# Ultrasound

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*Abstract*—**A brief accounting is given of the concerns for possible biological effects from diagnostic ultrasound, though none have been reported. A delineation of the activities of the NCRP Committee 66, regarding recommendations, is included. The AIUM STATEMENT remains useful for communicating basic ultrasound bioeffects information to a diverse medical community.**

## I. Introduction

ALTHOUGH ultrasound is also used in industry and military operations, the major opportunity for interaction with biological systems comes from its diagnostic and therapeutic uses in medical practice. In these medical applications, ultrasound is employed to: (1) interact with the system for the purpose of producing desired biological effects; and (2) interact with the biological speciment for the purpose of extracting information, but without producing biological effects. The former has now been available for approximately one-half century and the latter more than a quarter century. It is important to observe that it is almost exclusively due to these applications of ultrasound that ultrasonic energy enters the human body in a predetermined and prescheduled manner.

The medical application of ultrasound, in which a specific biological effect is the desired end point, extends from the use of ultrasound to vibrate a scalpel blade for the purpose of more effective surgical procedures, to ablation of neural tissue with highly focused ultrasound beams, to physical therapy and hyperthermia treatment of cancer, to perhaps the most recent development, viz., the ultrasonic renal lithotriptor. Each of these applications is associated with a specific range of wave amplitude and time durations of exposure, ranging from approximately one watt per square centimeter and many minutes for the therapeutic applications to thousands of watts per square centimeter at a few milliseconds for neurosurgical applications. It is the intent in each of these applications to produce an end point that identifies a different state of the medium as a result of the presence of ultrasound and/or the absorption of ultrasonic energy within the body of the tissue.

On the other hand, it is the intent of the diagnostic applications of ultrasound that tissue modification not occur, but that information regarding the current state of the organ and/or its functioning is to be obtained. Diagnostic applications continue to expand into new areas and have become very well established in obstetrics, cardiology, gynecology, neurology, ophthalmology, disorders of the breast and abdomen, the peripheral vascular system, etc.

The commonly held opinion in the medical profession is that ultrasound is a most effective diagnostic tool for which no adverse effects have been reported from ultrasound examinations. However, because of the widespread exposure of the general population to ultrasound and as a result of its popularity in medical diagnoses, the question of the possibility of adverse effects occurring is most important and is treated with considerable seriousness. Epidemiological studies have been negative, though the sample sizes have been relatively small and thereby lack the statistical power to detect small increases in the incidence of naturally occurring abnormalities.

Although deleterious effects of clinical diagnostic ultrasound have not been reported, possibly because epidemiological studies have not been as illuminating as may be desired, concern continues regarding the safety of diagnostic procedures.

## II. Recommendations

Scientific Committee No. 66 of the National Council on Radiation Protection and Measurements has dealt with this issue in their Report No. 74 [2] and promoted a series of recommendations. These recommendations cover diagnostic equipment, clinical practice, education, scanning of live models and sales personnel, ultrasound in physical therapy, and exposure levels, as follows, in a very abbreviated form.

*Diagnostic Equipment:* Recommendations on commercial devices implore manufacturers of diagnostic ultrasound equipment to make their data on exposure parameters public, and federal regulations now require manufacturers to report the acoustical specifications in diagnostic equipment operator manuals. Recommendations resembling the ALARA principle (as low as reasonably achievable) propose that ultrasound equipment should be designed so that the maximum levels which the equipment can produce are as low as practicable.

*Clinical Practice:* Physicians perceive a definite benefit from using ultrasound for patients. It is felt that only a small risk is possible and that the ALARA principle is considered appropriate as guidance. The NCRP recommendations related to clinical practice emphasized that though the decision to employ ultrasound clinically is a medical judgment, it should be made by the fully informed physician in consultation with the patient, that the users of ultrasound should know the exposure parameters of the ultrasound instrumentation they employ, that they should strive to obtain the most medically significant in-

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formation possible while producing the least ultrasonic exposure to the patient, and that routine maintenance and quality assurance practices should be implemented.

*Education:* The NCRP Report No. 74 involved eight recommendations dealing with education. These include recommendations that diagnostic procedures be performed by individuals fully trained and competent in the field, that the physical principles of ultrasonic techniques and the topic of biological effects be covered adequately in the training programs, that educational programs and schools providing the training in diagnostic ultrasound be evaluated in an established fashion, and that information on ultrasound diagnostic examinations be available to patients.

*Scanning of Live Models and Sales Personnel:* As a result of the common practice in which humans are exposed to diagnostic ultrasound for commercial or educational purposes, i.e., for purposes which do not yield direct medical benefit to the person exposed, the NCRP Report No. 74 proposed the following recommendations: that continuous prolonged scanning of human models and sales personnel for commercial purposes is deprecated, that scanning of the pregnant uterus for educational purposes should be performed *only* when some medical benefit to the patient is expected, and that the development of phantoms and test objects for evaluating instruments should be encouraged.

*Ultrasound in Physical Therapy:* In the practice of ultrasound physical therapy, it is often the case that an attempt is made to maintain the ultrasonic intensity just below the level that causes pain; the pain presumably arising from the temperature elevation associated with the absorption of ultrasound in the tissue. Thus, it is important that the patient have normal sensations of pain in response to temperature elevation, and the NCRP Report No. 74 includes a number of recommendations associated with ultrasound therapy, of which the following is an abbreviation; that ultrasound therapy should be applied by individuals adequately trained in this modality, that ultrasound therapeutic instruments should be routinely checked for proper calibration, performance, and electrical safety, that patient sensitivity for pain and temperature in the region being exposed be assured prior to treatment, that the therapist use the lowest intensity and the shortest duration required to achieve the desired clinical benefit, that no pregnant or potentially pregnant patient receive ultrasound therapy in an area of the body such that exposure of the fetus is likely, and that care be taken not to expose unnecessarily the epiphyseal lines of bones in children.

*Exposure Level:* Since information presently available is inadequate for establishing quantitative levels of exposure, the NCRP recommendations are more general on this topic. The most specific exposure recommendation of the NCRP Report No. 74 is expressed in terms of temperature rather than acoustical quantities and is based on evidence that temperature elevation of the fetus may lead to increased incidence of fetal abnormalities, viz., routine ultrasound examination of the human fetus should not be performed under exposure conditions where significant temperature elevation is to be expected (as the normal diurnal temperature variation exceeds 1°C, temperature elevations less than 1°C are not considered significant). A final recommendation of the NCRP Report No. 74 is that the establishment of a complete system of optimum exposure parameters for balancing benefit against risk should be accepted as a long-range goal.

## III. Criteria for Recommendations

The NCRP has charged Scientific Committee 66 to continue activities with the long-term view of needs relative to the development of exposure criteria. In so doing, the committee has chosen to further consider criteria considerations based upon physical mechanisms by which ultrasound may bring about reversible and irreversible changes in living systems. Two principal mechanisms have been identified as contributing to such tissue alterations and they have been studied to some extent. These are the thermal mechanisms, by which ultrasound energy is absorbed in the tissue and converted to heat, thereby increasing the temperature to possibly damaging levels depending upon the amplitude of the wave and the length of time of the exposure; and cavitation mechanisms which involve a variety of kinds of sonically generated activity involving small bodies of gas and/or vapor. Additionally, other mechanisms may also play a role in altering living systems based upon radiation force, viscous forces, etc.

NCRP Scientific Committee 66 is currently engaged in preparing a document and developing recommendations based exclusively on the thermal mechanisms. Herein, established theories for heat transport, including simplified models, are employed to allow calculation of expected temperature fields produced under specific exposure conditions. It appears possible to obtain useful results by assuming the square of the exposure acoustic pressure amplitude of the field to be proportional to the local value of the acoustic dissipation function, viz., the rate at which heat is produced by the sound field per unit volume. With some knowledge of the acoustic dissipation function, it is possible in principle to determine the temperature as a function of space and time. The bio-heat transfer equation, in which the incremental temperature above a specific reference level is described in terms of the thermal diffusivity of the medium and a perfusion time constant, is used for this purpose. Incremental temperatures have been calculated from appropriate solutions of the model for focused fields and absorbing media. It has emerged from the work thus far that it may be possible to assert that a diagnostic ultrasound procedure from which significant medical benefit is expected is acceptable from a benefit/risk standpoint if the temperature computed for a standard medium, for the given transducer characteristics, and for the anticipated dwell time does not exceed 1°C. The statement is, of course, based entirely upon the thermal mechanism being the only source of effect upon the tissue. As this is not the case, other mechanisms must be considered, as discussed below. The statement assumes that no problems will arise in its application as associated with "the standard medium" and that procedures for the temperature calculations would need to be developed and agreed upon.

The NCRP has in mind that Scientific Committee 66 will continue to function beyond the point of completion of the present document on the thermal mechanism and to continue with cavitation and other mechanisms. Herein it will be essential to distinguish among the various forms of cavitation that have been studied, and possibly to develop criteria and recommendations for each. Cavitation is a general term describing the growth and subsequent behavior of cavities in an acoustically perturbed liquid or liquid-like medium. Two types of cavitation can be identified. The violent type, viz., *transient or collapse cavitation*, produces intense hydrodynamic forces within the vicinity of the collapsing bubble, and is capable of severely disrupting biological structures. Highly reactive free radicals can also be byproducts of transient cavitation. For the less violent type, viz., *stable cavitation*, the bubble (or cavity) does not collapse but rather grows to a resonance size and oscillates or pulsates under the influence of the ultrasonic field. The hydrodynamic forces in the vicinity of the oscillating bubble have been shown to be responsible for affecting biological structures. These, then, are among the topics to be taken up by NCRP Committee 66.

## IV. Concluding Remarks

It may be appropriate here to refer to a generalization arrived at, and periodically reviewed and revised, by the Bioeffects Committee of the American Institute of Ultrasound in Medicine, and which is often referred to as the "AIUM Statement" (see Table I and Fig. 1). Note that the STATEMENT applies to confirmed results for *in vivo* mammalian systems only and not to experiments with insects, plants, or cell suspensions. Very few systematic studies have been conducted in which *in vivo* mammalian systems have been exposed to repeated short high-intensities pulses characteristic of pulse-echo techniques in diagnostic ultrasound. Data of biological effects, as gleaned from the literature, are consistent with the STATEMENT.

Numerous studies have been carried out on the biological effects of ultrasound, including studies of physical mechanisms responsible for producing effects. However, the information available for clinical situations is insufficient, at present, to provide quantitative estimates of risk as a function of exposure. It appears that the probability of a damaging event is small, too small to have been detected by physicians in the course of their medical practice. However, as the potential for harm cannot be ruled out, especially for procedures which involve the use of relatively high intensities, vigilance must continue.

## Acknowledgment

Critical remarks by Prof. W. L. Nyborg are appreciated.

## References

[1] "Biological considerations for the safety of diagnostic ultrasound," *J. Ultrasound Med.*, vol. 7, pp. S1–S35, 1988.

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

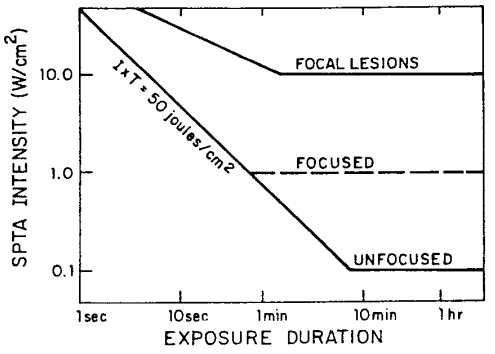


Fig. 1. Comparison of the minimum SPTA intensities required for ultrasonic bioeffects specified in AIUM Statement on Mammalian Bioeffects. The minimum levels required for focal lesions [2] are also shown for comparison [1].

TABLE I
American Institute of Ultrasound in Medicine Statement on Mammalian *In Vivo* Biological Effects. Approved August, 1976: Revised and Approved October 1987

A review of bioeffects data supports the following statement:

In the low megahertz frequency range there have been (as of this date) no independently confirmed significant biological effects in mammalian tissues exposed *in vivo* to unfocused ultrasound with intensities[a] below 100 mW/cm$^2$ or to focused[b] ultrasound with intensities below 1 W/cm$^2$. Furthermore, for exposure times[c] greater than one second and less than 500 seconds for unfocused ultrasound, or 50 seconds for focused ultrasound such effects have not been demonstrated even at higher intensities, when the product of intensity and exposure time is less than 50 joules/cm$^2$.

[a]Free-field spatial peak, temporal average (SPTA) for continuous wave exposures, and for pulsed-mode exposures with pulses repeated at a frequency greater than 100 Hz.

[b]Quarter-power (−6 dB) beam width smaller than four wavelengths or 4 mm, whichever is less at the exposure frequency.

[c]Total time including off-time as well as on-time for repeated pulse exposures.

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