

AMERICAN INSTITUTE OF ULTRASOUND IN MEDICINE

# Medical Ultrasound Safety

*Third Edition*

The association for medical ultrasound  
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AMERICAN INSTITUTE OF ULTRASOUND IN MEDICINE

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# Medical Ultrasound Safety

*Third Edition*

Part 1: Bioeffects and Biophysics

Part 2: Prudent Use

Part 3: Implementing ALARA

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# Preface to the Third Edition

Since the last edition of this document, many technological advances in ultrasonic scanning have occurred. The continuing improvements in ultrasonic instrumentation have made possible 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 in the United States has continually increased and is now in the millions each year. Along with the 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. It is incumbent on the user to be knowledgeable in the use of the ultrasound instruments and the potential for ultrasound-induced bioeffects. 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 care professional be aware of the potential harmful effects of ultrasound and how to minimize their occurrence.

—Marvin C. Ziskin, MD  
*Chair, Revision Task Force*  
*AIUM Past President*

# 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

# Introduction

The output display, available on current and future diagnostic ultrasound equipment, 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:

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## **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.

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## **Third Edition**

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

John G. Abbott, PhD

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# Bioeffects and Biophysics

## Chapter 1

### Is It Safe?

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#### 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.*

- 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.*

- 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.

*Everyone thinks ultrasound is safe*

*There is a potential risk*

*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 . . .*

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.

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*

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.

*If there's a potential for bioeffects . . .*

*No patient injury has ever been reported from diagnostic ultrasound*

*Diagnostic ultrasound equipment is regulated by the Food and Drug Administration*

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.”*

This statement was reapproved in March 2010 (see <http://www.aium.org/officialStatements/16>).

*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.



# Bioeffects and Biophysics

## Chapter 2

### Thermal Bioeffects

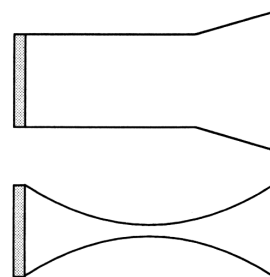
#### Issues Addressed:

- 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-



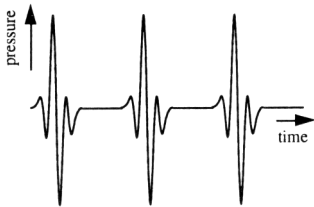
*Focused and unfocused ultrasound fields*



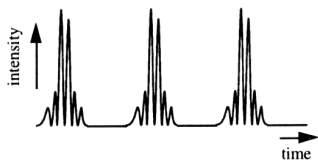
## Spatial considerations

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

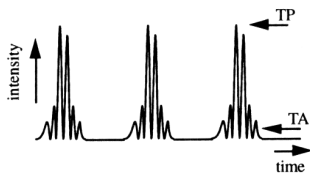
## Temporal considerations



Pulsed pressure waveform



Pulsed intensity waveform



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

Ultrasound exposure duration

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.

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?

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.

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.

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.

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.

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.

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.

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.

#### *Attenuation*

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

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

#### *Increasing attenuation coefficient:*

- *Water*
- *Biological fluids*
- *Soft tissues*
- *Skin and cartilage*
- *Fetal bone*
- *Adult bone*

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.

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.

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

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.

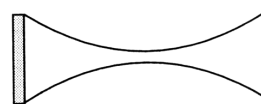
Q. Now let's talk about what all this means in practical terms. What is the situation of greatest interest?

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.

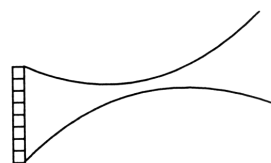
Q. What can we as operators do to minimize the temperature rise?

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*

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 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.

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?

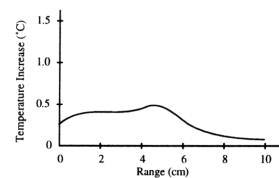
But look at what happens if the focal length is 2 cm. The temperature goes way up to about 1.3°C at a range of about 2 cm. What does that mean? It means that a significant increase in temperature near the beam's focus is more likely with shorter focal lengths because less overall attenuation of the beam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

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

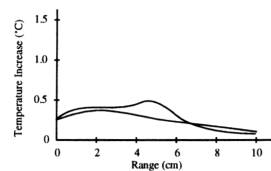
#### *Layered Tissue Model: Obstetric Scan*

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

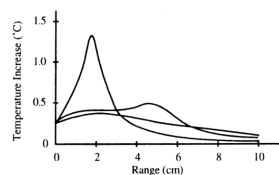
For this situation, we have a layered tissue model on the basis of an obstetric scan through the abdominal wall and through the fluid-filled bladder to the fetus. For the sce-



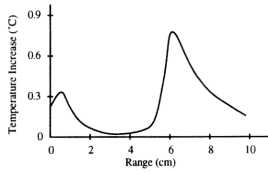
*Homogeneous soft tissue model:  
axial temperature increase profile  
for a transmit focal length of  
6 cm*



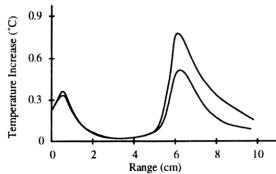
*Homogeneous soft tissue model:  
axial temperature increase profile  
for transmit focal lengths of  
6 and 10 cm*



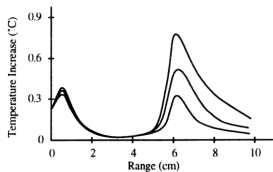
*Homogeneous soft tissue model:  
axial temperature increase profile  
for transmit focal lengths of  
2, 6, and 10 cm*



*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  $1.9^{\circ}\text{C}$  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  $4.2^{\circ}\text{C}$ .

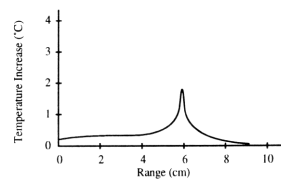
Q. How does all this apply to actually scanning a patient? Is this dangerous?

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.

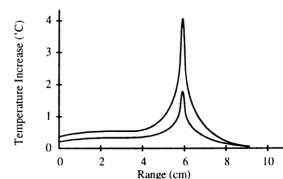
The temperature rise during an actual examination depends on many factors. For example, very few patients have as thin an abdominal wall as we assumed in this model. In addition, the exposure to bone must be continuous over time for local temperatures to rise. That seldom happens in actual examinations. 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.

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.



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



*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*



*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.

# Bioeffects and Biophysics

## Chapter 3

### Nonthermal Bioeffects

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#### Issues Addressed:

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

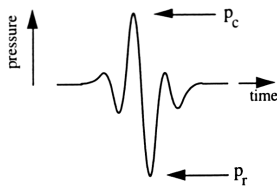
- Q. Nonthermal bioeffects means bioeffects not caused by a temperature rise. That tells us what they are not. Exactly what are nonthermal bioeffects?
- A. Nonthermal bioeffects are not as well understood as thermal effects. They are sometimes referred to as mechanical bioeffects because they seem to 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.

What is cavitation?

Positive pressure =  
compressional pressure

Negative pressure =  
rarefactional pressure



Peak compressional pressure ( $p_c$ ) and  
peak rarefactional pressure ( $p_r$ )

Cavitation depends on:

- Frequency
- Pressure
- Focused/unfocused beams
- Pulsed/continuous ultrasound
- Degree of standing waves
- Nature and state of material
- Boundaries

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.

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 non-contrast imaging unless otherwise necessary to obtain the desired diagnostic information.

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?

- 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.

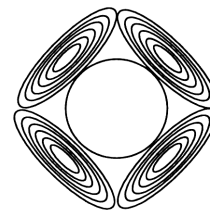
Stable cavitation is associated with vibrating gas bodies. In stable cavitation, a gas body oscillates or pulsates continuously around its equilibrium size. As the oscillations become established, the liquidlike medium around the gas body begins to flow or stream; we call this *microstreaming*. Microstreaming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

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  $1 \mu\text{m}^3$ . 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.

*Cavitation is related to the peak rarefactional pressure*

*Types of cavitation*

1. *Stable*
2. *Inertial (or transient)*



*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,  $MI \leq 1.9$ .

# 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

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

*Risks versus benefits*

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.

*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*

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.



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. Studies are continually being performed to reveal the exposure conditions that might lead to adverse effects of ultrasound on the embryo/fetus. In the early 1980s, the National Institutes of Health (NIH) held a consensus development conference to study the role of ultrasound imaging of the fetus. The conference panel did not recommend routine ultrasound examinations during pregnancy (screening), but it did suggest a number of appropriate clinical indications for the use of ultrasound imaging during pregnancy. Nevertheless, the routine use of ultrasound in pregnancy has continued to increase, and today approximately 90% of women who come to prenatal care in the United States 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*

In December 2012, the NIH, in conjunction with the Society for Maternal-Fetal Medicine, AIUM, American Congress of Obstetricians and Gynecologists, American College of Radiology, Society for Pediatric Radiology, and Society of Radiologists in Ultrasound, convened a Workshop on Fetal Imaging. In contrast to the previous NIH conference, the 2012 workshop panel unanimously agreed that at least 1 ultrasound examination should be offered routinely to all pregnant women between 16 and 22 weeks, preferably 18 and 20 weeks' gestation. The UK National Institute for Health and Clinical Excellence also recommended that ultrasound screening for fetal anomalies should be routinely offered and performed between 18 and 21 weeks' gestation for pregnant women who choose to have screening. Moreover, many more clinical conditions were recognized by the 2012 workshop as appropriate clinical indications for the use of ultrasound imaging during pregnancy.

## Balancing benefits and risks

### Ultrasound benefits:

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

### Prudent use

### New technology and applications

### Users assume more responsibility

Q. How do you balance the 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.

On the other hand, we have the risks: thermal and non-thermal 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.”

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.

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.

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

*Future benefit versus risk*

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.

# 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?

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.

*ALARA, or as low as reasonably achievable*

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.

*Users control the total exposure to the patient*

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 capabilities
- 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.

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.

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.

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.

#### *Transducer capabilities:*

- *Frequency*
- *Penetration*
- *Resolution*
- *Field of view*

#### *System setup:*

- *Starting output power*
- *Starting intensity outputs*
- *Scanning results*

#### *Scanning techniques:*

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





# Implementing ALARA

## Chapter 6 Knobology

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### 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.

*Controls directly  
affecting intensity:*

- *Application selection*
- *Output intensity*

*Application selection*

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.

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

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?

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.

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.

*Controls indirectly affecting intensity:*

- *System mode*
- *Pulse repetition frequency*
- *Focusing depth*
- *Pulse length*
- *Transducer choice*

*System mode*

Q. What about the 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.

*Pulse repetition frequency*

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

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.

*Focusing depth*

*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 ( $\text{mW}/\text{cm}^2$  or  $\text{mW}$ )
- 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.





# Implementing ALARA

## Chapter 7

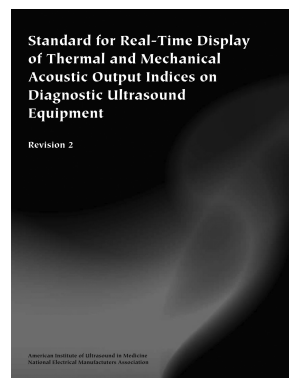
### The Output Display Standard

#### 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 (NEMA), the FDA, the AIUM, and many other medical and basic science societies. The output display standard (ODS) was originally the nickname for the original *Standard for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment*, promulgated by the AIUM and NEMA in 1992. As this document has been discontinued and its content adopted internationally by the International Electrotechnical Commission (IEC), the term “output display standard” has been broadened to mean the current practice and documentation on how the TI and MI are displayed. In particular, “output display standard” refers to the two IEC standards that define the output display: (1) IEC 60601-2-37, which contains the requirements for displaying the indices; and (2) IEC 62359, which contains the test methods for determining the indices.



Output display:

- Thermal index
- Mechanical index

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

	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 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.

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.

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.

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.

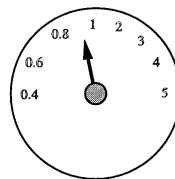
The TI is a relative indicator of the temperature rise. Thus, a TI reading of 2 represents a higher temperature rise than a TI reading of 1. Because the TI is not an accurate measure of the temperature rise in vivo, a TI of 1 should not be taken literally to mean an actual increase in temperature of 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.

- 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.

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

*The TI is a relative indicator of the temperature increase*

*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*



*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*

*Manufacturers are required to provide default settings*

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

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:

<i>Thermal Index</i>	<i>Tissues</i>	<i>Typical Examinations</i>
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?

#### *Color Flow Scan of the Portal Vein*

#### *Color Flow Scan of the Portal Vein*

The first example is a color flow scan of the portal vein of the liver. The TIS is the appropriate selection for nonob-

stetric abdominal examinations. Possible modifying factors 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.

#### *Doppler Cardiac Examination*

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.

#### *Doppler Ultrasound in the First Trimester*

The next example relates to the use of Doppler ultrasound during the first trimester, which is currently being promoted as a valuable diagnostic aid for screening for and diagnosis of some congenital abnormalities. The procedure requires considerable skill and subjects the fetus to extended periods of relatively high ultrasound exposure levels. Due to the increased risk of harm, the AIUM, in accordance with the World Federation for Ultrasound in Medicine and Biology (WFUMB) statement (<http://www.wfumb.org/about/statements.aspx>), recommends that when performing Doppler ultrasound examinations, the displayed TI should be less than or equal to 1.0, and exposure times should be kept as short as possible (usually no longer than 5–10 minutes) and not exceed 60 minutes.

#### *Pulsed Doppler Ultrasound in the Second Trimester*

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 sam-

#### *Doppler Cardiac Examination*

#### *Doppler Ultrasound in the First Trimester*

#### *Pulsed Doppler Ultrasound in the Second Trimester*



ple 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.

#### *Fetal Bone*

#### *Fetal Bone*

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.

#### *Overlying Tissue and Fluid*

#### *Overlying Tissue and Fluid*

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.

#### *Superficial Versus Deep Structures*

#### *Superficial Versus Deep Structures*

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.

*Transcranial Examination*

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.

*Neonatal Cephalic Examination*

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.

*Transcranial Examination**Neonatal Cephalic Examination*

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# Conclusion

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In more than 4 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.

# Medical Ultrasound Is Rapidly Evolving

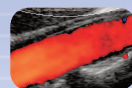
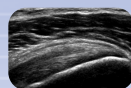
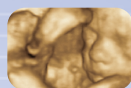
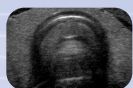
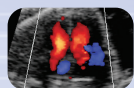
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