



**ARDMS Topic: Clinical Safety, Patient Care,
and Quality Assurance**

**Unit 24:
Patient Safety & Bioeffects**

**Sononerds Ultrasound Physics
Workbook & Lectures**

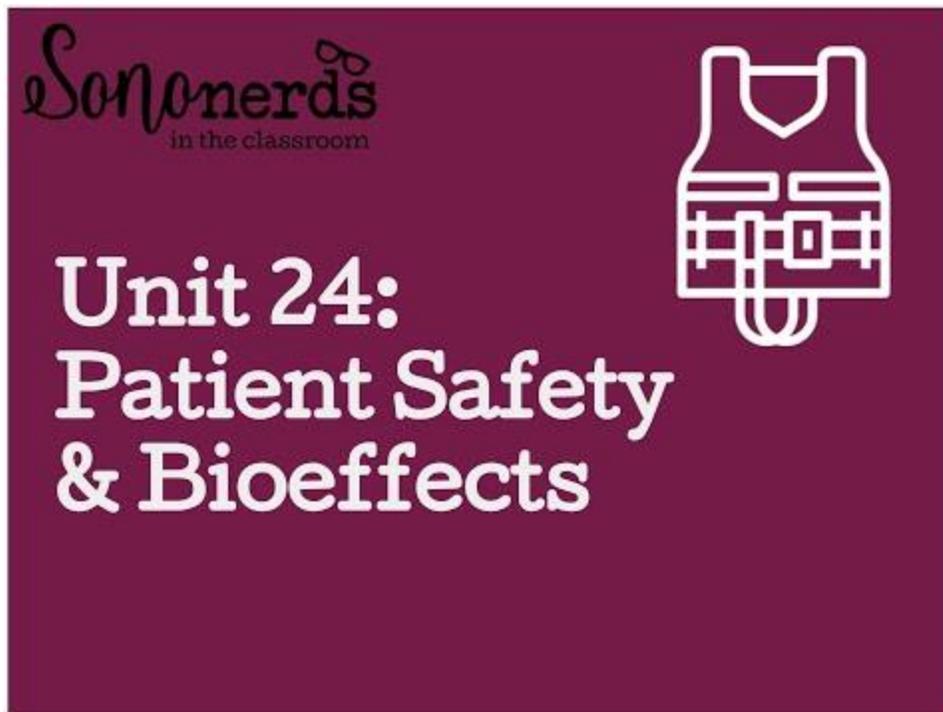
Unit 24: Patient Safety & Bioeffects

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Unit 24: Patient Safety & Bioeffects

[Entire Unit 24 Lecture:](#)



Did you know you can time jump to each section by using the “chapters” in the YouTube video playbar OR timestamps in the video description?

Unit 24: Patient Safety & Bioeffects

When we talked about intensities in Unit 5, we discussed briefly the idea of bioeffects. In ultrasound, when we explore the safety of using high frequency sound to image the body, we need to recognize that the sound energy could have some lasting consequences, which are bioeffects. There are two mechanisms by which bioeffects occur, **thermal and mechanical**.

In this unit we'll take a look at how bioeffects are studied, what tools are used and then break down the thermal and mechanical risks to the patient.

The section of the SPI test that contains safety, quality assurance and new tech is only about 10% of the test. That means that this broad category will only be about 10-12 questions. There is A LOT of information that pertains to the bioeffects of ultrasound, but to avoid information overload, we will try to balance good to know things so you have a foundation and **have to know** things for the test.

Section 24.1 Studying Bioeffects

The goal of studying bioeffects in relation to ultrasound is to ensure the safety of the patient undergoing an ultrasound exam. Studies are performed to determine safe levels of ultrasound energy.

The good news is that when ultrasound is used with intensities intended for diagnostic imaging, there are no known adverse effects noted.

However, we know that when ultrasound levels exceed those used in imaging, bioeffects do occur. WE can use it to our benefit, knowing that very intense ultrasound waves can heat the tissue and have a therapeutic effect, but again this is not imaging intensity.

We also don't know what bioeffects are instantaneous or those that will arise later. **Mechanistic studies** use hypotheses to guess what the bioeffects are and then tests the hypothesis, where **Empirical studies** look for patients that have already underwent an ultrasound exam and their outcomes are reviewed.

Another issue with studying bioeffects is how we can study them. **In vivo, which means in a live specimen (human or other test animal)**, makes it difficult to have a controlled environment and few people, especially obstetric patients, would consent to pushing the limit on safety.

In vitro studies or models that use computers to predict bioeffects are used instead. The data produced by the in vitro studies allows us to better regulate diagnostic imaging equipment to ensure the safety of the equipment.

When preparing a study on ultrasound bioeffects, it is best if the study is **prospective**, meaning the study is designed to answer a question and participants are then recruited and **randomized**, meaning the participants are randomly sorted into the experimental group and a control group. This can be difficult though as we mentioned with in vivo testing, there are a lot of outside factors that cannot be controlled and you need a large number of participants to conduct a better study.

24.1.1 United States Standards

In the United states, there are many groups and associations that have created guidelines around ultrasound safety. Most notably, the **American Institute of Ultrasound in Medicine (AIUM) and the Food and Drug Administration (FDA)**, play the largest roles in regulating ultrasound equipment.

The AIUM is key contributor to the science behind ultrasound bioeffects, the FDA considers the science and recommendations put forth by the AIUM and regulates the **output power (intensity)** that machines in the US can create.

The science tells us that the **SPTA (Spatial Peak, Temporal Average) intensity should be limited to:**

- **100 mW/cm² in unfocused ultrasound &**
- **1000 mW/cm² in focused ultrasound**

The science also highlights that it is **exposure time (exam duration)** that increases the risk of adverse effects for the patient the most.

The AIUMs official statement on Biological Effects in Vivo can be read [here](#).

In general, it acknowledges that there are bioeffects from ultrasound when pushed to certain limits in the laboratory setting, but that these effects have not been reproduced when a professional, trained in the use of ultrasound, performs an exam with the ALARA principle in mind.

24.1.2 ALARA

- **ALARA stands for As Low As Reasonably Achievable**

This means that as sonographers:

- We don't perform any ultrasounds that have not been ordered by a licensed provider
- We choose the correct ultrasound settings to minimize patient exposure to ultrasound energy
- We do not prolong the use of ultrasound unnecessarily

As a sonographer, you should choose the correct presets for the exam you're using (think early OB ultrasound compared to abdomen with penetration). Watch the thermal and mechanical indices and only use tools that are necessary for the exam.

- **Pulsed wave Doppler ultrasound uses a lot of power concentrated to one area and therefore creates the highest intensities.**
 - ◆ **Blood cells are weak reflectors and need more energy to produce meaningful echoes**
- **2D Doppler requires uses lower intensity waves.**
 - ◆ **Soft tissue reflects sound easily and does not need as strong of beams.**
 - ◆ **M-mode uses 2D ultrasound too and is generally safe for 1st trimester ultrasound.**

In addition to making sure to only use ultrasound as necessary, the sonographer should also make sure that the equipment is in proper working order. (Refer to Unit 22: Quality & Performance).

The machine can be a source of electrical and mechanical hazards as well.

- **A crack in the housing of the transducer or worn down coverings create the greatest risk to patient safety.**
 - ◆ **Electrical shock can occur if the transducer integrity is diminished.**

Section 24.2 Measuring Output

The United States sets standards for the power that the machine can put out during a diagnostic exam. The equipment needs to be tested to ensure that the output does not exceed the FDA limits.

To do this, the sound energy produced by the machine is measured. There are multiple tools to do this with:

- **Hydrophone**
- Radiation Force
- Acousto-Optics
- **Calorimeter**
- **Thermocouple**
- Liquid Crystals

These tools can calculate the “dose” of ultrasound a patient is getting.

Dosimetry is the determination and measurement of the amount or dosage of radiation absorbed by a substance or living organism by means of a dosimeter. Note: Dosimetry is often used to monitor personnel working with radioactive materials or patients receiving radiotherapy. Dosimeters are not typically worn by the sonographer but researchers continue to evaluate the long term bioeffects of ultrasound.



24.2.1 Hydrophone

There are 2 types of hydrophones:

Microprobe

A small needle has a small piece of PZT material at the end that connects to an oscilloscope

Membrane

Large PZT membrane with small metallic electrodes centered on both sides connected to an oscilloscope

The probe is inserted into the beam path and the oscilloscope displays the information received by the PZT.

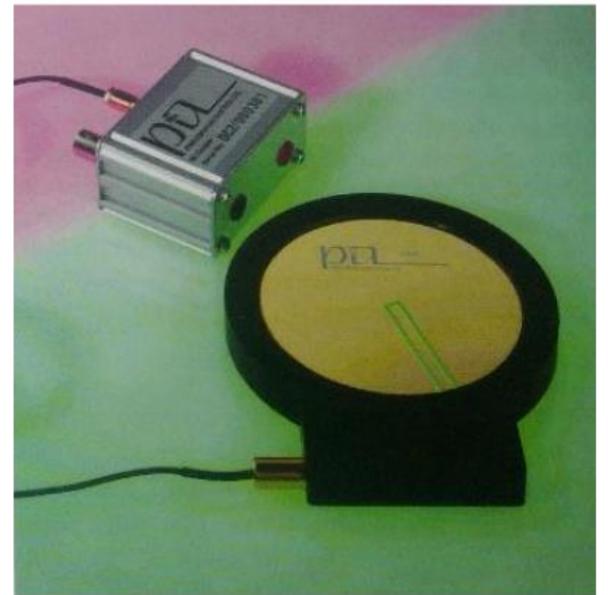
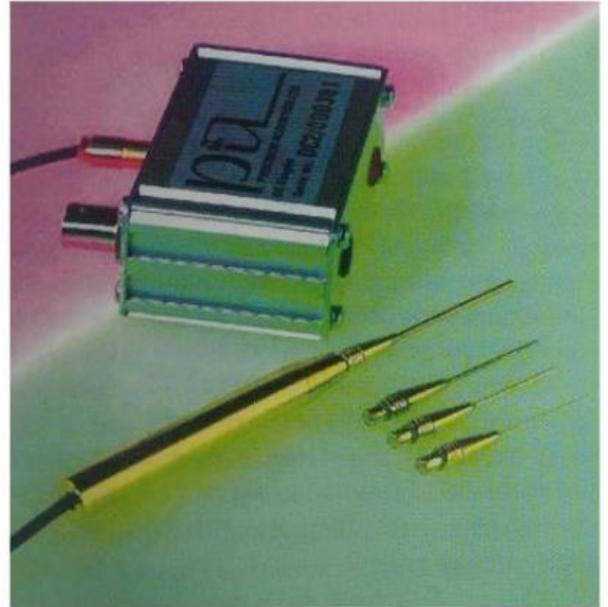
The hydrophone can detect:

- Amplitude
- Period
- Pulse durations
- PRP
- PRF
- Beam shape

Because of its size, the hydrophone can detect acoustic information at **specific locations** and can be moved to measure different locations within a beam.

The hydrophone can detect the **pressure in the sound beam** and calculate information about where its located, like the near field, focus, or far field.

- ★ This is probably the most important tool to be familiar with as it is the gold standard for measuring acoustics.



24.2.2 Radiation Force

Ultrasound waves can exert a small but measurable force on the object it strikes.

There are 2 methods used to measure radiation force:

Float Mode

Balance Mode



A ball is placed either in float mode or balance mode and ultrasound is applied to the ball. The machine can detect the very tiny movement of the ball to measure power of the beam. This can also test specific areas of a beam.

24.2.3 Acousto-Optics

Based on the interaction of sound and light.

The beam creates a "shadow" called a **schlieren**.

This allows us to see the shape of the beam and again look at specific parts.



24.2.4 Calorimeter

A calorimeter is used to **measure total power of the entire sound beam** by observing absorption. It measures the increase in heat as the sound beam travels through the absorbing material.



24.2.5 Thermocouple

Tiny electric thermometer that measures the power of the beam at **particular locations**.

The absorbing material on the thermometer is placed within the sound beam and the temperature is measured.



24.2.6 Liquid Crystals

Crystals change color based on temperature and give insight to the **total power** of the beam as energy changes to heat.

You have seen this before with “mood rings” that change color based on body heat.



24.2.7 Measuring Intensity

Notice that these tools can either measure the total power in the beam or measure in specific locations.

When we talked about measuring intensities, we learned that intensity changes based on the spatial consideration, being in the middle of the beam or towards the edge, which helped to find the average. The tools that can measure specific locations in the beam help to calculate the spatial intensity.

By observing the beam over time, then, the temporal considerations can be measured as well.

For bioeffects:

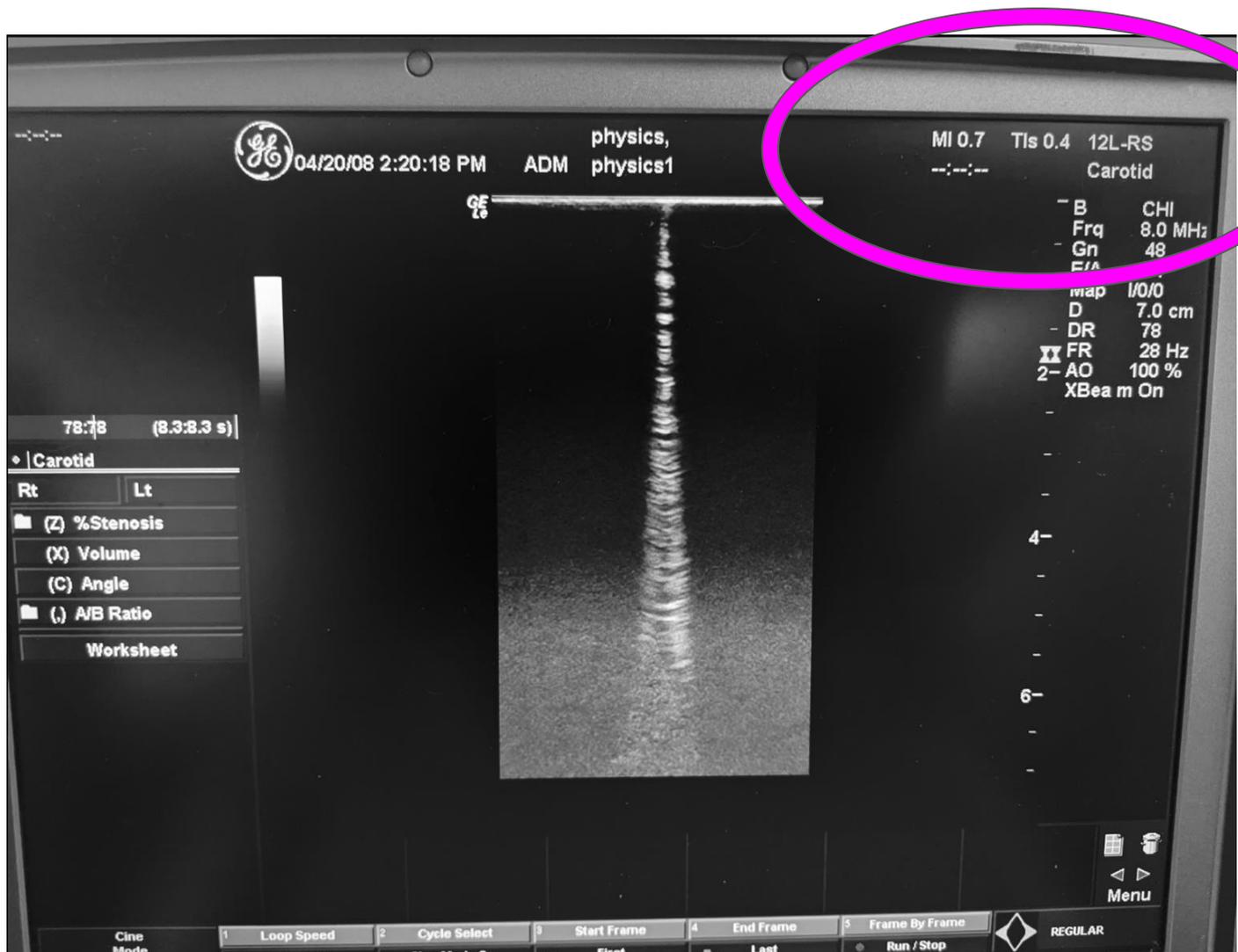
- **Thermal bioeffects are related to the spatial peak temporal average intensity (SPTA)**
- **The pressure that is measured by the hydrophone is related to mechanical bioeffects, but we also see it related to the spatial peak temporal peak (SPTP) intensity as well.**

Section 24.3 Bioeffect Mechanisms

We know that ultrasound does have the capability of producing bioeffects. The two types of bioeffects that we know of are:

- Thermal (heating of biological tissue)
- Mechanical (little bubbles that can destroy biological tissue)

Both of these mechanisms are monitored by the ultrasound system through the Thermal and Mechanical indices. These numbers can be found on the top of the screen.



24.3.1 Thermal Mechanism

Thermal bioeffects result from the temperature in the tissues rising

Humans operate efficiently around 37° C / 98.6° F. If the temperature exceeds this level, certain cellular functions become impaired. We know this from our bodies instinct to “run a fever” to combat bacteria and viruses that make us ill.

Remember that the body will attenuate the sound through absorption, scattering and reflection. Since absorption is the biggest factor of attenuation and that energy is converted to heat, thermal bioeffects are a real concern.

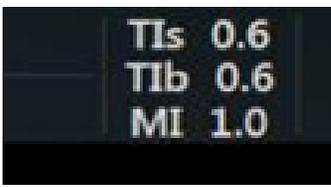
- **Bone is a strong absorber of sound –tissue near a bone is more likely to experience increased temperature.**
 - ◆ Fetal tissue is more likely to experience temperature changes, therefore the thermal indices need to be carefully observed during fetal ultrasound.

Heating will increase when the intensity or frequency increases, however because of attenuation high frequencies don't cause significant changes, especially deep into the body.

- **Temperature increases of more than 2° C have been shown to cause cellular impairment.**
 - ◆ **Up to a 2°C increase in temperature has no known bioeffect**
 - ◆ **2°C to 4°C increase in testicular temperature can result in infertility**
 - ◆ **4°C or more in fetuses is potentially harmful**

The thermal index on the machine tells us the *possible* temperature increase that can occur given the current machine settings. For example if the thermal index is indicated to be 1.0, then there is potential for an increase of 1 degree during the exam.

If the thermal index is 2.0, the exam is at the maximum recommended TI and the exposure time should be limited.



1st Tri OB



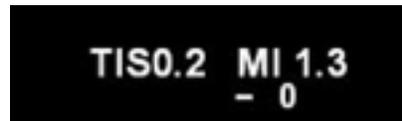
Peds Abdomen



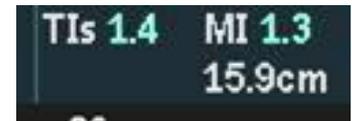
Peds Echo



2nd Tri OB



General Abdomen



Adult Echo



Thyroid



Transcranial Doppler



Carotid

The thermal index can be expressed in one of three ways depending on the type of exam that is being performed. It is more sensitive to changes that can occur when sound is interacting with different types tissue:

→ **TIS (soft tissue thermal index)**

- ◆ Assumes the sound is traveling mostly through soft tissue (typically little absorption during this use)

→ **TIB (bone thermal index)**

- ◆ Assumes that bone is at or near the focus of the sound beam
- ◆ Strongest intensity at the focus and bone absorbs a lot of energy, therefore can heat more

→ **TIC (cranial bone thermal index)**

- ◆ Assumes that skull bones are in the near field of the beam (again, more likely to absorb energy from the beam and heat more)
- ◆ Typically returns the highest TI value

24.3.2 Mechanical Mechanism

→ **Also known as non-thermal mechanism**

The mechanical mechanism for bioeffects looks at the pressure changes of the ultrasound beam as it cycles through tissue. Mechanical index or MI is calculated and informs the user of the likelihood that harmful bioeffects may occur due to **cavitation**.

Recall that as the beam oscillates, there are moments of compression (when the molecules are smooshed together) and moments of rarefaction (when the molecules are spread apart).

When the rarefaction portion of the beam interacts with gas filled bubbles, the bubbles expand. Under minimal pressure, the expansion is minimal, but under great pressure the bubble can **expand greatly and can rupture**. The concern is that when the bubbles rupture, the energy released could damage cells around the gas bubble.

There are naturally occurring gas bubbles all over our body. However, they are more heavily concentrated in the **lungs and intestines**.

→ **Mechanical index is based on peak rarefactional pressure and frequency.**

- ◆ **Cavitation is more likely to occur with lower frequency transducers.**

$$MI = \frac{\textit{Peak Rarefaction Pressure}}{\sqrt{\textit{frequency}}}$$

There are two forms of cavitation:

- **Stable**
- **Transient**

→ **Stable Cavitation - bubbles do not burst.**

Stable cavitation occurs at **lower MI levels**. The bubbles absorb the energy and expand and contract. However, during the expansion and contraction they create their own pressure waves which cause the surrounding cells to undergo **microstreaming, which causes shear stresses**. While unlikely, the shear stresses can cause damage to cells.

→ **Transient Cavitation - bubble burst.**

Transient cavitation is also known as inertial cavitation or normal cavitation and occurs with **higher MI levels**. The high ultrasound energy causes the small gas bubbles to burst. The rupture of the bubble can cause damage to a few cells in the immediate area. Transient cavitation occurs when the beam is 10% stronger than what creates stable cavitation, so it is easy to use too much ultrasound power.

When the bubbles burst they cause not only a sort of shockwave, but can cause a HUGE temperature increase. This is only detrimental to the very few **immediately adjacent** cells, but if you're only a few cells to begin with, like an embryo, we do not want to risk destroying cells.

The mechanical index principles apply to both contrast agents and naturally occurring gas bubbles in the body. However, contrast agents are meant to withstand the ultrasound pressure where the natural bubbles are more likely to be affected by ultrasound.

The MI is also indicated at the top of the image. The MI value refers to the megapascals (MPa) of pressure in the wave. **MI's less than 1.9 are considered generally safe in humans**. However, in testing of mice an MI of 0.4 caused lung hemorrhage and an MI of 1.4 caused hemorrhage in the intestines. Thus, it is crucial to be prudent with the use of ultrasound.

Section 24.4 Clinical Discussion

As a sonographer you will get asked if ultrasound is safe. Or a patient may mistakenly refer to the radiation that ultrasound produces. By being up to date on safety statements from professional organizations, we can help to educate our patients and reassure them that ultrasound is a safe and inexpensive imaging procedure with countless benefits to the medical field.

Nothing in medicine is without absolute risk, but when tests and medications are ordered, the ordering provider has evaluated the risks and benefits and it is clear that when the

→ **Benefits outweigh the risks**

the correct course of action is being taken.

As sonographers we need to be cognizant of our role in patient care and the scope of our practice. We need to make sure that we only perform exams when ordered by a licensed professional, use our machines in accordance with best practices and minimize patient risk by applying ALARA to every exam.

Section 24.5 Activities ← Link to Answer

Match the tool to the definition:

	When sound energy produces heat, it will change a substance to a different color
	This tool can detect many beam characteristics by using PZT material attached to an oscilloscope.
	This tool detects how much mush pressure a beam can create by the way it moves a small ball.
	Measures the total heat put out by a beam, by measuring absorption.
	Measures heat within a beam at specific points of the beam.
	Sees the "shadow" shape of a beam called a Schlieren.

- A. Hydrophone
- B. Acousto-Optics
- C. Radiation Force
- D. Calorimeter
- E. Thermocouple
- F. Liquid Crystals

Typically done outside of the living body, through computer modeling. This is how we know high intensity ultrasound is harmful.



Typically done within the living body, be it a lab rat or human. These studies are rarely done in the setting of high intensity ultrasound because we know it can cause genetic damage and cell death.



What are the two mechanisms of bioeffects in ultrasound?

What are the three thermal tissue indices that can be monitored?

How many degrees of temperature increase is allowable?

What are the two types of cavitation?

What is MI calculated from?

Stable Cavitation or Transient Cavitation



Studies that test hypotheses.



Studies that look at past data..



Tests done on living subjects.



Tests done through computer models.



Studies that plan for needs and recruit based on data needed.



Studies in which patients are grouped unknowingly.



Studies bioeffects.



Makes regulations based on studies.



Thermal intensity.



Mechanical Intensity.



Creates high intensity ultrasound beams.



Creates low intensity ultrasound beams.



Section 24.6 Nerd Check!

1. Why do we study bioeffects?
2. What adverse effects are known for diagnostic ultrasound?
3. What are mechanistic studies?
4. What are Empirical studies?
5. What does in vivo mean?
6. What does in vitro mean?
7. What is a prospective study?
8. What is a randomized study?
9. What are in vivo studies hard in ultrasound?
10. How does the AIUM contribute to patient safety?
11. Hows does the FDA contribute to patient safety?
12. What is regulated by the FDA?
13. What are the max intensities an ultrasound machine can emit?
14. What play the largest role in bioeffects of ultrasound?
15. What does ALARA stand for?
16. What are some things we can do to makes sure we follow ALARA?
17. How do the different types of ultrasound tools affect intensity?
18. What poses the greatest risk to the patient?
19. What is dosimetry?
20. What are the two types of hydrophones?
21. What is a hydrophone attached to?
22. What can a hydrophone measure?
23. Does the hydrophone test all of the beam or specific locations?
24. What is radiation forces testing?
25. What is acousto-optics testing?
26. What is calorimeter testing?
27. Does a calorimeter test all of the beam or a specific location?
28. What is thermocouple testing?
29. Does a thermocouple test all of the beam or a specific location?
30. What is liquid crystal testing?
31. What intensity is associated with thermal bioeffects?
32. What intensity is associated with mechanical bioeffects?
33. What are the two mechanisms of bioeffects in ultrasound?
34. Where can the monitoring data be found for bioeffects on the display?

35. What are thermal bioeffects?
36. What causes energy to be transformed to heat?
37. What body tissue is a strong absorber of sound energy?
38. What is the max allotment for tissue warming?
39. What is the thermal index?
40. What is TIS and what does it tell us?
41. What is TIB and what does it tell us?
42. What is TIC and what does it tell us?
43. What is another name for mechanical mechanism?
44. What part of the wave causes bubbles to expand?
45. Where are natural occurring gas bubbles found?
46. What is MI related to?
47. When is cavitation more likely to occur?
48. What are the two types of cavitation?
49. What is stable cavitation? How does it affect the surrounding cells?
50. What is transient cavitation? How does it affect the surrounding cells?
51. What are 2 other names for transient cavitation?
52. What MIs are considered safe for humans?
53. When should a test or medication be ordered?