Basic Concepts of Safety of Ultrasonic Diagnostic Equipment

Translated and edited by
AFSUMB Safety Committee

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https://www.jsum.or.jp/committee/uesc/pdf/safty.pdf

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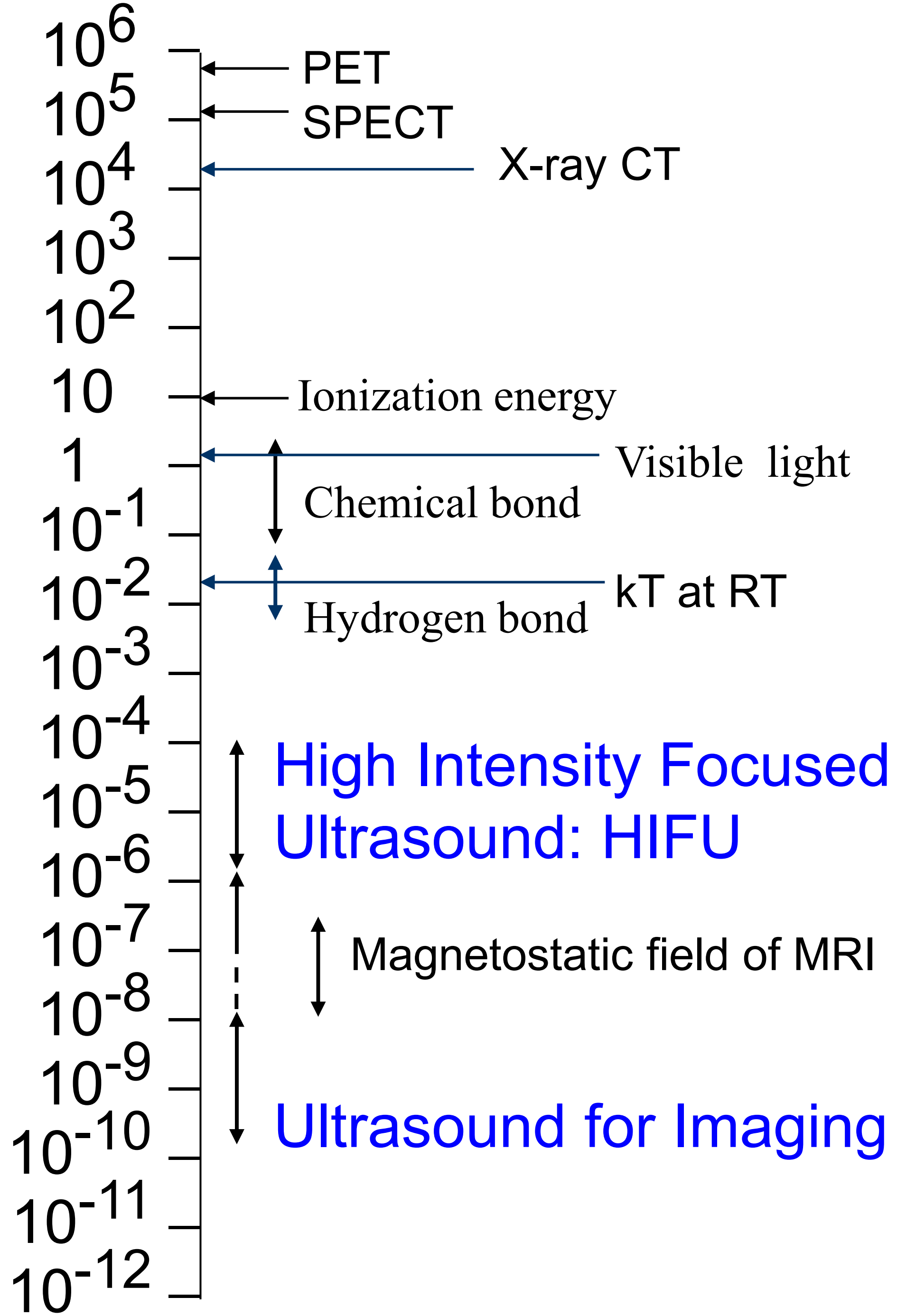
Outline

1. Safety of medical equipment using ultrasound.
2. Biological effects of ultrasound.
3. ALARA principle and index of safety; ***TI*** and ***MI***.
4. Guideline and regulations for safety use.

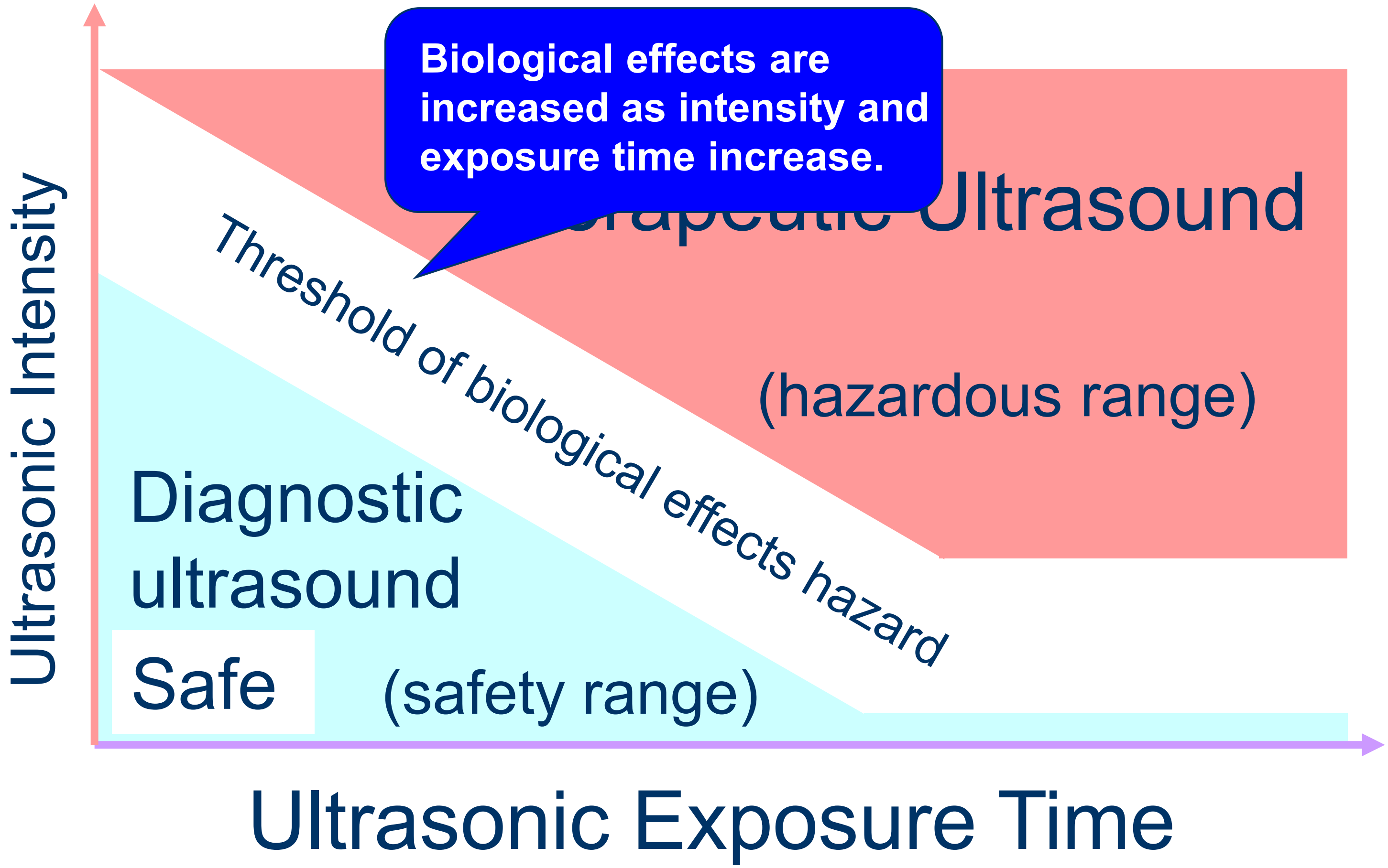
1. Safety of Medical Equipment using Ultrasound

Energy level (eV) of medical equipment

The energy in molecular level of ultrasonic medical equipment is much lower than the others.



Biological effects of diagnostic and therapeutic ultrasound



2. Biological Effects of Ultrasound

Biological Effects of Ultrasound

Ultrasound produces heating, pressure changes and mechanical disturbances in tissue.

Thermal effects

Diagnostic levels of ultrasound are capable of producing temperature rises that may be hazardous to sensitive organs and the embryo/fetus.

Non-thermal effects

Biological effects of non-thermal origin have been reported in animals but, to date, no such effects have been demonstrated in humans, except when a microbubble contrast agent is present.

Thermal Effects

Ultrasonic heat generation depends on the following factors;

- ✓Frequency (or waveform)
- ✓Pulse repetition frequency
- ✓Ultrasonic beam
- ✓Scanning mode
- ✓Thermal conduction and perfusion
- ✓Biological tissue property

Thermal effects by high intensity ultrasound

↓

- ➢Tissue denature
- ➢Abnormal development of fetus (confirmed by animal experiments)

Non-thermal Effects

Acoustic radiation pressure and mechanical operation by ultrasound causes cavitation. Cavitation causes various tissue damages.

✓ **Cavitation**

- **High temperature and pressure in tissues**
- **Free radical generation**
- **Collapse of microbubble**
- **Microstreaming**

→

Non-thermal effects by high intensity ultrasound

- **Activation of chemical effects**
- **Tissue hemorrhage**
- **Tissue rupture**

3. ALARA Principle and Index of Safety; *TI* and *MI*

ALARA Principle

ALARA → As Low As Reasonably Achievable

The phrase refers to a principle of keeping ultrasonic exposure to the environment as low as can be achieved, based on technologic and economic considerations.

Diagnostic information

Risk of biological hazard

AIUM in 1993 issued “Although the possibility exists that such biological effects may be identified in the future, current data indicate that the benefits to the patient of the prudent use of diagnostic ultrasound outweigh the risks, if any, that may be present.”

Thermal Index and Mechanical Index

The Thermal index (***TI***) is an on-screen guide to the user of the potential for tissue heating.

The Mechanical index (***MI***) is an on-screen guide of the likelihood and magnitude of non-thermal effects.

Check ***TI*** and ***MI*** for safe use,
Just like a speedometer!

- Users should regularly check both indices while scanning and should adjust the machine controls to keep them as low as reasonably achievable (ALARA principle) without compromising the diagnostic value of the examination. Where low values cannot be achieved, examination times should be kept as short as possible.

Definition of *TI*

Acoustic output *W* here is the same as *W* of IEC regulation.

$$TI = \frac{W_{\alpha}}{W_{\deg}}$$

W_{α} : Total acoustic power [W]

$W_{\deg}$: Acoustic power required to raise the tissue temperature by 1°C [W]

TI is a calculated estimate of temperature increase with tissue absorption of ultrasound

Three kinds of thermal indices are used for three different tissues.

TIS **Soft tissue thermal index**

TIB **Bone thermal index**

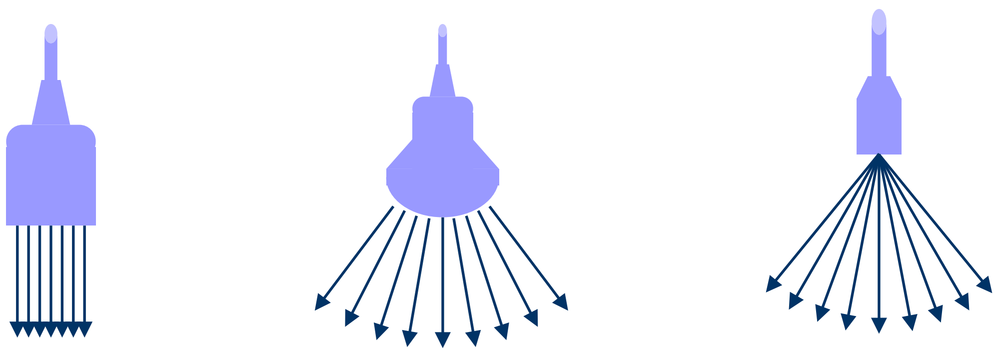
TIC **Cranial bone thermal index**

Types of Modes

Scanning mode

B-mode

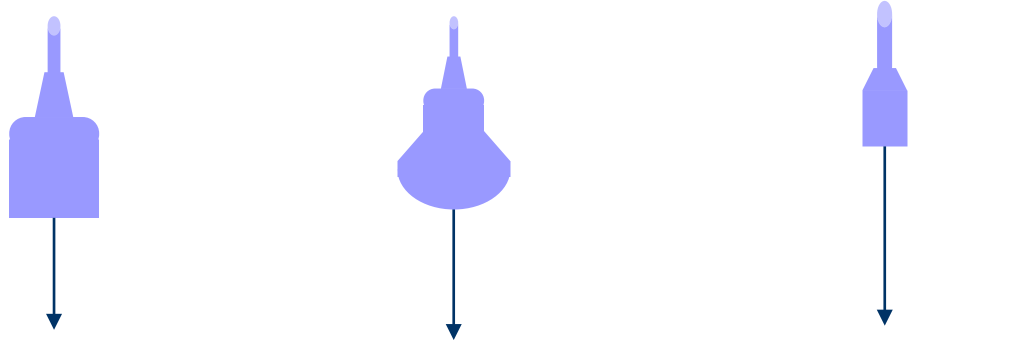
Color flow-mode



Non-scanning mode

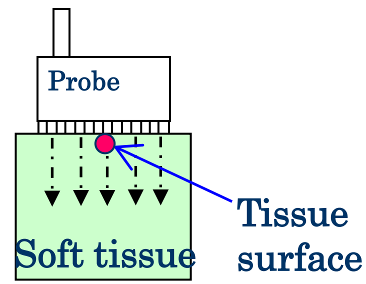
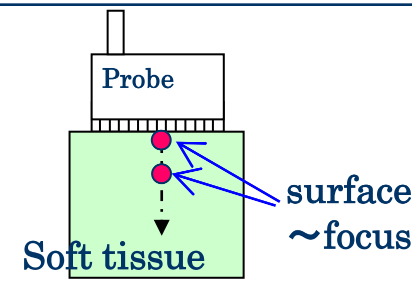
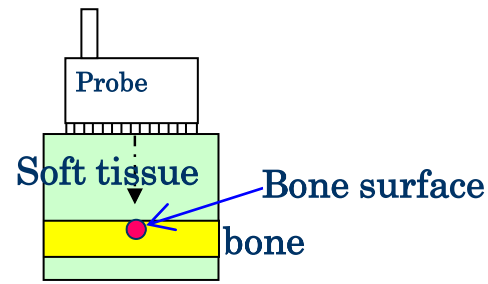
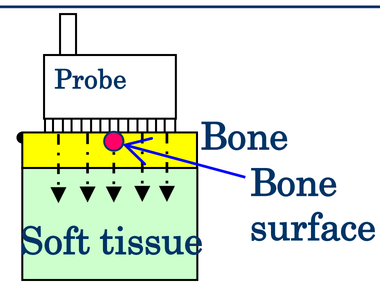
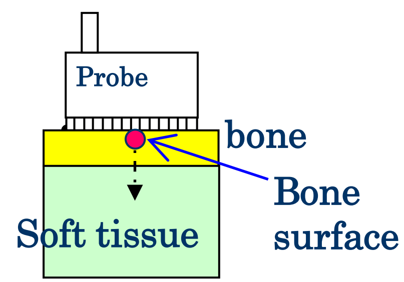
M-mode

Pulsed Doppler-mode



TI model

Position at which the highest temperature rise is assumed

	Scanning mode	Non-scanning mode
TIS Soft Tissue		
TIB Bone		
TIC Cranial-Bone		

Definition of *MI*

The possible occurrence of cavitation, either inertial or non-inertial, should be considered in assessing the safety of diagnostic ultrasound and of other forms of medical ultrasound. It has been shown experimentally that acoustic cavitation can alter mammalian tissues.

Index related to non-thermal effect by cavitation

$$MI = \frac{p_{r.\alpha}(z_{sp})}{\sqrt{f_c}}$$

$p_{r.\alpha}(z_{sp})$ Peak negative pressure during a pulse, which is derated by 0.3 dB/cm/MHz [MPa]

f_c Center frequency [MHz]

To decrease the values of *MI* and *TI*

- *Common for MI* and *TI* （common for modes）
  - Decrease acoustic output (decrease driving voltage)
  - Increase reception gain
- *MI* （for scanning mode ）
  - Increase ultrasonic frequency
- *TI* （for non-scanning mdoe）
  - Decrease pulse repetition frequency （decrease flow velocity range）
  - Decrease exposure time

4. Guideline and regulations for safety use

WFUMB Guideline

- A diagnostic exposure that produces a maximum *in situ* temperature rise of no more than 1.5℃ above normal physiological levels (**37 ℃**) may be used clinically without reservation on thermal grounds.
- A diagnostic exposure that elevates embryonic and fetal in situ temperature above **41 ℃** (**4 ℃** above normal temperature) for **5 mi**n or more should be considered potentially hazardous.
- The risk of adverse effects of heating is increased with the **duration of exposure**.
- The possible occurrence of **cavitation**, either inertial or non-inertial, should be considered in assessing the safety of diagnostic ultrasound and of other forms of medical ultrasound.
- A risk– benefit analysis should be performed if anticipated acoustic pressure amplitude at the surface of postnatal lung tissue exceeds **1 MPa**.
- Safety evaluations should consider the characteristics of the site of ultrasound exposure. Thresholds for non-thermal biological effects are lowest in:
  - (a) tissues that naturally contain gas bodies, e.g., postnatal lung and intestine, and
  - (b) all tissues in the presence of introduced gas bodies, e.g., ultrasonic contrast agents.

Regulations
IEC 60601-2-37, FDA,USA, Track3

- ***MI*** **of up to 1.9 to be used for all applications except ophthalmic (maximum 0.23).**
- **Maximum intensity of ultrasound $I_{spta,\alpha}$=720 mW/cm^2**

Ultrasound exposure during pregnancy

- The embryo/fetus in early pregnancy is known to be particularly sensitive. In view of this and the fact that there is very little information currently available regarding possible subtle biological effects of diagnostic levels of ultrasound on the developing human embryo or fetus, care should be taken to limit the exposure time and the Thermal and Mechanical Indices to the minimum commensurate with an acceptable clinical assessment.

Continued…

- Temperature rises are likely to be greatest at bone surfaces and adjacent soft tissues. With increasing mineralization of fetal bones, the possibility of heating sensitive tissues such as brain and spinal cord increases. Extra vigilance is advised when scanning such critical fetal structures, at any stage in pregnancy. Based on scientific evidence of ultrasound-induced biological effects to date, there is no reason to withhold diagnostic scanning during pregnancy, provided it is medically indicated and is used prudently by fully trained operators. This includes routine scanning of pregnant women. However, Doppler ultrasound examinations should not be used routinely in the first trimester of pregnancy.

Ultrasound Contrast Agents

- These usually take the form of stable gas filled microbubbles, which can potentially produce cavitation or microstreaming, the risk of which increases with ***MI*** value. Data from small animal models suggest that microvascular damage or rupture is possible. Caution should be considered for the use of UCA in tissues where damage to microvasculature could have serious clinical implications, such as in the brain, the eye, and the neonate. As in all diagnostic ultrasound procedures, the ***MI*** and ***TI*** values should be continually checked and kept as low as possible. It is possible to induce premature ventricular contractions in contrast enhanced echocardiography when using high ***MI*** and end–systolic triggering. Users should take appropriate precautions in these circumstances and avoid cardiac examinations in patients with recent acute coronary syndrome or clinically unstable ischemic heart disease. The use of contrast agents should be avoided 24 hours prior to extra-corporeal shock wave therapy.

Clinical Safety Statement for Diagnostic Ultrasound

- Diagnostic ultrasound has been widely used in clinical medicine for many years with no proven deleterious effects. However, investigations into the possibility of subtle or transient effects are still at an early stage. Consequently, diagnostic ultrasound can only be considered safe if used prudently.
- Biological effects (such as localized pulmonary bleeding) have been reported in mammalian systems at diagnostically relevant exposures, but the clinical significance of such effects is not yet known. Ultrasound examinations should only be performed by competent personnel who are trained and updated in safety matters. It is also important that ultrasound devices are appropriately maintained.
- The range of clinical applications is becoming wider, the number of patients undergoing ultrasound examinations is increasing and new techniques with higher acoustic output levels are being introduced. It is therefore essential to maintain vigilance to ensure the continued safe use of ultrasound.

Appendix: Q&A

Q1

Which conditions are most likely to cause biological effects?

① The intensity is low, and the exposure time is long.
② The intensity is high, and the exposure time is short.
③ The intensity is high, and the exposure time is long.

Answer: ③

Although the magnitudes of intensity and exposure time is unknown, in general, biological effects are more likely to occur as both intensity and exposure time increase.

Q2

What factors affect the amount of heat generation caused by ultrasound? (List as many as you can think of.)

Answer: e.g.,

- ✓ Frequency
- ✓ Pulse repetition frequency (PRF)
- ✓ Ultrasonic beam
- ✓ Scanning mode
- ✓ Thermal conduction and perfusion
- ✓ Biological tissue property

Q3

Which sentence is appropriate to explain the ALARA Principle?

① Obtain the information necessary for diagnosis by using the lower ultrasound power.

② Obtain the information necessary for diagnosis by using the higher ultrasound power.

Answer: ①

The ALARA is an abbreviation of "As Low As Reasonably Achievable." We should obtain the information necessary for diagnosis by using the lower ultrasound power.

Q4

Which is the correct unit of sound pressure?

① m/s
② MPa
③ mW

Answer: ②

Q5

Which is the correct unit of ultrasonic intensity?

① W/cm^2

② W/m

③ Pa･s

Answer: ①

Q6

What are the operating conditions of ultrasound diagnostic equipment that affect sound pressure and intensity?

(List as many as you can think of.)

Answer: e.g.,

- ✓ Image mode
- ✓ Probe type
- ✓ Depth of field, number of frames
- ✓ Focal depth
- ✓ Pulse repetition frequency (PRF)
- ✓ Beam pattern

Q7

What does W_{deg} mean in the definition of TI below?

$$TI = \frac{W_{\alpha}}{W_{\mathrm{deg}}}$$

① Total acoustic power

② Acoustic power required to raise the tissue temperature by 1℃

Answer: ②

Q8

What does $p_{r.\alpha}(z_{sp})$ mean in the definition of MI below?

$$MI = \frac{p_{r.\alpha}(z_{sp})}{\sqrt{f_c}}$$

① Positive sound pressure derated by 0.3dB/cm/MHz at z_{sp}.

② Negative sound pressure derated by 0.3dB/cm/MHz at z_{sp}.

Answer: ②

Q9

Which clinical diagnostic situation is the MI more important for safety?

① Contrast agents are used.

② Blood flow with good perfusion and no bubbles are scanned.

③ Tissues with no bubbles are scanned.

Answer: ①

Because the cavitation threshold decreases when the ultrasound contrast agents are used, the MI becomes more important and should be set as low as possible.

Q10

Which of the following is an appropriate method to decrease both TI and MI?

① Decrease ultrasonic frequency.

② Set to non-scanning mode.

③ Decrease acoustic output.

Answer: ③

① *Decreasing ultrasonic frequency increases the MI.*

② *Non-scanning mode results in the higher TI.*

③ *Decreasing the acoustic output decreases both TI and MI.*