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Ultrasound Output: Thermal (TI) and Mechanical (MI) Indices

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Published in:
Ultraschall in der Medizin

DOI:
[10.1055/s-0033-1335843](https://doi.org/10.1055/s-0033-1335843)

2013

[Link to publication](#)

Citation for published version (APA):
Kollmann, C., ter Haar, G., Dolezal, L., Hennerici, M., Salvesen, K. A., & Valentin, L. (2013). Ultrasound Output: Thermal (TI) and Mechanical (MI) Indices. *Ultraschall in der Medizin*, 34(5), 422-434. <https://doi.org/10.1055/s-0033-1335843>

Total number of authors:
6

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Key words:

Ultrasound, output, safety, thermal index, mechanical index

Educational objectives

- to know the general exposure concept and its application
- to recognise the concept's limitations and drawbacks
- to get to know related safety implications
- to be familiar with TI/MI limits that require user action during scanning

Ultrasound output: Thermal (TI) and Mechanical (MI) Indices

Basic Terminology

ALARA – As Low As Reasonable Achievable

a principle that should be followed whenever possible. The aim is use the lowest machine settings that are compatible with obtaining the required diagnostic information during an ultrasound investigation, and thus to reduce the patient's exposure to ultrasound.

FDA – U.S. Food and Drug Administration

American agency that is responsible for protecting public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, the nation's food supply, cosmetics, and products that emit radiation.

MI - Mechanical Index –

a unitless parameter that is calculated online to give a rough estimate of the risk, from mechanical causes, associated with the ultrasound beam. This is dependent on the actual settings of the device and is indicative of non-thermal bio-effects.

ODS – Output Display Standard -

an American Standard that describes the calculation and display of TI and MI.

TI -Thermal Index -

a unitless parameter that is calculated online to give a rough estimate of the risk, from thermal causes, associated with the ultrasound beam. This is dependent on the actual settings of the device and is indicative for the potential for temperature rise. A higher TI meaning that the temperature rise might be higher than with a lower TI. Depending on the tissue path involved for the application there are 3 different indices defined:

TIS – Thermal Index for soft tissue

TIB – Thermal Index with bone near the focus

TIC – Thermal Index for cranial applications

Introduction

The exposure of tissue to ultrasound is associated with two biophysical mechanisms for producing biological change: thermal and mechanical. Both interaction mechanisms depend on the configuration of the device, and determine the safety of an ultrasound exposure. A scheme that helps to inform the user about the exposure being used during any examination was introduced by the American Institute for Ultrasound in Medicine (AIUM) and National Electrical Manufacturers Association (NEMA) in 1991 [1]. This Standard that shortened name is known as "Output Display Standard- ODS" gives equations for calculating a thermal index (TI) and a mechanical index (MI) associated with the ultrasound scan. The international standard IEC 62359 (Ed. 2), incorporates the ideas of the ODS and explains the rationale and derivation of the equations in detail. The user is updated with this information using a visual display whenever the scan settings are changed [1,2].

Fig.1: TI/MI indices values are displayed in real time on the screen/console (above) and/or ultrasound image (below)

Regulations which control the sale of equipment throughout the world make reference to the ODS, and hence to the Thermal and Mechanical Indices.

Manufacturers wishing to sell equipment in the US, but also in Europe, now must design equipment with a visual display of MI and/or TI (Fig.1), and it is these indices that give users of ultrasound equipment initial information with which to judge its safe use. The validity of the assumptions underlying the calculations used for TI and MI, which have their limitations, have still not been fully explored [3]. However, the TI and MI indices represent an initial step towards informing the user about safety issues.

Depending on the manufacturer's decision if the diagnostic ultrasound systems conform with the ODS or not, the FDA gave two-track restrictions for the maximum output intensity (Tab.1). Track 1 is valid for systems that do not follow the ODS, while Track 3 recommendations are for systems conform with the ODS. A major feature of the ODS is that the responsibility for safety is transferred to the user since, at the time of its introduction, upper limits on output power were significantly increased for most applications. Only the ophthalmic levels are lower because of the low blood perfusion of the eye.

Table 1: maximum acoustic output exposure levels according to ODS/FDA for applications

Basic science

The Mechanical Index - MI

The Mechanical Index calculation uses the measured peak-rarefractional pressure p_r in megapascal (Mpa), where the „attenuated“ peak-rarefractional acoustic pressure ($p_{ra}(z_{MI})$) at the depth z_{MI} is derived from a measurement in water under laboratory conditions, and assuming a coefficient to account for ultrasonic attenuation by tissue in the beam path:

$$MI = \frac{p_{ra}(z_{MI})}{C_{MI} \sqrt{f_{awf}}}$$

where f_{awf} is the acoustic working frequency in MHz and C_{MI} a normalising coefficient (1MPa MHz^{-1/2}).

MI is unitless, and has a maximum allowable value of 1.9 as defined by the ODS [1,2]. Increased pulse amplitudes result in proportionately higher MI values.

Acoustic cavitation is the formation and activity of small (micron sized) gas bubbles in an ultrasound field. Two types of cavitation are existing: inertial (previously called transient) with changes in volume of the bubbles and eventual collapse and non-inertial (also named stable) with oscillations of the bubbles but no change in volume.

The bubbles oscillate and collapse in response to the ultrasound pressure wave, creating localised streaming, pressures changes or further secondary effects (e.g. adiabatic reactions). The rationale for using the MI relies on the fact that there is a threshold acoustic pressure needed to cause cavitation, and hence potential damage. In order to try to relate the mechanical Index to what might happen in vivo, the pressure measured in water is reduced by two factors which increase with both ultrasonic frequency and depth:

- The first is the "attenuation" factor, which gives an estimate of the acoustic pressure within the tissue, assuming a simple tissue model (a process called derating). In general an acoustic attenuation coefficient α of 0.3 dBcm⁻¹MHz⁻¹ is chosen as a compromise.
- The second is a frequency dependence of $1/\sqrt{\text{frequency}}$. This factor is a conservative estimate, intended to compensate for the increase of cavitation threshold with frequency, although underlying evidence for this dependence in tissue is still sparse.

The Thermal Index – TI

The Thermal Index values are intended to give a rough guide to the user about the probable maximum temperature rise during ultrasonic exposure at the particular settings in use.

The method of determination of the thermal index depends on the tissue model for different

exposure conditions (*TIS*, *TIB* or *TIC*). In general the thermal indices are steady state estimates based on the acoustic output power required to heat a particular target tissue, calculated as the ratio of the attenuated acoustic power at a specified point (P) to the attenuated acoustic power required to raise the temperature at that point by 1 °C (P_{deg}), and using a homogeneous tissue 0.3 dB cm⁻¹ MHz⁻¹ attenuation model:

$$TI = \frac{P}{P_{deg}}$$

The TI has thus been deliberately defined to be without units and has a maximum allowed value of 6 [2,4,5]. The equations have evolved from calculations giving estimates of worst-case average values and should not be interpreted as the numerical value of heating in degrees Centigrade within insonated tissues.

Tissue models for calculating TI values

The models used for predicting temperature rise are more varied than those for mechanical index (MI).

Table 2: Classification of index categories

Three thermal index categories are used (Table 2) and depend on different tissue models. The largest value calculated is displayed.

In each case the category used takes account of the three main factors which control heating :

- The potential of the beam to heat tissue depends on the total acoustic output power, which is central to the definition of Thermal Index. When heating is assessed within tissue, the local power is estimated using the simple homogeneous attenuation model described above. In some circumstances, acoustic power is estimated from a measurement of spatial peak temporal-average intensity, I_{spta} , using some simplifying assumptions. All the formulae contain power or intensity as one of the factors.
- The energy absorbed in the tissue is calculated by assuming a value for tissue absorption. For bone a constant fraction of the energy is assumed to be absorbed, independent of the ultrasonic frequency used. For soft tissue, account is taken of the greater energy deposited at higher frequencies, and therefore frequency appears in the formulae.

- The heat lost from the tissue depends on its thermal properties, and on the size of the beam. A number of assumptions are made in the models about the thermal capacity and conductivity of the tissue, and on the extent to which blood perfusion might be expected to cool the tissue. The constants which appear in the formulae derive from these assumptions.

Which index is displayed - MI, TIS, TIB or TIC ?

All four indices, MI, TIS, TIB and TIC can be calculated for any beam generated by a scanner, and in principle all four could appear on the screen to advise the user about safety issues. Some manufacturers may choose to give such information to users, either because the user asks for such a display, or because prudent design encourages it. However strict adherence to the ODS only requires the manufacturer to display an index under a somewhat restricted set of circumstances and after they reach some threshold values (i.e. TI or MI have to be ≥ 0.4) [1]. The Index displayed is selected as being that which might arguably dominate for any particular application (Table 2). For B-mode imaging only the value of MI is displayed. In pulsed Doppler, colour Doppler and M-mode, TI takes precedence. For these modes the selection from the three alternative TI values depends on the application. TIC is only displayed for transcranial applications. For any other application the manufacturer will display TIS or TIB, whichever might seem to be more appropriate for the particular clinical application identified, although the user should have the ability to alter this selection. Nevertheless it must be hoped that manufacturers will display an index at all times, even though they are not actually obliged to do so.

Safety implications

The Index values which are displayed can give very valuable information, previously hidden from the user, about the way in which the operation of the front panel controls alter both the pulse amplitude (and hence MI) and the time-average exposure intensity and acoustic power, and hence the mechanical and thermal risk potential.

The trend towards increasing values of mean pressure and intensity (Fig.2a,b) has continued for modern diagnostic equipment [4], which means that MI and TI values are also rising to the upper end within the FDA output limits.

Figure 2a: Output surveys: maximum intensity values averaged over all modes (data points show the mean and standard deviation) [4]

In general, the risk for non-thermal bioeffects arising during use of diagnostic equipment depends on the frequency used and many current transducers are capable of generating rarefaction pressures exceeding 1 MPa.

Figure 2b : Output surveys: maximum rarefactional pressure values averaged over all modes (data points show the mean and standard deviation) [4]

The potential risk of causing thermal effects in sensitive organs and other tissue, especially during fetal scanning, increases linearly with exposure time, but exponentially with temperature. The heating risk also depends strongly on the dwell time, transducer movement and the presence of bone.

TI/MI values displayed during routine scans of different application fields have been determined [6] and confirm that the maximum values of TI indices occur when colour or spectral Doppler modes are chosen, especially during angiology or cardiology examinations.

Table 3: Limits of TI/MI indices that require user action

The British Medical Ultrasound Society (BMUS) [7] recommends a need for user action for special examinations if the displayed TI/MI values exceed limits specific to different applications derived from in-vitro observations and animal experiments (Table 3). For the user it is essential to obey the ALARA principle in general [8-9,] and especially for obstetric examinations. The maximum scanning times recommended for specific displayed indices given by BMUS may be followed to lower the potential risk [7]. However, the fact that many modern scanners are capable of generating exposures towards the upper end of the permitted range means that it is important for the user to monitor the actual displayed values and to follow safety guidelines. It should be remembered that images may be improved at low output settings by increasing the receive gain. Good practice would maximise these settings before increasing those affecting the transmit power.

Limitations of TI / MI indices

As with any method of evaluating risk, some care is necessary in the use and interpretation of these index values. The conditions under which indices must be displayed to the user according to the ODS are given above. In addition several other limitations to in-vivo conditions exist and these are briefly listed below:

- **simple assumptions for tissue models are used** (these are not adequate for describing 1st trimester scanning through a full bladder or conversely, heating of poorly/highly- perfused tissue is probably under-/over-estimated)
- **"reasonable worst-case" physiology and anatomy is assumed** (but patients vary widely !)
- **temperature rise in tissue due to transducer surface self-heating has not been taken into account**
- **finite amplitude effects are not included**
(non-linearity effects)
- **the scanning time is not considered**
(e.g temperature rise due to stationary scanning is underestimated)
- **thermal indices are steady state estimates and may not be appropriate for new imaging techniques** (e.g. radiation force imaging, pulse or pulse burst imaging, shear wave techniques)
- **the TI value displayed on-screen is not correlated directly to the actual temperature change** (depending on the way calculations are performed, an error by a factor of 2 or even 6 is possible !)
- **TI/MI values are not valid for ultrasound contrast agent applications** (contrast agents lower the threshold of cavitation)
- **the method used by the manufacturer to update the index dynamically may use algorithms not specified by the ODS** (resulting errors should be described in the user manual, and may be as great as 100%)

Conclusions

In conclusion, the user is informed by the indices principally about the levels of exposure changes whilst scanning. These initiatives should be encouraged and refined in future, and users will come to expect that such information is available and useful. The actual display of the Mechanical and Thermal Indices represents an important step in this direction. It is very important, however, to recognise that there remain real difficulties in the complete on-line representation of heating and cavitation hazard, and the display of TI or MI on the screen

should only be taken to be generally indicative of the possibility of a safety concern, and not of well validated measurements of the true heating or cavitation potential caused in tissue during any actual scanning procedure. Prudent use of the equipment settings combined with the ALARA principle is appropriate for balancing the risk to benefit of the scanned patient. In order to be able to follow the ALARA principle, the ultrasound operator must understand the information provided by the indices on screen. Unfortunately, the evidence is that such knowledge may be lacking among ultrasound experts (10-13). More education of ultrasound users on questions of ultrasound safety is clearly needed.

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10 Questions (5 answers, 1 correct)

(the correct one is underlined)

1. Which statement is correct ?

The Output Display Standard ...

- (a) gives information about pre-settings on the display
- (b) gives equations for calculating a thermal and mechanical index
- (c) only gives equations for calculating a mechanical index
- (d) gives equation for calculating a thermal index only
- (e) is not relevant at all for clinical use

2. The thermal index (TI)

- (a) should be interpreted as the temperature rise in degrees centigrade
- (b) should not be interpreted as the temperature rise in degrees centigrade
- (c) should be interpreted as the minimum temperature rise that might be expected in tissue
- (d) does not account for attenuation in tissue
- (e) represents the maximum temperature measured in water under laboratory conditions

3. According to the Output Display Standard the maximum allowable value of TI is

- ...
- (a) 0.7
 - (b) 1.0
 - (c) 1.9
 - (d) 6.0
 - (e) 3.0

4. According to the Output Display Standard the maximum allowable value of MI is

- ...
- (a) 0.7
 - (b) 1.0
 - (c) 1.9
 - (d) 6.0
 - (e) 3.0

5. How many thermal index categories are defined ?

- (a) 1
- (b) 2
- (c) 3
- (d) 4
- (e) 5

6. The potential risk of causing thermal effects to sensitive tissue or organs ...

- (a) increases linearly with exposure time and linearly with temperature
- (b) increases exponentially with exposure time and exponentially with temperature
- (c) increases exponentially with exposure time and linearly with temperature
- (d) does not increase linearly with exposure time and exponentially with temperature
- (e) increases linearly with exposure time and exponentially with temperature

7. Which statement underlying the TI/MI concept is not correct?

- (a) temperature rise in tissue due to transducer surface self-heating has not been taken into account
- (b) finite amplitude effects are not included
- (c) "reasonable worst-case" physiology and anatomy is assumed
- (d) the scanning time is considered
- (e) simple assumptions for tissue models are used

8. Which statement is correct when the value of TI is > 3

- (a) this value does not occur for modern machines
- (b) this does not occur: the TI is limited to 1.9
- (c) there is no potential thermal risk
- (d) the embryo or fetus should not be scanned
- (e) this value should be used for to obtain a good Doppler image

9. TI/MI values are ...

- (a) updated whenever the patient changed
- (b) updated whenever the user changed
- (c) updated whenever the scan settings are changed
- (d) updated every second
- (e) not updated because they are fixed pre-set calculations

10. The highest TI values are most likely to occur ...

- (a) when the M-mode is chosen
- (b) when colour and spectral Doppler modes are chosen
- (c) when the B-mode is chosen
- (d) when the 3D- or 4D-mode is chosen
- (e) when the highest gain or TGC-settings are chosen

Tables für CME „Ultrasound output: Thermal (TI) and Mechanical (MI) Indices “

Table 1: maximum acoustic output exposure levels according to ODS/FDA for applications

use	not conform with ODS (Track 1) I _{SPTA,3} (mW/cm ²)	conform with ODS (Track 3) I _{SPTA,3} (mW/cm ²)
peripheral vessel	720	720
cardiac	430	720
fetal imaging & other*	94	720
ophthalmic	17	50

* abdominal, intraoperative, pediatric, small organs (breast, thyroid, testes etc.), neonatal cephalic, adult cephalic

I_{SPTA,3}: spatial-peak temporal-average intensity reduced by an attenuation coefficient (.3) corresponding to soft tissue. This intensity is the maximum value of the temporal-average intensity in an acoustic field or in a specified plane

Table 2: Classification of index categories

index category	definition /application:
TIS	soft tissue within sound path (e.g. abdominal scanning)
TIB	bone near the focus of the beam (e.g. 2 nd & 3 rd trimester scanning)
TIC	bone is at the surface (e.g. paediatric/adult transcranial scanning)
MI	B-Mode scanning only

Table 3: Limits of TI/MI indices that require user action especially in obs/gyn

Index value	kind of user action
MI > 0.3	reduce exposure time for neonatal lung & intestine
MI > 0.7	potential risk with ultrasound contrast agents
TI > 0.7	reduce exposure time while scanning embryo & fetus
TI > 1	eye scanning not advisable
TI > 3	do not apply while scanning embryo or fetus