

# Diagnostic Ultrasound Safety Ultrasound Safety Indices

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## Abstract

Although diagnostic ultrasound safety is confirmed when the output intensity, it is hard to determine ultrasound level in clinical use of ultrasound diagnosis, therefore thermal and mechanical index values of diagnostic ultrasound are displayed on the monitor screen to confirm the ultrasound intensity, where the ultrasound is safe if the index values are less than 1.0, The ultrasound user controls the ultrasound output to lower the index values below 1.0, if the index values are higher than 1.0 on the monitor screen. Pulsed Doppler wave was recorded reducing the bone thermal index from 1.0 to 0.1.

**Keywords:** Ultrasound; Heating; Fetal animal malformation; Thermal index; Mechanical index; Pulsed Doppler

## Introduction

The recognition of thermal and mechanical ultrasound bioeffects are mandatory in the discussion of diagnostic ultrasound safety. Ultrasound output intensity of diagnostic ultrasound device is also a measure of ultrasound bioeffect. Usually a spacial peak temporal average (SPTA) intensity is measured for the purpose of bioeffect estimation, e.g. the compression of growth curve of cultured cells was detected by the SPTA intensity of pulse and continuous ultrasound [1-3]. Thermal bioeffect is measured by the temperature rise caused by the absorption of ultrasound by the exposed tissue, where the heated ultrasound transducer by the driving electricity should be strictly prevented to warm the exposed subject. e.g. the subjects are exposed to the propagating ultrasound in temperature stabilized water at 37°C water but separated from the electrically heated transducer, i.e. the subject is heated only by the absorbed ultrasound. Direct attachment of ultrasound transducer or probe to the subject should be strictly avoided [1-3], because it may produce the artifact in the experiment of ultrasound bioeffect.

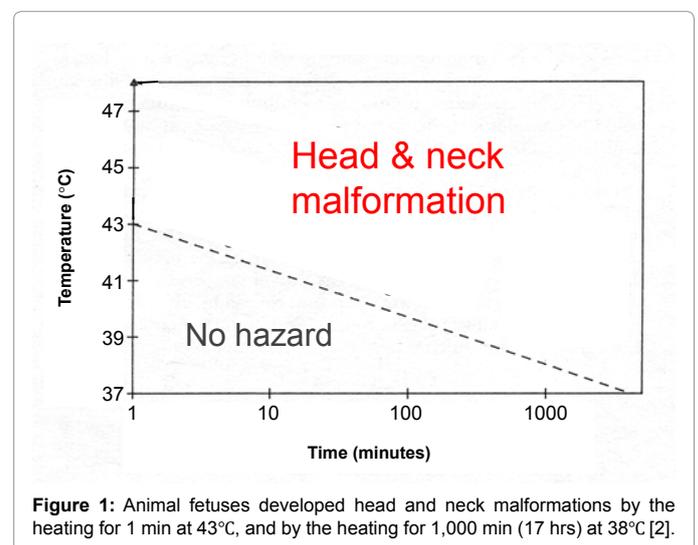
Mechanical ultrasound bioeffect is produced by the pressure of ultrasound. The cavitation, which produce high temperature, high pressure and free radical at the collapse of vacuum bulb, is related to the negative (rarefactional) pressure of ultrasound pulse, therefore the mechanical index (MI) is measured by the rarefactional pressure (Megapascal) divided by the square root of ultrasound frequency (Megahertz). Positive pressure of ultrasound pulse is not the component of mechanical index, but positive pressure will be parallel to negative pressure.

## Methods and Results

### Thermal effects and thermal index

The thermal index (TI) is the most fundamental safety index. The ultrasound beam is absorbed by tissues in the propagation reflecting from the tissue to form ultrasound image, but at the same time the tissue is slightly heated and elevates the tissue temperature by the absorbed ultrasound. The elevated temperature is a tool to measure ultrasound bioeffect. In biological experiments, actively heated animal fetus develops head and neck malformations. The malformation frequently developed when the temperature was high and the exposure time was long Figure 1 [1,2]. In ultrasound, the tissue was highly heated when the ultrasound intensity was high and exposure time was long. Therefore, the ultrasound bioeffect was indirectly known by the temperature rise

and exposure time, by which ultrasound intensity was determined. However, as the ultrasound was attenuated by the propagation and the cooling of local perfusion, standard attenuation and perfusion were taken into account in the intensity determination. By this way, the ultrasound intensity to rise local temperature for 1.0°C was defined as 1.0 thermal index. Thermal effect of diagnostic ultrasound was defined in TI 1.0 to TI 6.0 Figure 2 [2,4], where the temperature rise was one to 6°C, and actual temperature was 38°C to 43°C. Safely exposable times were 1,000 min (17 hrs) in 1.0 TI and 1 min in 6.0 TI according to Figure 1 and 2. The output ultrasound intensity was about 210 mW/cm<sup>2</sup> when TI was 1.0, according to our calculation, thus 1.0 TI intensity is lower than the threshold to suppress cultured cell growth curve, which was SPTA 240 mW/cm<sup>2</sup> [1,3], and it is safe if TI is less than 1.0. Since fetal bone absorbs more ultrasound and temperature elevation was higher than soft tissue, TI was divided into TIs, TIb and TIc. TIs are soft tissue TI, TIb is bone TI, and TIc is cranial TI. TIs are used in

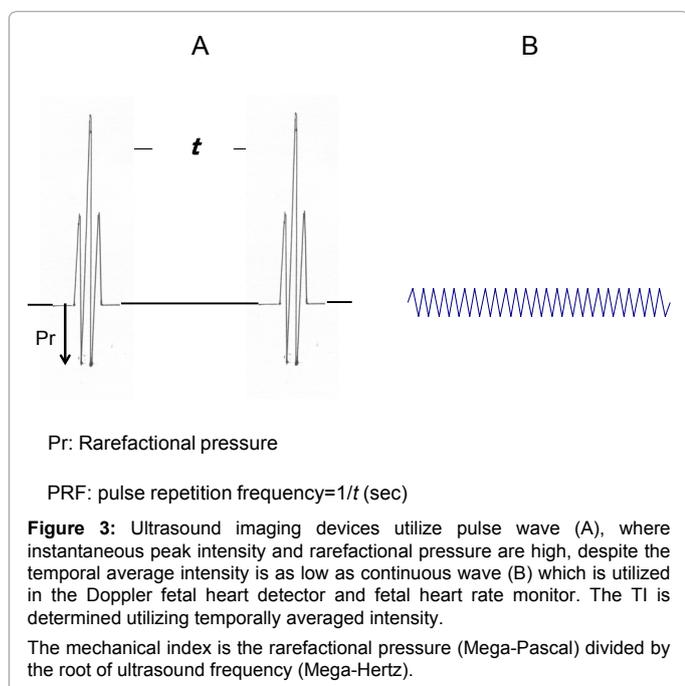
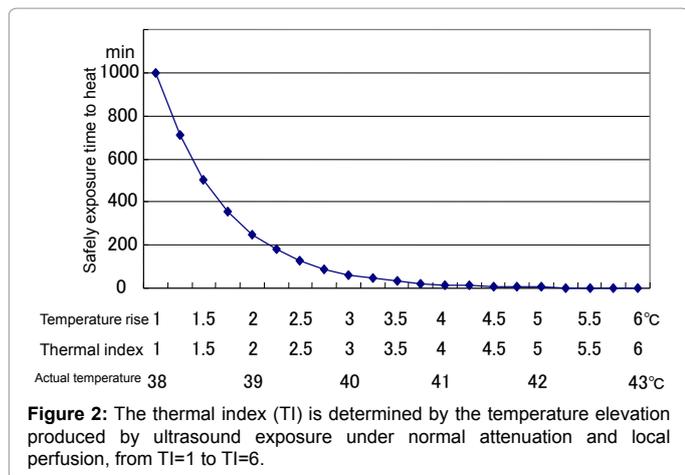


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the embryonal stage before fetal bone formation, and TIb is used after 10 weeks of pregnancy when fetal bone is formed. TIC is used in the transcranial scan.

Caution should be paid for the temperature of the tissue exposed to diagnostic ultrasound in febrile patients, where the basic temperature is higher than 37°C. For example, if TI is 2 in 38°C febrile patient, the temperature rise above physiologic condition is 3°C, the situation is the same as TI 3 in non-febrile normal temperature case, and therefore, long ultrasound exposure is inappropriate in the case.

**Mechanical effect and mechanical index**

The mechanical index (MI) is used for the determination of mechanical bioeffect of ultrasound. The MI is rarefactional sound pressure (Pr) expressed in Megapascal (MPa) Figure 3 divided by square root of ultrasound frequency determined in MHz. The large negative pressure pulse forms vacuum bubbles, of which collapse (cavitation) accompany high pressure, high temperature and forms free radical. Although the bubble is not formed in the cell plasma due

to its high viscosity, and the free radical formed in the liquid hardly reaches cells due to its short life, the high pressure of pulse waves may produce any bioeffect, therefore, even simple imaging devices should be carefully handled in the relation to mechanical effect, because instantaneous pressure is high in the pulse wave ultrasound despite the average intensity is low in the imaging ultrasound of B-mode device. Therefore, it will be important to use diagnostic ultrasound device, of which TI and MI are less than 1.0. Since the hemorrhage is found in neonatal animal lung after the exposure to intense ultrasound, lower MI than 1.0 is recommended in neonatal examination at the chest. Therefore, the MI is less than 1.0 in obstetrical setting.

Biological effects of acoustic streaming, capillary blood cell stasis by the standing wave or the direct ultrasonic pressure requires further basic studies. Ultrasound wave distortion is a cause to increase the intensity.

It is requested to ultrasound user to lower the output intensity of diagnostic ultrasound devices and keep the TI and MI lower than 1.0, when the TI or MI displayed on the monitor screen is higher than 1.0, because the user is responsible to the ultrasound safety [3].

**Discussion**

1. Diagnostic capacity with reduced TI lower than 1.0

The diagnostic ultrasound was reported safe, when the thermal and mechanical indices were less than 1.0. However these days, fetal diagnostic ability of ultrasound with less than 1.0 thermal index is frequently studied.

Since 1.0 TI was 210 mW/cm<sup>2</sup> in our calculation, successful ultrasound diagnosis was expected with the TI lower than 1.0, i. e. Japanese Industrial Standard limited the ultrasound below 10 mW/cm<sup>2</sup> [5], where 10 mW/cm<sup>2</sup> corresponds 0.05TI, and fetal heart rate and movement were normally recorded using 1 mW/cm<sup>2</sup> ultrasound in commercial actocardiogram [5], where the TI is 0.005. Also power Doppler flow velocity curve record will be achieved by the TI lower than 1.0. Fortunately, the TI measuring device was provided by ISUOG staffs.

Actually, 1.0 TI, 0.5 TI and 0.1 TI ultrasounds were able to record the color Doppler flow mapping and pulse Doppler flow velocity waves [6,7] as well as the output reduction had no influence on fetal Doppler measurements in mid pregnancy [8]. These reports are new knowledge's, and according to the ALARA principle, the reduction of ultrasound output without disturbing the diagnosis is very useful for the safety of diagnostic ultrasound. Although the transient increase of animal fetal hepatic cell apoptosis index by the pulsed Doppler ductus venosus blood flow study with the ultrasound devices of which TI was less than 1.0 [9], and the caution to the pulsed Doppler study in the 11-13+6 weeks of pregnancy was declared [10], repeated fetal animal experiments in the 1<sup>st</sup> trimester is hoped by using 0.1-0.2 TI Doppler device.

Despite these output reduction efforts, the output intensity of equipment's reported to US FDA tends to increase [7]. Doppler studies show significantly higher levels of TI, which can reach 1.5 and above [8]. The tendency to raise pulsed Doppler ultrasound will be inappropriate in the trend to reduce pulsed Doppler ultrasound intensity.

**Conclusion**

Recent studies on thermal index of ultrasound devices

In a total of 50 ultrasound nuchal translucency (NT) examinations,

mean gestational age was  $12.3 \pm 0.6$  weeks, mean duration of the ultrasound examination was  $11.6 \pm 4.2$  min, mean TI was  $0.2 \pm 0.1$ , mean MI was  $1.1 \pm 0.1$ , and mean NT was  $1.4 \pm 0.4$  mm [11,12].

To keep the fetus safe in fetal Doppler, knowledge of thermal and mechanical indices in potential bioeffects is mandatory, the 2 most important rules are: to keep thermal index below 1 and use the lowest possible output for the shortest possible time compatible with obtaining diagnostic information [13].

American Institute of Ultrasound in Medicine made 5 recommendations on the TI formulations, entirely new thermal risk indicator, exponential dependence of risk on temperature, inclusion of nonlinear propagation, and a new indicator for risk from thermal mechanism [14].

Ziskin [15] proposed the addition of exposure time (D) to the thermal index. It is called the thermal dose index (TDI), which uses the thermal index (TI) and the examination duration to compute a dimensionless index. The greater the TDI value, the greater the risk of a thermally induced adverse effect. If TDI is 1 or less, there is no expectation of a thermally induced adverse effect.

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