area may have a lower thermal risk than indicated because blood flow transports heat away from the tissue.

Third, even if the index value is low, can I bring it down? Because there is uncertainty about how high is "too high," we should always be alert to ways to adjust the system to reduce the indices. In many cases, an index reading can be reduced without decreasing the quality of the image.

Finally, how can we minimize the ultrasound exposure time without compromising diagnostic quality? This does not mean that we rush through the examination and take the chance of not getting information necessary for an accurate diagnosis. It means that we should get the best image possible with as little exposure time as necessary. There are a number of ways to reduce the exposure time. For example, if the system does not disable pulsing during a freeze frame, remove the transducer from the patient while working with a frozen image on the ultrasound display. Don't scan obstetric patients twice, once to obtain necessary diagnostic information and again to show images to the patient's family and friends. Don't use additional modes, such as Doppler or color, unless they benefit the diagnosis. Only scan areas of the body that are necessary to the diagnosis or contribute to the medical care of the patient.

Q. Give us some examples that show how the indices can be used to implement ALARA.

A. We will look at several examples. When we consider the MI, it might be reduced by selection of the appropriate transducer type, ultrasonic frequency, focal zone, and receiver gain.

Implementation of ALARA by using the indices

Because there are 3 TIs, it is not so simple. As we go through the examples, remember the 4 questions we should ask related to the TI:

- Which TI?
- Are there modifying factors?
- Can we reduce the index value?
- Can we reduce the exposure time?

The first example is a color flow scan of the portal vein of the liver. The TIS is the appropriate selection for nonobstetric abdominal examinations. Possible modifying fac-

tors include capillary perfusion and body size. High perfusion in the imaged tissue will reduce thermal effects, whereas conversely, a lack of perfusion may increase them. With increasing body size, extra tissue attenuation decreases mechanical and thermal effects at the focus. Also, when considering the focus for a soft tissue examination, remember that the greatest heating might occur at the surface, at the focal point, or somewhere in between. For scanned modes, such as B-mode and color flow imaging, and for sector transducers, the greatest heating is usually close to the surface.

The second example is a pulsed Doppler cardiac examination. Again, the TIS is the appropriate TI. The cooling effect of cardiac blood flow is a very important modifying factor. Therefore, the risk of a thermal bioeffect would be significantly reduced.

The next example is a second-trimester pulsed Doppler fetal examination. In most cases with unscanned modes, such as pulsed Doppler, the TI indicates the thermal risk near the surface. If bone is not present, the greatest heating is likely to occur between the surface and the focus or sample volume, and the TIS is the relevant index. But if bone is present, the greatest heating will occur at the location of the bone. In this example, the TIB is the relevant index, although it will overestimate the thermal risk unless the bone is located within the focal zone or sample volume.

The presence of fetal bone near the focal zone is the important factor. If the pulsed Doppler mode is used to measure umbilical blood flow, and we are sure that there is no bone near the sample volume, the TIS is appropriate. However, because the transducer may be moved, it is usually best to make the more conservative choice and select the TIB for all second- and third-trimester examinations. Of direct concern are the fetus's developing neural tissues, such as the brain and spinal cord, that may be in a region of exposed bone.

Other modifying factors include the type of overlying tissue, whether it is fluid or soft tissue, and the exposure time at the particular tissue region. The presence of fluid

is important because if more than half of the path is fluid filled, then the actual thermal risk may be higher. To reduce the potential thermal risk, consider aiming the transducer to miss most of the bone structure without losing the region of interest, if possible, and optimize receiver gain and sample volume controls.

An additional consideration is whether greater heating is likely to be near the surface (in the mother's tissues) or deeper (in the fetal tissues). This depends mostly on whether we are using a scanned (2D or color) or unscanned (M-mode or Doppler) mode. For scanned modes, the greatest heating tends to be near the surface; for unscanned modes, it is closer to the focal zone. However, in most cases in which bone is located along the beam axis, the maximum will occur at the location of the bone.

Another example is a transcranial examination, in which the TIC is the appropriate TI. The presence of bone near the surface is the important factor in this case. To reduce the TIC reading, consider scanning through a thinner part of the skull, so that a lower output setting can be used.

The final example is a neonatal cephalic examination. The choice of the TI depends on the location of bone. Generally, in an examination through the fontanel, the TIB is the appropriate index because of the chance of focusing near the base of the skull. The TIS might be appropriate if the focal zone will always be above the base of the skull. If the examination is through the temporal lobe, the temporal bone near the surface makes the TIC the appropriate index.

CME Test 3 Questions

The following questions are based on "Medical Ultrasound Safety, Second Edition, Part 3: Implementing ALARA." Both true-or-false and multiple-choice questions are included. Each question has only 1 correct answer. Photocopy the CME Test and Evaluation Form and send along with the applicable nonrefundable fee to Medical Ultrasound Safety, Second Edition *CME Test, AIUM, PO Box 79862, Baltimore, MD 21279-0862 USA. This test may also be taken online at www.aium.org. Online participants can print their CME certificates instantly with a passing grade of 70% or higher. All tests must be received by March 30, 2012. For complete CME Test Information, see page 23.*

Objectives: After completing this activity, the participant should be able to discuss the use of output display indices and system control features to implement the ALARA (as low as reasonably achievable) principle.

1. Which operator-adjustable controls indirectly affect intensity and risk for bioeffects?
   A. Pulse repetition frequency.
   B. Pulse length.
   C. Focusing depth.
   D. All of the above.

2. In pulsed Doppler ultrasound, increasing the Doppler sample volume length usually increases the pulse length and temporal-average intensity.
   True or False

3. Increasing the temporal-average intensity value both raises the temperature in the tissue and slightly increases the likelihood for cavitation.
   True or False

4. More energy is delivered to targeted tissue volumes by scanned modes, such as 2-dimensional or color, than by unscanned modes, such as M-mode or Doppler.
   True or False

5. Which thermal index (TI) is appropriate when focusing at or near fetal bone during a second- or third-trimester examination?
   A. Bone TI.
   B. Cranial bone TI.
   C. Soft tissue TI.
   D. None of the above.

(continued)

CME Test 3

CME Test 3 Questions

The following questions are based on "Medical Ultrasound Safety, Second Edition, Part 3: Implementing ALARA."

6. The potential for mechanical effects is thought to increase as the ultrasonic frequency increases.
   True or False

7. During a fetal examination, if more than half of the path is fluid filled, then the actual thermal risk to the fetus may be higher than that suggested by the TI display.
   True or False

8. Which statement is always true when the index value is high?
   A. The bioeffects risk is high.
   B. The bioeffects risk is low.
   C. Bioeffects are occurring
   D. The index value should be reduced if possible but not to the point that diagnostic quality is reduced.

9. High perfusion in imaged tissue significantly increases the risk of a thermal bioeffect.
   True or False

10. Which factor is not taken into account by either the TI or mechanical index?
    A. Exposure time.
    B. Frequency.
    C. Intensity.
    D. Pressure.

Send your completed forms along with the applicable nonrefundable fee to *Medical Ultrasound Safety, Second Edition* CME Test, AIUM, PO Box 79862, Baltimore, MD 21279-0862 USA, or submit tests online at www.aium.org.

CME Test and Evaluation Form

"Medical Ultrasound Safety, Second Edition, Part 3: Implementing ALARA." All tests must be received by March 30, 2012.

Please print. This section must be completed in order to receive CME credit.

Name _____

Degree _____

Street Address _____

Institutional Affiliation _____

City, State, ZIP Code _____

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Profession

Professional organizations in which you hold membership:

_____

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Primary Profession

☐ Physician ☐ Scientist ☐ Sonographer or Technologist ☐ Other

Your Primary Employer is a(n)

☐ Academic Institution ☐ Hospital ☐ Private Practice ☐ Combination ☐ Other

Certifications (Please check all that apply):

ARDMS Certifications

☐ Abdomen
☐ Adult Echocardiography
☐ Breast
☐ Neurosonology
☐ Obstetrics/Gynecology
☐ Ophthalmic Biometry
☐ Ophthalmology
☐ Pediatric Echocardiography
☐ Vascular Technology
☐ Fetal Echocardiography

Medical Board General and Subspecialty Certifications

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  ☐ Neuroradiology ☐ Pediatric Radiology ☐ Vascular and Interventional Radiology
☐ Emergency Medicine
☐ Family Practice
☐ Internal Medicine
  ☐ Cardiovascular Disease ☐ Endocrinology ☐ Gastroenterology ☐ Nephrology
☐ Neurology
☐ Nuclear Medicine
☐ Obstetrics and Gynecology
  ☐ Maternal and Fetal Medicine ☐ Reproductive Endocrinology ☐ Urogynecology
☐ Ophthalmology
☐ Pediatrics
☐ Podiatry
☐ Surgery
  ☐ Breast Surgery ☐ General Vascular Surgery
☐ Urology
☐ Other

I attest to having completed this CME activity.

Signature: _____

(continued)

CME Test and Evaluation Form

Payment

Please check the appropriate fee. This section must be completed in order to receive CME credit. Fees subject to change.

Physicians	☐ Member	$20	(AIUM ID # _____)
	☐ Nonmember	$40	
Sonographers	☐ Member	$10	(AIUM ID # _____)
	☐ Nonmember	$20	

☐ I have enclosed a check made payable to the AIUM, in US dollars, in the amount of $_____.

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Test 2

Please circle the appropriate answer. This section must be completed in order to receive CME credit.

1. A. B. C. D.
2. True or False
3. True or False
4. True or False
5. A. B. C. D.
6. True or False
7. True or False
8. A. B. C. D.
9. True or False
10. A. B. C. D.

Evaluation

Please rate the overall educational effectiveness of this CME activity (rating of 5 = superior, rating of 1 = poor).

1. Quality of "Part 3: Implementing ALARA" CME activity. 5 4 3 2 1

2. Appropriateness of the test questions. 5 4 3 2 1

3. The extent to which the stated educational objectives (at the top of the CME test page) were reached. 5 4 3 2 1

4. Choose "Yes" or "No."
   This activity will influence how I practice ultrasound. ☐ Yes ☐ No
   I learned something new from reading this section. ☐ Yes ☐ No
   Did this presentation appear to be influenced by an unreported conflict of interest? ☐ Yes ☐ No

   If yes, please explain:_____

5. As a result of this CME activity, which of the following best describes a change that you would consider making in how you practice ultrasound?
   ☐ A. I will slightly modify what I currently do.
   ☐ B. I will make a major change in what I currently do.
   ☐ C. I will implement a technique/technology that is completely new to me.
   ☐ D. I will implement a technique/technology that I currently use but for a different purpose.
   ☐ E. None of the above, but with some change to my practice.
   ☐ F. I am not currently considering any changes in the way I use ultrasound after completing this CME activity.

6. Please describe any change(s), if any, that you plan to make in the way you practice ultrasound as a result of this CME activity.

_____

_____

_____

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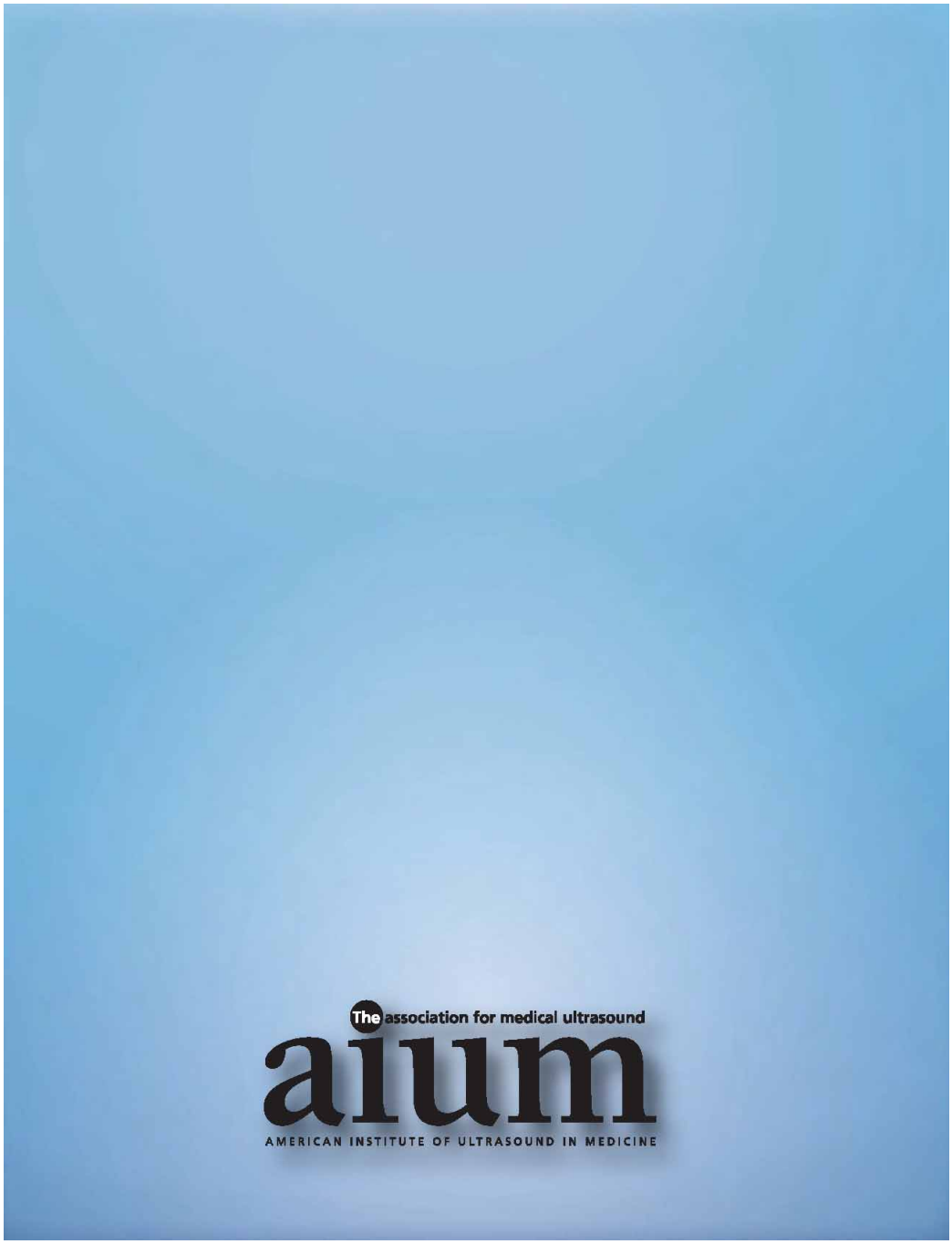
Conclusion

In more than 3 decades of use, there has been no report of injury to patients or to operators from medical ultrasound equipment. We in the ultrasound community want to keep that level of safety.

In the past, application-specific output limits and the user's knowledge of equipment controls and patient body characteristics have been the means of minimizing exposure. Now, more information is available. The MI and TI provide users with information that can be specifically applied to ALARA. MI and TI values eliminate some of the guesswork and provide an indication of both what may actually be happening within the patient and what occurs when control settings are changed. These make it possible for the user to get the best image possible while following the ALARA principle and, thus, to maximize the benefit/risk ratio.

Notes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