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ACOUSTIC OUTPUT LEVELS AND ULTRASOUND OUTPUT DISPLAY STANDARD

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This paper discusses rationale behind the development of output display standard (ODS) and points out its clinical implications. Physical mechanisms of interaction between ultrasound and biological tissue are reviewed and basic ultrasound field parameters needed to understand and appreciate the impact of Mechanical Index (MI) and Thermal Index (TI) on clinical practice are introduced. Definition of indices is presented and their dependence on acoustic field generated by the scanning probes is discussed. The applicability of MI as an predictor of the potential mechanical effects in B-mode imaging and TI's relevance in Doppler, M-mode and color flow imaging is indicated. Three different tissue models, namely, homogeneous and layered, and bone/tissue interface are presented in detail and the influence of each of the models on the potential temperature increase prediction is stressed. The importance of implementation of ALARA (As Low As Reasonably Achievable) principle is also noted out.

1. Introduction

In the past few decades, ultrasound has become the primary imaging procedure for an increasing number of conditions. Ultrasound imaging is an integral part of obstetrics, gynecology, radiology, cardiology, neurology and neurosurgery, pediatrics, gastoenterology, urology, angiology, surgery, and internal medicine.

It is well known that frequency is one of the key parameters determining the overall resolution of the ultrasound imaging system. However, as the attenuation of the acoustic wave energy in tissue increases with increasing frequency, the use of higher frequency transducer requires more acoustic output in order to visualize structures located at a greater depth. Therefore, to scan deeper at the same output intensity a lower frequency transducer must be used. In clinical practice, that results in a trade off between the

desired image quality and the ability of the system to produce a satisfactory image of deeply lying tissue structures. It is interesting to note that this trade off exists in order to minimize the potential for bioeffects. The output of the commercially available diagnostic sonographic equipment is regulated and cannot exceed prescribed limits. In the USA these limits are established by Food and Drug Administration, Center for Devices and Radiological Health. In Europe the safety standards are usually guided by by IEC (International Electrotechnical Commission). Detailed guidelines for measurements of acoustic output parameters together with information on accepted intensity levels can be found in [1–4].

This paper discusses rationale behind the development of Output Display Standard (ODS) and examines its clinical implications. Physical mechanisms of interaction between ultrasound and biological tissue are briefly reviewed and basic ultrasound field parameters needed to understand and appreciate the impact of Mechanical Index (MI) and Thermal Index (TI) on clinical practice are introduced. Definition of indices is given and their dependence on temporal and spatial parameters of the acoustic field generated by the scanning probes is explained.

2. Physical mechanisms of interaction between ultrasound and biologic tissue

It is widely accepted that there are two basic mechanisms, namely, thermal and nonthermal, by which ultrasound is known to affect biologic materials [5, 6, 17, 19, 20, 25, 26]. Nonthermal mechanisms include cavitational and noncavitational effects, which are associated with certain mechanical aspects of the acoustic or ultrasonic field. These aspects can be described in terms of second-order phenomena, such as radiation pressure, radiation force, radiation torque, and acoustic streaming, and are comprehensively reviewed in other sources [17, 19].

2.1. Thermal mechanism

This mechanism is associated with the absorption of acoustic energy by tissue and the generation of heat. The thermal mechanism appears to be the best understood, and analytic models have been developed to predict the possible temperature elevation in tissue [26]. These models relate acoustic energy to the associated temperature increase, provided that absorption coefficients for the tissues considered are known.

When an ultrasound beam traverses tissue layers, the rate of energy deposition is determined by the factors defined by the operational characteristics of the imaging system and the physical parameters of the tissue being imaged. The system's operating characteristics are functions of the imaging and/or Doppler mode being used, as well as of the focal characteristics of the transducer and its frequency. B-mode energy is distributed over a large volume, whereas in unscanned modes, such as PW Doppler (pulsed Doppler), the acoustic energy is aimed along a single line. Similarly, a highly focused transducer has the potential for a highly concentrated energy deposition, whereas weakly focused

transducers tend to spread the energy over larger volumes. Whether or not energy is deposited in a given tissue volume is determined by that tissue's absorption characteristics, which may vary significantly depending on the organ considered. For example, there is almost no absorption in liquids such as amniotic fluid, blood, and urine. However, an adult bone absorbs about 60% to 80% of the acoustic energy if it falls on ossified bone [25]. The absorption coefficient $\alpha(f)$ is defined by the tissue characteristics, whereas the *in situ* intensity is determined by both the imaging system and the attenuation of the over lying tissues. The relation between the intensity in a given tissue layer and its absorption deserves a brief discussion here. A highly focused beam whose focal point is in amniotic fluid will not cause significant heating of the fluid simply because the absorption of the fluid is low. In this situation, the value of $\alpha(f)$ is relatively low, whereas the intensity has a relatively high value. The same beam with its very high focal intensity will cause a significant temperature rise if it strikes ossified bone, which has an $\alpha(f)$ value that is significantly higher than that of amniotic fluid[16].

Another important determinant of local heating involves the degree of attenuation in tissue layers in front of the point of interest. An increased amount of attenuation in the overlying tissues decreases the energy available for conversion into heat. Thus, the use of fetal Doppler through a thick abdominal wall is less likely to cause a significant temperature increase than are examinations involving patients with thin abdominal walls.

There are at least two mechanisms of heat loss, namely blood perfusion and heat conduction. Blood perfusion is an efficient mechanism for heat removal. The degree of blood perfusion varies between the tissue types: among the best perfused organs are the kidneys, heart, and brain, whereas bone and resting muscle are among the least perfused. The degree of thermal conductivity is relatively uniform among the tissues and is fairly close to that of water, with the exception of bone, which is highly conductive, and fat, which is a poor thermal conductor [22].

There seems to be an agreement that an in *situ* temperature rise to or above 41° C is considered hazardous in fetal exposures because it may lead to undesired effects [7].

Experimental studies indicate that intact mammalian systems (*in vivo*) do not show a significant rise in temperature when exposed to pulsed imaging equipment [6, 7, 20]. However, the recently developed peripheral vessel pulsed and continuous-wave (CW) Doppler equipment, when used for a relatively long time (1–10 min), may be an exception [7, 24]. Therefore, the Doppler system should be used with care, especially during the recently developed applications in which Doppler is used for the study of blood velocities in the umbilical cord and the fetus.

2.2. Cavitational mechanism

The term cavitation refers to phenomena associated with the vibration and motion dynamics of small gaseous bodies when exposed to an ultrasound field [7, 17, 20]. In the first approximation, these gaseous bodies are treated as microbubbles about 1 μm in diameter. Such gaseous bodies may expand because of "rectified diffusion" [13, 15] until their radius grows to the magnitude at which mechanical resonance takes place.

Near the frequency of mechanical resonance, the vibration amplitude of the bubble wall is large and may range up to 100 times the value of the radius at equilibrium [12]. If the bubble does not collapse during the ultrasound exposure, the condition is referred to as stable cavitation, in contrast to inertial (collapse) cavitation [10] during which the vibration amplitude of the bubble wall increases so much that the bubble implodes. This implosion generates highly localized shock waves and is also associated with extremely high local temperatures (up to 10,000° K) [23]. In addition to the temperature elevation, the implosion results in the generation of free radicals such as hydroxyl radicals and hydrogen. These radicals are very active and may lead to some undesired biologic changes, such as spontaneous biochemical reactions within the tissue. It is appropriate to point out here that certain tissues such as lungs may be more prone to cavitation-like events than others. Here, it should be noted, that these findings appear to be relevant to the situation in which the fetus undergoes prolonged exposure to ultrasound in an early state of pregnancy and in the ultrasound visualization of neonates. Therefore, the ultrasound examination time should be minimized, consistent with the requested diagnostic information.

3. Ultrasound field parameters

Certain acoustic information is to be supplied by manufacturers of diagnostic ultrasound equipment. This information consists of values for selected acoustic parameters, chosen for their relevance to performance and safety, or a combination of safety and performance. For example such quantities as center frequency, pulse duration, and source diameter (see Table 1 below) although important primarily for their relevance to achievable resolution, will also govern achievable intensities in various anatomical locations.

Table 1. Associated field parameters.

Center frequency	Affects the resolution, the penetration depth, the absorption coefficient (and hence, the possibility of thermal bioeffects) and other aspects of performance and safety.
Pulse duration	Affects the axial resolution, is proportional to the energy scattered in a pulse; is important in determining the likelihood of cavitation.
Entrance beam dimensions	Relevant to safety as the power P divided by the entrance beam area gives the spatial-average temporal-average intensity in the entrance region.
Focal length	Important for performance and safety as indication of position where I_{SPTA}, I_{SPPA}, and P_r apply, (see Fig. 1 and text below).
Focal depth and cross-sectional dimensions	Important to performance and safety as dimensions and locations of regions to which I_{SPTA}, I_{SPPA}, and P_r apply. The focal cross-sectional dimensions are critically important in recent statements and conclusions relative to safety.

At the other extreme, "acoustic intensity" is most critical in determining penetration. The potential for adverse effects from the ultrasound also depends on the above parameters, as well as on others. In this section, each of the labeling parameters is taken up and its importance to safety and/or efficacy discussed.

It is common practice to relate the bioeffects of ultrasound to intensity or I expressed in units (W/cm^2). As a combination of spatial and temporal intensities is needed to relate an observed bioeffect to ultrasound field parameters, it is important to distinguish between spatial peak, spatial average, temporal (or time) peak, and temporal average intensities (Fig. 1). In addition, spatial peak, pulse average intensity (I_{SPPA}) is often used. In fact, an I_{SPPA} intensity of $190\,W/cm^2$ constitutes a limit for temporal peak output levels of diagnostic ultrasound equipment, while the AIUM statements [5, 7] refer to the I_{SPTA} values.

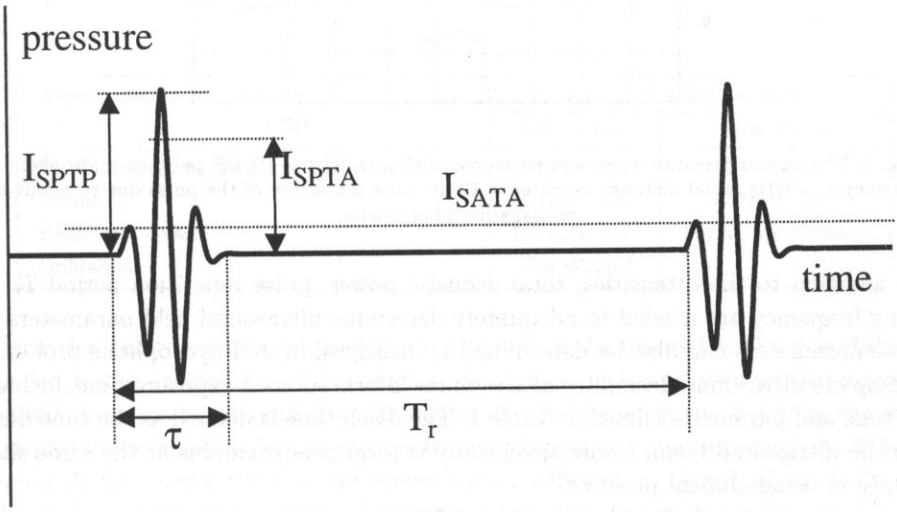

Fig. 1. Schematic representation of the ultrasonic pulses and quantities used in calculation of I_{SPTA}, I_{SPTP} and I_{SATA} intensities.

Spatial peak (SP) intensity is defined as the maximum point intensity measured in the field of a radiating transducer; spatial average (SA) intensity is the average of the intensity across a given area; temporal peak (TP) intensity is the maximum intensity for a given time interval; and time average (TA) intensity is the average of the intensity for a given time interval.

All intensities mentioned above including, I_m – instantaneous maximum [1, 7] are found by analyzing the pressure-time waveform recorded at the prescribed position in the ultrasound field in water, the beam pattern distribution taken at this position, and the measurements of focal distance and imaging frequency [1, 6, 21]. The acoustic pressure-time waveform (Fig. 2), if measured with a calibrated receiver, contains the information required to determine most of the ultrasound exposure parameters. Thus, the waveform contains information about the working frequency of the imaging transducer,

positive and negative peak pressures P (measured in pascals or Pa; 10^3 kPa = 1 bar $\sim$ 1 atmosphere), the pressure gradient, and possible nonlinear propagation phenomena [18, 27]. Knowledge of peak negative rerefactional pressure amplitude P_r is needed to determine the value of the MI (see Sec. 4).

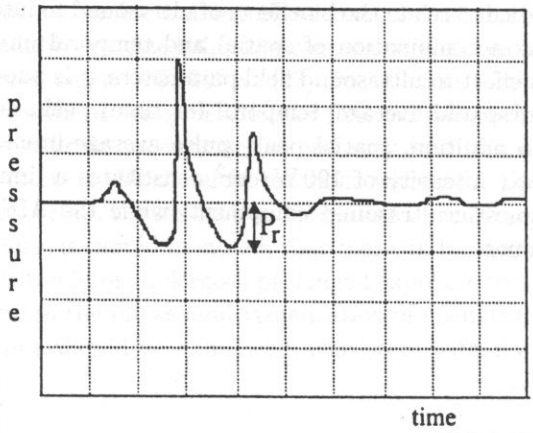

Fig. 2. Ultrasound pressure waveform measured with a wideband PVDF polymer hydrophone, frequency = 5 MHz, axial distance in water = 10 cm; note distortion of the pulse due to nonlinear propagation phenomena.

In addition to the intensities, total acoustic power, pulse repetition period T_r and imaging frequency are needed to adequately determine ultrasound field parameters. All of these parameters can also be determined by using calibrated hydrophone probes.

Complete ultrasound dosimetry also requires information on exposure time, including dwell time and parameters listed in Table 1. The dwell time is defined as the time during which the ultrasound beam (more specifically is focal zone) remains at the same site of the body in usual clinical practice.

As already mentioned each expression of intensity serves a different purpose [21]. Briefly, the I_{SPPA} is a measure of the ultrasound energy associated with a single pulse, and I_m intensity characterizes the maximum instantaneous energy in the period of the pulse duration. The I_{SPTA} corresponds to the energy averaged over a period of time and is proportional to the T_r. Although a typical imaging system has a $f_r = 1/T_r$ on the order of 1 kHz, a f_r as high as 20 kHz may be used in blood flow velocity measurements using Doppler devices.

4. Thermal and mechanical indices

In 1992 NEMA (North American Manufacturers Association) and AIUM (American Institute of Ultrasound in Medicine) agreed on a voluntary standard for on-screen labeling of diagnostic ultrasound devices. The Output Display Standard (ODS) is described in an AIUM publication entitled "Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment", (AIUM, 1992,

and second printing, 1996) and has become a part of FDA's guidance to manufacturers [2]. Manufacturers now have the option to market systems that exceed previously allowed, application-specific levels of ultrasound exposure, as long as the new levels of exposure are displayed on-screen. The exposure levels are expressed in terms of two new indices which reflect the potential for biological effects. This new policy requires more responsibility by the users of these devices for patient exposure levels, but may provide potentially grater diagnostic capability. To maintain an equivalent level of safety, FDA requires that the manufacturers educate users about the new capabilities of these devices, as well as the meaning of the ODS and the attendant responsibilities.

To give an idea of how much change there has been in acoustic output levels, Table 2 shows the relative acoustic output levels between the pre-output-display machines (which complied with application-specific limits set by FDA), and the current, high-output machines.

Table 2.

Application-Specific Limits	I_{SPTA} intensity (derated)	
	Pre- O.D.S.	New Level
Fetal imaging, neonatal, pediatric and other	94 mW/cm^2	
Cardiac	430 mW/cm^2	720 mW/cm^2
Peripheral vessels	720 mW/cm^2	For all applications
Ophtalmic	17 mW/cm^2	

Term derated refers here to predicted reduction in the intenstity. Derating factor [1] is applied to the values of acoustic output parameters such as pressures and intensities measured in water to account for ultrasonic attenuation of tissue between the source and a particular location in the tissue. In acoustic output measurements it is widely accepted [1] to assume the average attenuation coefficient to be 0.3 dB/cm MHz along the beam axis in the body. Derated parameters are denoted with a subscript ".3", e.g. $P_{0.3}(z)$ is the peak pressure amplitude derated by 0.3 dB/cm MHz to the point on the beam axis which lies within tissue (or within the body) at the distance z. It should be noted that the amplitude attenuation coefficient value of 0.3 dB/cm MHz assumes the body tissue to be homogeneous. If this assumption can not be applied, the derating factor may need to be modified. The details of the modification procedure are fairly complex and are beyond the scope of this paper, however, interested readers can find them in [Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, American Institute of Ultrasound in Medicine, Dec. 17, 1997, Appendix D, p. 93–96.]

The new high-output devices are allowed to produce a maximum output of 720 mW/cm^2 for all applications (see Table 2), as long as the Thermal Index (TI) and Mechanical Index (MI), which are defined below, are displayed for every possible setting of transducer type, output setting, focus, frame rate, and pulse rate. This means that, for fetal applications there is a possible 8-fold increase in the allowed maximum derated I_{SPTA} intensity, if the user chooses to use the highest output possible under this new regulation. For ophthalmic use, there is a theoretical 42-fold increase in the maximum

allowed I_{SPTA} intensity, but the MI must be kept below 0.23. Obviously, users of these new, high-output devices do not have to use these high intensity levels, and must be aware, from the day the machine comes into the scanning laboratory, that this is a new kind of machine, and that there are no automatic safeguards on the output. These machines have pre-set default levels that are switched on automatically when the machine is first turned on, or when an application is chosen. For most machines, these pre-set levels correspond to less than maximum output for all applications, but some machines allow the user to change the pre-set default levels to any level that is desired during all ultrasound examinations. It is obvious that the TI and MI indices should be kept as low as possible, consistent with obtaining the required diagnostic information.

The only way to make sense out of the Output Display Standard is to understand the foundations, which consist of the Thermal Index (TI) and the Mechanical Index (MI). The reason for introducing these indices includes the fact that intensity levels alone do not give an accurate estimate of biological exposure. Other factors, such as temperature elevation and the potential for mechanical vibration of tissue can bring about alteration, or damage to tissue. The temperature rise and the possibility of cavitation are, in turn, dependent on such factors as the total energy output, the mode, the shape of the ultrasound beam, the position of the focus, the center frequency, the shape of the waveform, the frame rate, and the amount of time during which the beam produces energy. The TI and MI indices are designed to take all these factors into account, except for time, and give the user instant information about the potential for thermal or mechanical bioeffects, which is more significant than simple output intensity level information.

4.1. Thermal index

The relationship between thermal rise and tissue bioeffects is well known and although present acoustic output measurement parameters, such as: P – output power, I_{TA} – axial temporal-average intensity, and I_{SPTA} – spatial peak of I_{TA} are not individually suitable as indicators or estimators of ultrasound-induced temperature rise, combination of these parameters, along with specific geometric information, can be used to calculate indices which provide an estimate of temperature rise in soft tissue or bone.

Because of the difficulties in thermal modeling of the many ways in which the ultrasound energy interacts with the human body, simplified models based on average conditions are used. Four user-selectable thermal index categories corresponding to different anatomical combinations of soft tissue and bone encountered in imaging applications are defined. Each category uses one or more TI models briefly summarized below which are calculated, based on system information and imaging mode, including transducer aperture or acoustic beam dimensions.

The Soft-tissue Thermal Index (TIS) provides information on temperature increase within *soft homogenous tissue* which resembles the situation encountered in an abdominal exam involving soft tissue only. An example of the temperature increase using homogeneous model is shown in Fig. 3. The plots were calculated for the following parameters: ultrasonic center frequency = 3 MHz, transducer diameter = 19 mm, transmit focal lenghth = 2 cm, 6 cm and 10 cm, output power = 100 mW. At the focal length equal to

6 cm the temperature exhibits 0.5° C increase at about 5 cm depth. At 10 cm focal length the temperature plot flattens whereas at the focal length equal to 2 cm the temperature increases by about 1.3° C. It means that a significant increase in temperature near the beam focus is more likely with shorter focal length because less overall attenuation of the ultrasonic energy has occurred.

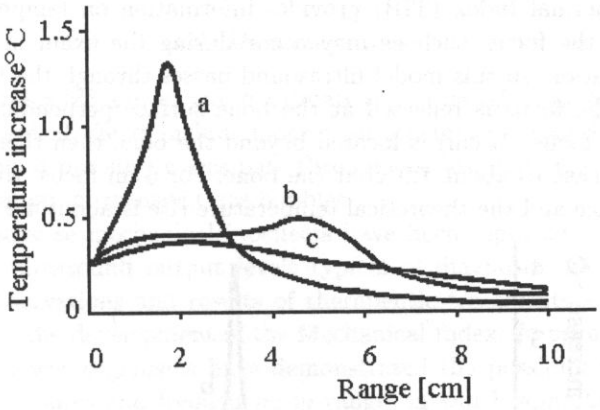

Fig. 3. Homogeneous soft tissue model (TIS) – temperature increase along the propagation axis at three different focal depths: a) 2 cm, b) 6 cm and c) 10 cm. [5] (reproduced with permission of American Institute of Ultrasound in Medicine).

For obstetrics exam more appropriate is *layered tissue model*, Fig. 4. It is based on an obstetrical scan through the abdominal wall and through fluid filled bladder to the fetus. The model assumes a thin abdominal wall of 1 cm and a 5 cm fluid path. At the focal length of 6 cm the far side of the bladder is exposed and the temperature increases by about 0.8°C. However the temperature rises only about 0.4°C in the abdominal wall. For longer focal length of 10 cm, the temperature rise at the at far side of the bladder is

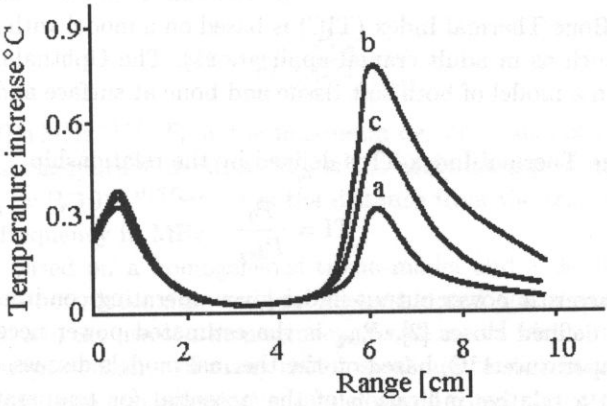

Fig. 4. Layered tissue model – temperature increase along the propagation axis at three different focal depth: a) 4 cm, b) 6 cm and c) 10 cm. [5] (reproduced with permission of American Institute of Ultrasound in Medicine).

about 0.5°C, less than for the beam focused at 6 cm. When the beam focuses at a 4 cm depth in front of the far side of the bladder then the temperature rises about 0.3°C. For all three cases the increase in temperature in the abdominal wall is about 0.4°C. Also, almost no temperature elevation took place in the bladder fluid, as ultrasound absorption in the fluid is negligible.

The Bone Thermal Index (TIB) provides information on temperature increase of bone at or near the focus, such as may occur during the exam in second and third trimester of gestation. In this model ultrasound passes through the homogenous tissue and in or near the focus is reflected at the bone surface perpendicular to the beam, Fig. 5. When the focus (10 cm) is located beyond the bone then there is a peak in the temperature increase to about 1.9°C at the bone. For 6 cm focus, the beam is focused at the bone surface and the theoretical temperature rise is about 4.2°C.

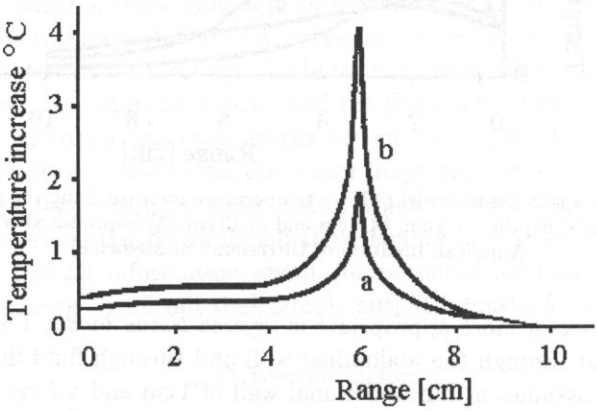

Fig. 5. Fetal bone model (TIB) – temperature increase along the propagation axis at two different focal depths: a) 6 cm and b) 10 cm. [5] (reproduced with permission of American Institute of Ultrasound in Medicine).

The Cranial Bone Thermal Index (TIC) is based on a model with bone located close to the surface (such as in adult cranial applications). The Ophthalmic Thermal Index (TIO) is based on a model of both soft tissue and bone at surface and uses the TIS and TIC models.

In general, the Thermal Index TI is defined by the relationship

$$\mathrm{TI} = \frac{P_0}{P_{\mathrm{deg}}} \tag{1}$$

where P_0 is the acoustic power output under given operating conditions which does not need here to be defined closer [2], P_{deg} is the estimated power necessary to raise the target tissue temperature 1°C, based on the thermal models discussed above.

The TI gives a relative indication of the potential for temperature increase at a specific point along the ultrasound beam. The reason for the term 'relative" is that the assumed conditions for heating in tissue are so complex that this index cannot be assumed to give the actual increase in temperature for all possible conditions. Thus, a TI

of 2 represents a higher temperature rise than a TI of 1, but does not necessarily represent a rise of 2°C. This temperature rise is a theoretical estimate, based on experimental conditions that may not apply to actual clinical conditions. The important point to remember about the TI is that it is designed to make the user aware of the possible temperature rise at a particular point in tissue.

4.2. Mechanical index

A Mechanical Index MI is intended to estimate the potential for mechanical bioeffects. Examples of mechanical effects include motion (or streaming) around compressible gas bubbles as ultrasound pressure waves pass through tissues, and energy released in the collapse, via cavitation, of transient gas bubbles.

Although no adverse mechanical bioeffects have been reported to date in humans from exposure to ultrasound output levels typical of diagnostic ultrasound imaging, several *in vitro* observations and results of therapeutic treatments such as lithotripsy have contributed to the development of the Mechanical Index. *In vitro* experiments and observations with lower organisms have demonstrated the possibility of cavitation at ultrasound peak pressures and frequencies in ranges in which some diagnostic imaging systems can operate. In lithotripsy, mechanical bioeffects can be induced by ultrasound with peak pressures in the same range as are sometimes used in diagnostic imaging, however at markedly different frequencies [7, 11].

Conditions that affect the likelihood of mechanical effects are not yet well understood, however it is generally agreed that this likelihood increases as peak pressure increases, and decreases as the ultrasound frequency increases. Further, it is generally believed to be a threshold effect such that no effect occurs unless a certain output level is exceeded [7, 14].

Although the existing limited experimental data [9] suggest a linear frequency relationship, a more conservative root-frequency relationship was eventually selected [7]. The mechanical index is now defined as [1]:

$$\text{MI} = \frac{P_{r,a}}{(f_{\text{awf}})^{1/2} \cdot C_{\text{MI}}} \tag{2}$$

where $C_{\text{MI}} = 1\,\text{MPa}\,\text{MHz}^{-1/2}$, P_r is the maximum derated value of peak rerefactional or negative pressure amplitude in MPa, $P_{r,a}$ is the attenuated peak-rarefactional pressure in MPa, $P_{r,a} = P_r\, 10^{-0.015 f_{\text{awf}} z}$, z is the distance from the transducer, f_{awf} is the acoustic-working frequency in MHz.

Equation 2 is based on a homogeneous tissue model and a derating factor which is a compromise. Other attenuation models were evaluated and rejected, such as fixed distance models [8] and the use of a homogeneous tissue model with a higher attenuation factor value more representative of many radiological and cardiac imaging applications. However, using more than one attenuation model would entail an increase in equipment complexity and need for user input to select appropriate attenuation schemes. Therefore, it was not felt that the extra complexity in attenuation modeling was justified given the level of understanding of the conditions required to produce mechanical bioeffects. With

the selected compromise attenuation model, the mechanical index is simple to implement, use and, most importantly, sufficient to allow users to minimize acoustic output and any corresponding potential mechanical bioeffects.

As previously mentioned the MI gives a relative indication of the potential for mechanical effects, such as cavitation (the violent collapse of a bubble in tissue), which in scanning modes may be more significant than thermal effects. Thus, the MI is displayed for B-mode imaging. According to the Output Display Standard [3, 17] the MI can range up to 1.9 for all uses except ophthalmic, which has a maximum MI limit of 0.23.

5. Conclusions

The biological index MI and/or TI displayed by the ultrasound machine depends on the transducer being used, and the mode being used. As previously noted for B-mode imaging, the MI will be displayed. For Doppler, M-mode or color flow imaging, the TI will be displayed. Since there are three sub-categories of TI, (i.e. TIS, TIB, and TIC), only one of these is required to be displayed at a time, but the machine must allow the user to retrieve the other two, if needed.

The user needs to remember that only systems capable of exceeding an MI or TI of 1 are required to display these indices. If the system can produce TI or MI higher than 1, then the system must start displaying these index values beginning at 0.4 and ranging up to the maximum, to help the user to implement the ALARA (As Low As Reasonably Achievable) principle. For every new patient to be scanned, a prudent starting point would be to set the machine for the lowest index setting, which is just below 0.4 (except for ophthalmic use, where the index is always kept below 0.23) and then modify (up or down) from this level until a satisfactory image or Doppler signal is obtained, keeping track of the TI or MI. It is important to stress that the index levels do not indicate that a biological effect is actually happening, but only inform the user concerning the relative probability of a biological effect. This is the reason for learning to implement the ALARA principle, using the TI and MI values that are as small as possible, while keeping the quality of the scan as high as possible.

In summary, MI and TI indices constitute a useful expansion in applications of modern diagnostic ultrasound. It is worthwhile to note that with emerging new evidence on ultrasound tissue interaction the requirements for display of indices may be adjusted in the future.

Acknowledgements

Permission to reprint Figures 3, 4 and 5 from the American Institute of Ultrasound in Medicine (AIUM) publication entitled Medical Ultrasound Safety is gratefully acknowledged.

References

[1] *510 (k) Guide for measuring and reporting acoustic output of diagnostic ultrasound devices*, Food and Drug Administration, Washington, DC., 1985 (revisions 1993-6).

[2] National Electrical Manufacturers Association (NEMA), NEMA Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, UD-2-1992, NEMA (Washington, DC.) and AIUM (American Institute of Ultrasound in Medicine) Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment.

[3] National Electrical Manufactures Association (NEMA), NEMA Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, UD-3-1993, NEMA and AIUM (American Institute of Ultrasound in Medicine) Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment.

[4] IEC Ultrasonics – Field Safety, Part 1: Classification Scheme for Medical Diagnostic Fields (International Electrotechnical Committee Draft 87/62B (sec) 63/218, Jan. 1994).

[5] *Medical ultrasound safety*, American Institute of Ultrasound in Medicine, p. 1-40, 14750 Sweitzer Lane, Suite 100, Laurel, MD 20707-5906, 1994.

[6] *Biological effects of ultrasound: Mechanisms and clinical implications*, NCRP Report No. 74, MD, National Council on Radiation Protection and Measurements, Bethesda 1984.

[7] *Bioeffects and safety of diagnostic ultrasound*, pp. 1–40, Laurel, MD, American Institute of Ultrasound in Medicine, 1993.

[8] NCRP, *Exposure criteria for medical diagnostic ultrasound: I. Criteria based on thermal mechanisms*, NCRP Report No. 113, National Council on Radiation Protection and Measurements, Bethesda MD 1992.

[9] R.E. APFEL and C.K. HOLLAND, *Gauging the likelihood of cavitation from short-pulse low-duty cycle diagnostic ultrasound*, Ultrasound Med. Biol., **17**, 179–185 (1991).

[10] S.E. BARNETT, G.R. HAAR, M.C. ZISKIN *et al*, *Current status of research on biophysical effects of ultrasound*, Ultrasound Med. Biol., **20**, 3, 205 (1994).

[11] E.L. CARSTENSEN, S.Z. CHILD, C. CRANE, K.J. PARKER, *Lysis of cells in Elodea leaves by pulsed and continuous wave ultrasound*, Ultrasound Med. Biol., **16**, 167–173 (1990).

[12] C.C. CHURCH, H.G. FLYNN, *A mechanism for generation of cavitation maxima by pulsed ultrasound*, J. Acoust. Soc. Am., **76**, 505 (1984).

[13] L.A. CRUM, G.M. HANSEN, *Growth of air bubbles in tissue by rectified diffusion*, Phys. Med. Biol., **27**, 412 (1982).

[14] C.K. HOLLAND, R.E. APFEL, *Thresholds for transient cavitation produced by pulsed ultrasound in a controlled nuclei environment*, J. Acoust. Soc. Am., **88**, 2059–2069 (1989).

[15] P.A. LEWIN, L. BJORNO, *Acoustic pressure amplitude thresholds for rectified diffusion in gaseous microbubbles in biological tissue*, J. Acoust. Soc. Am., **69**, 846 (1981).

[16] P.A. LEWIN, B.B. GOLDBERG, *Ultrasound bioeffects for the perinatologist*, [in:] Gynecology and Obstetrics, J.J. SCIARRA [Ed.], pp. 1–19, Lippincott-Raven, Philadelphia 1997.

[17] D.L. MILLER, *A review of the ultrasonic bioeffects of microsonation: Gas-body activation and related cavitation-like phenomena*, Ultrasound Med. Biol., **13**, 443 (1987).

[18] T.G. MUIR, E.L. CARSTENSEN, *Prediction of nonlinear effects at biomedical frequencies and intensities*, Ultrasound Med. Biol., **6**, 345 (1980).

[19] W.L. NYBORG, *Physical mechanisms for biological effects of ultrasound*, US Department of Health, Education, and Welfare, Publication No. 78-8062. Washington, DC, Government Printing Office, 1977.

[20] W.L. NYBORG, M.C. ZISKIN, *Biological Effects of Ultrasound*, New York, Churchill-Livingstone 1985.

[21] W.L. NYBORG, J. WU, *Relevant parameters with rationale*, [in:] Ultrasonic Exposimetry, M.C. ZISKIN, P.A. LEWIN [Eds.], pp. 85–112, CRC Press, Boca Raton, FL 1993.

[22] K.M. SEEKINS, A.F. EMERY, *Thermal science for physical medicine*, [in:] Therapeutic Heat and Cold, J.F. LEHMANN [Ed.], pp. 70–132, Williams & Wilkins, Baltimore 1982.

[23] C. SEHGAL, R.G. SUTHERLAND, R.E. VERRAL, *Sonoluminescence of NO- and NO_2-saturated water as a probe of acoustic cavitation*, J. Phys. Chem., **84**, 396 (1980).

[24] H.S. STEWART, P.X. SILVIS, S.W. SMITH, *Patient exposure data for Doppler ultrasound*, Clin. Diagn. Ultrasound, **34**, 187 (1986).

[25] M.E. STRATMEYER, H.F. STEWART, *An overview of ultrasound: Theory measurements. Medical applications and biological effects*, Washington, DC, US Department of Health and Human Services. Publication No. (FDA) 82–8290, 1982.

[26] K.E. THOMENIUS, *Estimation of the potential for bioeffects*, [in:] Ultrasonic Exposimetry, M.C. ZISKIN, P.A. LEWIN [Eds], pp. 371–407, CRC Press, Boca Raton, FL 1993.

[27] P.N.T. WELLS, *Physics of ultrasound*, [in:] Ultrasonic Exposimetry, M.C. ZISKIN, P.A. LEWIN [Eds], pp. 9–45, CRC Press, Boca Raton, FL 1993.