Thermal (TI) and Mechanical (MI) Indices (update 2022)

Basic Terminology

ALARA - As Low As Reasonable Achievable -
a principle that should be followed whenever possible to reduce the device's exposure to the patient during ultrasound scanning.

FDA - U.S. Food and Drug Administration -
United States administration that is responsible for protecting the 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 -
a 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 of thermal bio-effects. 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: thermal and mechanical. Both mechanisms depend on the configuration of the device, and are related to the safety of an ultrasound exposure. A concept that helps to inform the user about the exposure being used during any examination was introduced by the American AIUM/NEMA association in 1991 in the "Output Display Standard - ODS" [1]. The ODS gives equations for calculating a thermal index (TI) and a mechanical index (MI) associated with the ultrasound exposure. The user is updated with this information whenever the scan settings are changed, using a visual display [1,2].

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

Regulations which control the sale of equipment throughout the world now make reference to the ODS and to the Thermal and Mechanical Indices.
Manufacturers wishing to sell equipment in the U.S., 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 ensure its safe use. The validity of the assumptions underlying the calculations used for TI and MI have still not been fully explored and they have their limitations [3]. However, the TI and MI indices represent initial steps towards informing the user of safety issues. 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 removed for most applications.

Basic science

The Mechanical Index - MI

The Mechanical Index is calculated from the measured peak-rarefractional pressure p_r in MPa, and uses the „attenuated“ peak-rarefractional acoustic pressure calculated using an attenuation coefficient of 0.3 dB cm^{-1} MHz^{-1} to account for energy attenuation by tissue in the beam path:

$$MI = \frac{p_{r0.3}}{C_{MI}\sqrt{f_{awf}}}$$

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

MI is unitless, and has a maximum allowable value of 1.9 as defined by the ODS [1]. It indicates to users the amplitude of the ultrasonic pulses being used at any time. Increased pulse amplitudes result in proportionately higher MI values. The rationale for using this index 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.
- The second is a frequency dependence of *1/ frequency*. This factor is 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 likely 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 (W) required to heat a particular target tissue, described by a „homogeneous tissue 0.3 dB $cm^{-1}MHz^{-1}$ attenuation model“ divided by 1˚C (W_{deg}):

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

The determination of the acoustic output power depends on the imaging mode (scanning or non-scanning mode). 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 of the insonated tissues.

Tissue models for calculating TI values

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

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 1: Classification of index categories

Three thermal index categories are used (Table 1) and depend on the different tissue models being used. 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 attenuating model described above. For some circumstances acoustic power is estimated from a measurement of spatial peak intensity, I(spta), using some simplifying assumptions. All the formulae have 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 if 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 reaching some marginal values [1]. The Index displayed is selected as being that which might arguably dominate for any particular application (Table 1).

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.1a,b) has continued for modern diagnostic equipment [4], which means that MI and TI values are rising to the upper end within the FDA output limits, too (Table 2).

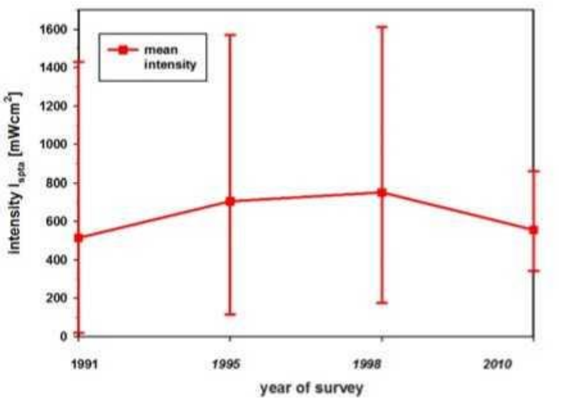

Figure 1a: Output surveys: mean intensity values averaged over all modes [4]

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 rarefraction pressures exceeding 1 MPa.

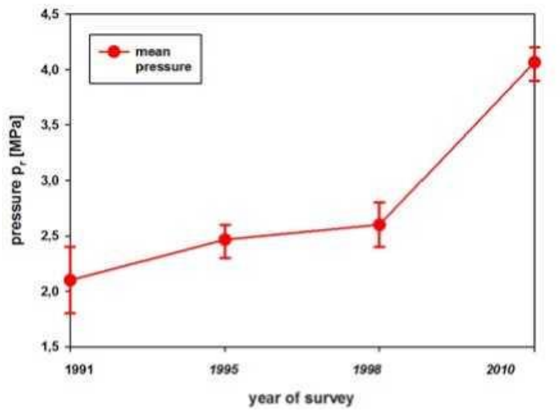

Figure 1b : Output surveys: mean pressure values averaged over all modes [4]

The potential risk of causing thermal effects to sensitive organs and other tissue, especially during fetal scanning, increases linearly with exposure time, but exponentially with temperature. Besides this the heating risk 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.

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

Table 2: Limits of TI/MI indices that require user action

BMUS [7] recommends a need for user action for special examinations if the displayed TI/MI values exceed limits derived from *in-vitro* observations and animal experiments (Table 2). For the user it is essential to obey the ALARA principle in general [8-9,] and for obstetric examinations in particular. The maximum scanning times 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 value and to follow safety guidelines.

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)
- **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's manual, and may be as great as 100%)

Conclusions

In conclusion, therefore, users are given safety information in the form of indices 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 Index 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/benefit of the scanned patient.

References

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[7] BMUS: Guidelines for the safe use of diagnostic ultrasound equipment (2009). www.bmus.org

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