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ULTRASOUND

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CONTENTS

		Page
I.	INTRODUCTION TO ASSESSMENT OF OCCUPATIONAL HAZARD	1
	Description of Ultrasound	1
	Ultrasound in Occupational Settings	7
	Potential for Hazards to Health	16
	Conclusions	25
II.	OCCUPATIONAL EXPOSURE TO ULTRASOUND	27
	Uses of Ultrasound and Extent of Exposure	27
	Levels of Exposure and Occupational Hazards	30
	Secondary Hazards Associated with Use of Ultrasound	42
	Measurement Techniques	44
	Control of Exposure	45
	Conclusions	46
III.	EXPOSURE STANDARDS AND FEDERAL AGENCY ACTIVITIES	48
IV.	HEALTH EFFECTS OF EXPOSURE TO ULTRASOUND	52
	Subjective and Biologic Effects on Humans	53
	Biologic Effects on Animals	60
	Effects on Reproduction	69
	Thresholds for Effects and Potential for Hazards	73
V.	CONCLUSIONS AND RECOMMENDATIONS	88
	Potential for Hazardous Exposure to Ultrasound	88
	Analysis of Process-Related Hazards	91
	Plant Visits and Site Measurements	92
	Need for Document on Ultrasound	93
VI.	REFERENCES	98
VII.	APPENDIX I - Physics of Ultrasound	132
VIII.	APPENDIX II - Applications of Ultrasound	139
IX.	APPENDIX III - Manufacturers and Users of Ultrasonic Equipment	152
X.	APPENDIX IV - Trade Associations and Labor Unions	182
XI.	APPENDIX V - Biophysics of Absorption of Ultrasound Energy	193

CONTENTS (CONTINUED)

		Page
XII.	APPENDIX VI - Ultrasonic Probes	196
XIII.	APPENDIX VII - Biologic Effects of Ultrasound	205
XIV.	APPENDIX VIII - Search Strategy and Criteria for Evaluation of Literature	305

I. INTRODUCTION TO ASSESSMENT OF OCCUPATIONAL HAZARD

The intent of this chapter is to introduce the subject of ultrasound, specifically as it is used in the workplace and, consequently, may act as an occupationally hazardous physical agent. Ultrasound is defined, the extent of its use and the level of occupational exposure presented, and the interaction of ultrasonic energy with biologic tissues described. Although the information presented here can be used in conjunction with detailed information provided in the appendixes (Chapters VII-XI) to gain a complete understanding of the physical nature of ultrasound and its presumed effect on animal tissues, the discussion is meant to be self-contained. Its purpose is to introduce the concerns addressed in Chapters II-IV and provide a sound scientific basis for their evaluation.

Description of Ultrasound

Sound can be described most simply as a form of energy in which a mechanical disturbance is transmitted through an elastic medium. The mechanical motion induces momentary displacements of the molecules (commonly referred to as particles) of the medium from their equilibrium positions. Elastic restoring forces then return the molecules to their initial, or mean, positions. If the disturbance is created by periodic vibrations of some material body, such as a tuning fork, reciprocating piston, or gas column, then sound waves that can be characterized by a definite frequency, wavelength, speed, amplitude, and intensity are produced. These propagate in the form of successive displacements of separate volume elements of the medium. Since the only form of elasticity present in fluids is compressional, the wave motion in gases and liquids is limited to longitudinal displacements, ie, those parallel to the direction of propagation. In solids, transverse waves perpendicular to the displacement and propagation directions and surface waves can be produced in addition to longitudinal waves. The physics of sound propagation is described fully in Chapter VII.

The motion of the molecules produces similar periodic variations in pressure, which are accompanied by variations in density, temperature, and particle velocity and acceleration. These five variables represent physical properties inherent to any medium. As such, they are significant to at least two processes that may occur during the propagation of sound: (1) changes in pressure at regions of differing density are responsible for the major nonthermal effect of ultrasound, namely cavitation, and (2) the transmission of ultrasonic energy across a boundary between two dissimilar media is dependent on the degree of mismatch in their respective acoustic impedances, which are determined by the relative pressures and particle velocities or the densities and propagation velocities of the two media.

(a) Propagation of Ultrasound

As the sound wave propagates through a medium, its intensity will decrease owing to geometric considerations and attenuation by the medium. The effect of the first factor can be illustrated most easily by considering the simplest shape for a source of sound energy: a sphere. As the wave spreads out in a spherical manner from that source, the constant amount of energy available will be dispersed over an increasingly larger surface area, given by $4\pi r^2$, and will decrease in proportion to the square of the distance from the source.

The second factor relates to absorption of energy by a homogeneous medium, mainly in the form of heat. This takes the form of an exponential decrease in intensity or displacement amplitude. The absorption coefficient, which is the constant of proportionality between the distance traveled by the wave in the medium and the logarithm of the relative intensity, describes the loss in intensity or amplitude per unit distance. The above relationship implies that at any frequency this reduction in intensity of the wave is a constant fraction for a given thickness of material. For example, if a wave lost 0.9 of its energy in passing through 10 cm of material, then each successive 10-cm distance would reduce the intensity of the wave by 0.9 or 90%. The intensity at a depth of 10 cm within the material would be 0.1 that at the surface, at 20 cm it would be 0.1 that at 10 cm and 0.01 that at the surface (0.1 x 0.1 = 0.01), etc. A large absorption coefficient implies that more energy is deposited within a unit thickness of material and, thus, that the sound wave will not penetrate as far; ie, most of the energy will be absorbed close to the incident surface.

The propagation of sound energy is also dependent on the uniformity of the media. Regions of dissimilar density or interfaces between different materials, such as air and water or muscle and bone, will produce reflections of the wave at the boundaries. The more dissimilar the materials or media, the greater the amount of energy reflected at their boundary; for example, very little sound energy (less than 0.1%) will be transmitted to a solid body if the sound wave has been traveling through a gas such as air. The large absorption of sound energy by gases (specifically air) and its poor transmission across air/solid boundaries have forced the use of a so-called coupling medium in most industrial and diagnostic applications. This material is interposed between the transducer, or source of the sound, and the object being irradiated. Several examples of processes that depend on the use of couplers are ultrasonic cleaning, soldering, drilling, and flaw detection.

The amount of sound energy propagated through any material is determined mainly by its absorption and transmission characteristics, which are usually referred to as macroscopic properties of the medium. Microscopic properties, such as are responsible for scattering of the sound wave, also affect propagation, but only to a limited extent, and therefore will be ignored in this discussion. Absorption and transmission as they relate to human bioeffects, human exposure, and the relative biohazard of sound energy are discussed in the section Potential for Hazards to Health in this chapter.

(b) Interaction of Ultrasound with Matter

During the interaction of ultrasonic energy with matter, energy is transferred from the wave to the medium by any of several processes: absorption, cavitation, and scattering. Absorption, which ultimately leads to the production of heat in, and changes in the temperature, pressure, and volume of, the medium, occurs at the level of inter- and intramolecular organization. The transfer of coherent mechanical energy to molecular or structural energy levels is due to resistance of the material to displacement. For example, viscosity, or frictional lag, opposes the shearing forces induced in the medium and leads to a quadratic increase of the absorption coefficient with frequency. Thermal relaxation processes contribute, on the other hand, to absorption in a linear frequency-dependent manner. At the molecular level, these are due to an incomplete, asynchronous transfer of energy between internal and external degrees of freedom of the particles of the medium. When that transfer lags behind the temperature changes induced by the pressure variations of the wave, the excess thermal energy results in an irreversible heat loss. Structural relaxation processes depend on a lag in the reorientation of the molecules of the medium following pressure changes. The extra energy is also transformed into heat. A third mechanism entails relative motion between the matrix and the suspended particles.

At low sound intensities, less than 1.5 W/cm^2, absorption is independent of intensity (and, hence, amplitude) but dependent on temperature. So-called nonlinear, ie, amplitude-dependent, effects become important at higher intensities. These include radiation pressure, microcurrents, and acoustic streaming in inhomogeneous media. The effects are manifest as microscopic movements of suspended particles or domains. The mechanisms responsible for these effects will be described in more detail later in this chapter, since they are more relevant to ultrasound-induced effects in cells of organisms than to industrial processes. Scattering is due to the presence of acoustic inhomogeneities, eg, density differences, in a material. These regions vibrate at different amplitudes and reradiate different fractions of the incident energy. Viscous forces absorb the remainder of the ultrasonic energy.

The greatest contribution to nonthermal attenuation comes from cavitation. This process is limited to liquids and is dependent on the presence of submicroscopic gas bubbles, or cavities, throughout the medium. During the rarefaction phase of the propagating wave, the bubbles aggregate until they attain a size that is mechanically resonant with the sound frequency. In stable cavitation, the oscillations in the expansion and contraction of the bubbles produce periodic pressure waves in the medium. In collapse cavitation, the bubbles contract rapidly and completely during the compression phase and produce shock waves in the liquid. Ultrasonic cleaning is based on this principle.

(c) Definition of Ultrasound

As mentioned above, sound can be considered to refer to all mechanical vibrations propagating through elastic media. These are usually separated into three distinct frequency ranges: sound waves with frequencies between 20 Hz and 20 kHz are called audible sound; those below 20 Hz, infrasound; and those above 20 kHz, ultrasound. This nomenclature has been adopted mainly for the sake of convenience. Audible sound refers to sound waves within the expected physiologic range of human hearing; sound at other frequencies is either below or above that range and cannot be detected by humans. Ultrasonic energy is not imperceptible, however. Rats can hear and vocalize sound at frequencies up to 25 kHz. In practice, most uses for ultrasonic energy are limited to frequencies below 10 GHz. This is partly due to physical limitations in the generation of ultrasound.

Ultrasound in Occupational Settings

(a) Generation of Ultrasound

Several methods exist for producing ultrasonic energy, the choice of which generator and source to use being dependent on the frequency of the required radiation and the medium of propagation. The upper limits for the different techniques are as follows:

Tuning fork	90 kHz
Whistle	
Galton	50 kHz
Hartmann	100 kHz
Siren	50 kHz
Electromagnetic coil	30 kHz
Magnetostrictive material	200 kHz
Piezoelectric crystal	500 MHz

The first four techniques produce sound waves mechanically, using the vibrations of a resonating material such as a metal tuning fork, a gas column moving through a resonant chamber, or a disk-interrupted air jet. Their use is, for the most part, limited to propagation of ultrasound in gases. The latter three rely on the transduction of electric or magnetic energy into mechanical vibratory energy, or sound; and, since they have become the most widespread methods for the generation of ultrasound, sources of ultrasonic energy generally are known as transducers.

Piezoelectric and magnetostrictive transducers are used almost exclusively for producing ultrasonic energy for propagation through liquids and solids. Both operate on the same principle: electromagnetic oscillations induce oscillations at ultrasonic frequencies in the dimensions of some material. In magnetostriction, the applied magnetic field produces changes in the size of various magnetic domains of ferromagnetic materials such as nickel. This causes a small, periodic expansion and contraction on the order of 3×10^{-5} of the dimensions of the material, which in turn produces a propagating sound wave. Anisotropic crystalline materials, such as quartz, barium titanate, or lead zirconate titanate, respond to an alternating electric field with a distortion of their crystal structure along the axis parallel to that field. This is known as the reverse piezoelectric effect and leads to alternating expansion and contraction of the crystal dimensions and production of ultrasonic waves. With both techniques, the change in dimension and the ultrasonic energy produced will be maximal at the natural mechanical resonance frequency of the material, which depends on not only the type but also the thickness of that material. Conversion of electromagnetic into mechanical energy is highly efficient, 80-95%, at this frequency. Hence, most magnetostrictive and piezoelectric materials are used to produce ultrasound at a frequency corresponding to mechanical resonance.

Magnetostrictive	10-80 kHz
Piezoelectric	
Titanates	10 kHz - 1 MHz
X-cut quartz	400 kHz - 15 MHz
Cadmium sulfide, zinc oxide, gallium arsenate, and lithium niobate	GHz range

(b) Uses of Ultrasound

As stated above, the physical properties of sound waves of all frequencies are similar. Nevertheless, ultrasound is preferable to audible sound for many industrial applications for the following reasons:

(1) Ultrasound is inaudible.

(2) The waves can be focused; ie, a well-defined, directional beam (a coherent wave with a minimally divergent beam width) can be produced.

(3) The shorter wavelengths make possible examination of smaller quantities of material and of smaller scale variations in structure.

(4) The high frequencies permit physical phenomena with short time periods, eg, viscous relaxation, to be measured.

(5) It is more convenient to produce high intensities.

It should be noted that many of the effects of sound energy, such as coagulation, emulsification, and chemical, thermal, and biologic effects, depend only on intensity and not on frequency or directionality of the irradiating beam. Thus, ultrasound is not inherently more efficient than audible sound for these tasks. Applications such as flaw detection and sonar, however, require a well-defined beam of ultrasonic waves and, thus, depend on frequency rather than intensity. For convenience, most applications of ultrasound can be classified as either low intensity or high intensity. In the case of the former, ultrasonic energy is used to investigate the physical properties of materials and represents one aspect of what is now called nondestructive testing. With the latter, the ultrasonic waves mechanically alter the material.

That sound waves at ultrasonic frequencies could be propagated through air was discovered in 1899, and the first sources of ultrasound waves to be developed were whistles and electromagnetic (spark gap) generators. Experimentation on biologic effects was the first actual use of ultrasound, and the first papers describing killing of animals and destruction of cells were published in 1927. The earliest industrial application of ultrasound was ultrasonic cleaning, which was first patented in Germany during world war II and still represents the most widespread use of ultrasound. Other applications are listed in Chapter VIII (Tables VIII-1 to VIII-3). Representative information on the frequency ranges, power outputs, and radiation mode is presented in Table I-1 and in Chapter VIII (Tables VIII-4 and VIII-5).

The unique aspects of industrial ultrasound can be illustrated by briefly describing some of the processes in which it is used. Cavitation phenomena are responsible for ultrasonic cleaning; thus, baths or tanks, some holding up to 1,000 liters of liquid, are required. Emulsification or homogenization, defoaming, degassing molten metals and glasses, and removal of oxide films from aluminum or copper prior to soldering also result from cavitation. Metal welding with ultrasound does not require heat. Here, the metal surfaces are pressed into contact, and transverse ultrasonic waves are generated in both surfaces. Solid-state bonding occurs, and the technique has been found to be more efficient for metals such as copper and titanium than conventional welding methods. Finally, ultrasonic energy promotes nucleation in crystallization processes and can be used for extraction of solid materials by liquids and electrodeposition of metals. An indication of the extent of the ultrasound industry can be obtained by considering the lists of manufacturers, users, trade associations, and unions involved with ultrasonic equipment. These appear in Chapters IX and X.

TABLE 1-1

FREQUENCY AND POWER RANGE OF ULTRASONIC DEVICES

Application	Frequency Range	Average Power	Power Mode*
Industrial cleaning and machining	15-50 kHz	100 W - kilowatts	CW
Dental scaling	20 kHz	20 W	CW
Medical diathermy	80 kHz - 1 MHz	"	CW
Medical diagnostic	1-30 MHz	1-100 mW	CW and PW
Industrial nondestructive testing	"	"	PW
Cleaning	13 kHz - 1 MHz	4-8 W/cm^2	CW
Welding			
Plastic	20 kHz	1 kW	CW
Metal	10-60 kHz	5 kW	CW

*CW, Continuous wave; PW, pulsed wave

(c) Output of Industrial Sources

For industrial, commercial, and medical sources of ultrasound, output powers in the kilowatt range are possible. However, in those cases where the size of the transducers is taken into consideration, the output intensities do not exceed 10^5 W/m^2 (10 W/cm^2). These values have been determined for industrial cleaners, probably the most intense sources of ultrasonic energy.

Chapter II presents data on the intensity levels generated by representative commercial ultrasound equipment. How these data correlate with known thresholds for biologic effects is considered in Chapter IV. It appears that most instruments do not produce, even at the transducer, doses sufficient to induce certain bioeffects.

(d) Irradiation Conditions

In fully describing the exposure of an organism to ultrasound, many physical and environmental factors, such as those listed in Table I-2, need to be detailed. Such a requirement would also apply to individual occupational exposures. However, neither the manner in which each of the factors presented in the table effects physiologic changes nor the contribution of each to an observed change is clear. This fact is due, in spite of the large number of published experimental and clinical observations, to the lack of complete information on exposure conditions in many of the reported investigations.

TABLE I-2

ACOUSTIC DETERMINANTS OF EXPOSURE TO ULTRASOUND

(1) Field shape
    (a) Plane traveling wave
    (b) Nonplane wave
    (c) Standing wave

(2) Intensity
    (a) Peak
    (b) Average
    (c) Total effective irradiation area

(3) Mode
    (a) Continuous wave
    (b) Pulsed wave
        (i) Duty cycle (pulse width and repetition rate)
        (ii) Use cycle

(4) Frequency

(5) Duration of exposure

(6) Ambient conditions
    (a) Temperature
    (b) Pressure
    (c) Relative humidity
    (d) Propagating medium
    (e) Physiologic conditions (pH, osmotic balance, oxygen tension, age, species, etc)

Compilation of all available data for even one variable does not permit a complete evaluation of its effects to be made. For example, the acoustic frequencies commonly referred to as "ultrasonic" range from 20 kHz to 100 GHz, yet most animal experiments deal with frequencies near 1 MHz and most clinical observations report results of exposures to ultrasound between 100 kHz and 10 MHz. Thus, although it can be assumed that the ultrasonic field will have to be defined to at least the extent indicated

in the table before a judgment on the relative hazard potential of an occupational exposure can be made, whether any, most, or all of the factors can be ignored remains to be determined.

(e) Extent of Exposure

Estimates of the extent of exposure will be extremely crude, since neither the number of ultrasonic units in use nor the number of workers directly and indirectly involved is known. A 1973 NIOSH projection for the total sales volume of ultrasonic equipment is presented in Table VIII-6; no estimate of the number of apparatus these figures represented was given. Whether the threefold increase in volume observed between 1968 and 1973 corresponded to a threefold increase in apparatus sold cannot be determined, since the figures were not expressed in constant (eg, 1968) dollars nor was the price per unit in each of the 2 years given. Furthermore, whether a similar threefold increase would have occurred by 1978 could not be reliably predicted at that time (1973), since future development was largely dependent on progress in research and technology.

In 1972, the Bureau of Radiological Health (BRH) suggested that 50,000 ultrasonic cleaners were in use for various industrial and nonhome applications, whereas other commercial and industrial applications accounted for another 50,000 ultrasonic units. In regard to medical applications, approximately 10,000 ultrasonic diagnostic devices and 33,000 diathermy units were in use in 1972. These figures represented a greater than threefold increase in the use of medical ultrasound apparatus since 1970.

Projections for the number of ultrasonic devices in use by 1980 are as follows:

Cleaning	200,000
Commercial-industrial	180,000
Medical diagnostic	175,000
Medical diathermy	100,000

NIOSH surmised in 1976 that 50,000-200,000 workers could be exposed to ultrasound. These estimates would appear to be low, however, when the projected usage figures (approximately 650,000 devices) are considered. It is more likely that currently some 250,000-500,000 workers are occupationally exposed to ultrasonic energy.

Potential for Hazards to Health

In the preceding two sections, ultrasound was defined and its various commercial, industrial, and medical uses were described. Those sections dealt with the potential for biophysical effects from occupational exposure to ultrasonic energy. In this section the types of effects observed or expected to occur in humans following ultrasonic irradiation are discussed, the mechanisms presumed or known to be responsible are described, the likelihood of the production of these effects under occupational situations is estimated, and the potential contribution of additional exposure factors to the production and extent of bioeffects is suggested. A scope for the document is then presented.

(a) Types of Biologic Effects

As mentioned above, the first biologic experiments with ultrasound, the results of which appeared in 1927, described its lethal effects on animals. The first reports of human effects were published in the 1940's and discussed observations of ultrasonic sickness or hangover in aircraft mechanics and other maintenance personnel working around jet engines. Since that time, experimental studies on the physiologic response of animals to ultrasonic irradiation, observations on the results of medical therapeutic and diagnostic procedures using ultrasound, as well as in vitro experiments on tissues and cells have indicated that a wide range of biologic effects, in addition to subjective complaints, can follow exposure to ultrasound. These include damage to the eyes, ears, liver, bone marrow, general viscera, central nervous system, musculoskeletal system, skin, kidneys, gonads, and heart, as well as teratogenic and mutagenic effects. Table I-3 lists some of the effects observed in animals and humans.

Although it has been averred that no substantial bioeffects have been reliably demonstrated at power densities (or so-called intensities) of less than 10^3 W/m^2 (100 mW/cm^2), physiologic changes have been reported following exposure to ultrasonic energy at levels as low as 10 W/m^2. Threshold data for some effects are presented in Chapter XI (Figure XI-1) in the form of a graph of power density versus time of exposure. It appears from this graph that the threshold dose, that is, the product of exposure time and density, for a variety of ultrasound-induced bioeffects

TABLE I-3

BIOEFFECTS OF ULTRASONIC IRRADIATION

Affected Area	Response
Blood	Change in biochemical and immunologic proportion of serum lipoproteins, increase in solubility of fibrinogen, alteration in immunocompetence, decrease of iron-binding capacity, destruction or alteration in numbers of erythrocytes and leukocytes, hemolysis, change in albumin/globulin ratios, decrease in blood sugar levels, changes in colloidal properties, vasodilation
Adrenals	Histopathologic changes, adrenal failure
Thyroid	Uptake of iodine decreased
Oral tissue	Tooth enamel damage, cemental and dental defects, discoloration and fracture of teeth, pulp tissue damage consisting of vacuolization, edema, fibrosis, and congestion of blood vessels
Bone	Changes in bone mineral metabolism, reduction of calcium uptake, coarsening of trabecular bone pattern, new periosteal bone formation, localized bone necrosis, bone fractures, production of circumscribed sclerotic foci and cystic and pseudocystic growths
Eye	Damage to lens, vitreous humor, iris, and retina, ciliary body engorgement, stromal hemorrhage, reduction of intraocular pressure, superficial erosion of cornea, structural changes in ocular fundi, atrophy of retinal nerve layers, erythrocytic extravasion, demyelinization 'f optic nerve
Ear	Vasodilation, presence of protein exudate in endolymph, production of petechial hemorrhage in labyrinth, degeneration of neuroepithelium of labyrinth and vista, cochlear damage, collapse of membranous labyrinth, vacuolization, pyknosis, atrophy of sensory and secretory epithelium

TABLE I-3 (CONTINUED)

BIOEFFECTS OF ULTRASONIC IRRADIATION

Affected Area	Response
Alimentary mucosa	Ulceration, necrosis of intestines
Skin	Necrosis, epidermal enlargement, retardation of healing
Heart	Denaturation of sarcoplasmic reticulum
Liver	Hepatic lesions
Central nervous system	Damage to pyramidal tract cells of spinal cord and to cerebral cortex, functional paralysis, behavioral changes
Brain	Induction of convulsions, release of the neurotransmitter acetylcholine, hypertrophy of astrocytes, production of necrotic lesions
Reproductive system	Testicular lesions, mutagenesis, chromosomal abnormalities
Subjective effects	Pain, fatigue, nausea, stress, changes in oculomotor and audiomotor reactions and vestibular function, giddiness, somnolence, irritability, anorexia, euphoria, nervousness, apprehensiveness
Cellular effects	Depolymerization of polysaccharides, polyribonucleic acids, and proteins, nucleic acid denaturation, reduction in respiratory coenzyme levels, alteration of membrane permeability, change in viscoelastic properties of cytoplasm, destruction of microsomes and mitochondria

is $5x10^5$ J/m^2 (50 $W.s/cm^2$ or $5x10^4$ $mW.s/cm^2$). The production of effects at the extrema of the plot has been attributed to two distinct mechanisms.

(b) Biophysical Mechanisms Responsible for Effects

Thermal effects are considered to dominate at low power densities and long exposure times, less than 500 W/cm^2 and on the order of 1 second and above, respectively. At power densities greater than $3x10^3$ W/cm^2, where exposures are 1 millisecond (ms) or less, cavitation phenomena predominate. Direct mechanical mechanisms are thought to account for most bioeffects in the third, intermediate region. All of these interactions represent absorption processes in which ultrasonic energy is transformed into heat, pressure, or other forms of energy at the site of interaction. Scattering processes represent a second form of interaction between ultrasound and tissue. Here, the energy is reradiated at a different amplitude, direction, phase, and frequency and can thus produce effects owing to secondary absorption at sites other than the primary interaction region.

A list of bioeffects and the presumed mechanisms responsible for their induction is presented in Table I-4. Cavitation is a frequency-dependent phenomenon that produces lesions by microbubble resonance or collapse. Weak, or stable, cavitation occurs at low power densities and usually at frequencies greater than 1 MHz; strong cavitation, designated also as transient or collapse cavitation, follows irradiation at high power densities and leads to more severe cell and tissue damage. A liquid medium is required for cavitation to occur, and most of the observed effects have been produced in cells and tissues in suspension. Thus, the extent to which cavitation can occur within the body is uncertain. Thermal effects

TABLE I-4

BIOPHYSICAL MECHANISMS RESPONSIBLE FOR
ULTRASOUND-INDUCED BIOEFFECTS

Mechanism	Effects
Weak cavitation	Cellular respiratory disorders, increased cell permeability, destruction of mitochondria and cell membrane, suppression of iodine uptake by thyroid, microscopic changes in adrenals, reduction of nucleic acid content of testes, decrease in prothrombin activity, morphologic changes in bone marrow cells, loss of iron-binding capacity of blood, histologic changes in inner ear, production of mutations
Strong cavitation	Effects similar to those occurring with weak cavitation, gross histologic changes
Mechanical forces	Specific effects unproved; indications of parathrombosis, paralysis, spinal cord inactivation, and chromosomal aberrations
Thermal factors	Necrosis of brain cells, histologic changes in liver and brain, production of mutations, physiologic changes in tendons, loss of nerve conduction, reduction in conduction velocity, facial palsy, hearing loss, nystagmus, edema, fibrin formation, damage to blood

following ultrasonic irradiation are usually accompanied by local temperature increases and in many cases have been mimicked by direct heating of tissues and cells.

That other, mechanical processes act at the physiologic level has been presumed from experimental observations in which cavitation and thermogenesis were ruled out as causes for the bioeffect being investigated.

These direct mechanisms include radiation pressure or force, microstreaming, acoustic streaming, and perhaps sonochemical action. Radiation pressure operates in inhomogeneous media or in particulate suspensions by forcing the suspended structures to move relative to the suspending medium. Streaming is due to the oscillatory flow of a liquid (or, in more general cases, fluid) within a sound field. Large-scale motion, so-called acoustic streaming, will occur near boundaries such as cell membranes, and shear gradients can result. Small-scale, or micro-, streaming takes the form of eddies or steady circulations throughout the oscillating medium and can also occur near any suspended particle. Shearing forces are the direct result of all these types of movement. Cells or intracellular organelles, such as a mitochondrion or red blood cell, whose densities differ from that of the surrounding medium, are subject to such forces.

The extent to which the direct mechanisms act within the tissues of the body is not known, but several effects have been postulated to be the immediate results of the mechanical forces involved. There are, in addition to the effects listed in Table I-4, a few phenomena that cannot be attributed to any of the aforementioned mechanisms: decreases in the number of glycogen granules in the liver and muscle, alterations in membrane transport, aberrant cell division, ultrastructural changes in muscle tissue, destruction of hepatocyte lysosomes, and swelling of mitochondria.

(c) Absorption and Transmission of Ultrasound

The extent to which any of the mechanisms presumed to effect alterations in the physiologic state of an organism act will depend first on the amount of ultrasonic energy available. How much of the energy emitted from some source reaches a particular site within the body will be affected by absorption, reflection, and refraction along the path of propagation of that energy. In the majority of industrial exposure situations, the energy will be transmitted from the source through air before it reaches and is transmitted through the body. Furthermore, the body is not a homogeneous medium: the skin, fat, muscle, bone, organs, circulatory system, and other parts of the body constitute layers of tissues with differing properties. Thus, an ultrasonic wave will travel through several regions of differing densities and will cross several boundaries or interfaces between these regions as it propagates. To determine the likelihood that an effect will be produced, the physical factors determining the transmission of ultrasonic energy must be considered (see Chapter XI).

(1) Biologic Systems

Representative absorption coefficients determined experimentally for human tissues are presented in Table XI-1. Note that the values are two to five orders of magnitude greater than that for water, despite the fact that a large proportion (up to 80%) of the cell is water. Thus, absorption by water does not contribute to any great extent to absorption of ultrasonic energy by an organism. Except for lung tissue, bone exhibits the greatest attenuation for ultrasound, and consequently those regions of the body closest to the skeletal structure will be subject to the most rapid and intense heating. As stated above, absorption is frequency dependent and will increase with frequency for most body tissues.

The absorption coefficients represent the reduction in ultrasonic energy as it passes through a medium. Most of the tissues have coefficients on the order of 0.1 cm^{-1}; this corresponds to a half-wave thickness, that is, the distance in which the intensity is reduced by one-half, of 7 cm. This concept can be better illustrated by considering the penetration of an ultrasound wave into various tissues. Relative values for the penetration distance are also presented in Table XI-2. That table shows, for example, that ultrasonic energy will travel approximately 1,200 times as far in water as it will in a nerve and that most of the energy will be deposited in the nerve close to the incident surface.

Penetration into the body will also depend on the reflection and transmission of the ultrasonic energy at boundaries between different tissues. Table XI-3 presents reflection coefficients for some tissue interfaces; for example, 92% of the energy traveling through fat will enter muscle tissue.

(2) Air and Other Media

Absorption and transmission of ultrasound through water has already been described. Because water attenuates the beam only minimally, it is, along with other liquids, an efficient coupler for ultrasonic energy. Air, however, is a much better absorber. Dry air has an absorption coefficient of 0.31 cm^{-1}, similar to that of muscle and approximately 10^4 times as great as that of water. Propagation through air, which is also frequency dependent, is essentially zero above 100 kHz. Furthermore, reflection at air/body interfaces is large; eg, only 0.02% of the ultrasonic energy propagating though air and incident on muscle will be transmitted into the tissue. Thus, that a large fraction of airborne ultrasound will ever enter the human body is unlikely.

Conclusions

The information provided in this chapter and Chapters VII-XI has included:

(1) A definition of ultrasound and the parameters that define the ultrasonic field

(2) The types of ultrasonically induced bioeffects and their putative biophysical mechanisms

(3) Absorption and transmission of ultrasonic energy in biologic systems and the occupational environment

(4) Potential occupational exposure situations and dose levels, either measured or calculated

It appears that definite biologic effects follow exposure of organisms, tissues, and cells to acoustic energy at frequencies above 20 kHz, distinct from those produced by audible and infrasound. Cavitation-induced phenomena are not likely to occur in humans; thus, the effects of thermal and direct mechanical mechanisms can be considered to be responsible for the majority of expected bioeffects. Occupational exposures to airborne ultrasound are expected to be at low levels owing to, first, the absorption and transmission properties of air and the human body and, second, the low power output of most industrial, commercial, and medical sources. Whether the doses produced would be sufficient to cause the thermal effects associated with ultrasound exposure is also unlikely.

The scope of the document will cover all of the concerns stated above. The conclusions presented here represent a cursory examination of the review and experimental literature in the field of ultrasound. A proper judgment requires the more thorough evaluation of such literature given in Chapters II-IV. Nevertheless, it does appear that the potential for occupational exposure to hazardous doses of ultrasound is small.

II. OCCUPATIONAL EXPOSURE TO ULTRASOUND

In addition to determining the biologic effects of ultrasonic energy, occupational exposures must be analyzed to determine the relative hazard of ultrasound to workers. This chapter discusses ultrasonic equipment, common exposure conditions in various occupational settings, and the extent of exposure and likelihood of hazard. Various methods for measuring ultrasonic energy are described, and the introductory material to the section on measurement techniques defines the physical variables that determine an ultrasonic field. Current related exposure standards will be presented for comparison in Chapter III; no Federal standards for exposure to acoustic energy at frequencies from 20 kHz to the gigahertz range exist at present.

Uses of Ultrasound and Extent of Exposure

An extensive listing of the uses of ultrasound is presented in Chapter VIII. In Chapter I, it was estimated that over 650,000 ultrasonic devices would be in use by 1980 [US0662] and that the number of workers occupationally exposed to ultrasound could range from 250,000 to 500,000. Considering the fact that the first industrial use of ultrasound was developed only during the second world war [US0744], these figures indicate that the growth in the extent and diversity of use of ultrasound has been rapid.

As early as 1947, McKenzie and Rockett [US0965] reviewed a large number of applications for ultrasound, and several specialized applications were described by White [US0096] and Penn [US0740] in 1948 and 1951, respectively. These included air cleaning, materials testing, welding of plastics, and ageing and ripening of foodstuffs. Hulst [US0738] discussed the use of ultrasonics for welding metals, and Boyce [US0683] and Brown [US0685] described the technique of ultrasonic spectroscopy, using broadband, high-frequency ultrasound, for testing and inspecting materials.

Several reviews of the current applications and future prospects for industrial ultrasound were published between 1964 and 1977: Carlin [US0672], Steinberg [US0892], Rahnenfuhrer [US0743], Weissler [US0676], Reeve [US0744], Jacke [US0992], Lynnworth [US0728], and Shoh [US0746, US0760]. Medical applications, including both therapeutic and diagnostic ultrasound reviewed by Stewart et al [US0631] in 1973 and Smith [US0630] in 1976, respectively, have also become widespread. Devices for such purposes account for more than 40% of those projected by BRH to be in use in 1980 [US0662].

Examples of the types of processes in which ultrasound is used are listed in Tables II-1 and II-2. They are grouped into low-frequency, high-intensity and high-frequency, low-intensity uses. The division, which occurs at approximately 0.1-1 MHz, is arbitrary to the extent that overlap does occur: the applications are frequency sensitive insofar as they are cavitation sensitive, and many of the original choices of frequency were based upon the availability of apparatus [US0672].

TABLE II-1

APPLICATIONS OF ULTRASOUND

Low-Frequency, High-Intensity Uses

Cleaning and degreasing by immersion in cavitated solution
Drilling and abrading using an abrasive slurry
Soldering, brazing, and tinning without a chemical flux
Bonding metals by arc- or spark-free welds
Welding plastics by frictional melting
Foaming of beverages to displace air
Defoaming and degassing of liquid chemicals
Emulsification, dispersion, and homogenization
Metal insertion for injection molds
Atomization for aerosol formation and vaporization
Solid particle precipitation and agglomerization
Electroplating
Impregnating porous materials such as textiles
Degassing melts of glass and metal
Drying of plastic, paper, and textiles
Food treatment and sterilization
Acceleration of chemical reactions

High-Frequency, Low-Intensity Uses

Measurement of fluid flow and particle size
Sensing and switching controls
Determination of liquid level
Communications and alarms
Nondestructive testing and inspection for flaws
Thickness measurements
Hardness measurements
Viscosity measurements
Medical diathermy
Dental scaling
Medical diagnosis through neurologic, cardiac, abdominal, and ophthalmic imaging
Obstetric and gynecologic examinations
Measurement of blood flow

TABLE II-2

INDUSTRIAL MEASUREMENT, TEST, AND PROCESS CONTROL APPLICATIONS

Flowmetry
Thermometry
Density, porosity
Pressure
Dynamic force, vibration, acceleration
Viscosity in fluids
Transport properties
Level
Location of low-reflectivity interfaces
Phase, microstructure, modularity
Thickness
Position
Composition
Anisotropy, texture
Nondestructive testing
Grain size in metals
Stress and strain
Acoustic emission
Imaging, holography
Elastic properties
Particles and bubbles
Gas leaks
Burglar detection
Sound beam interruption

Adapted from reference US0728

Levels of Exposure and Occupational Hazards

One of the first factors that must be considered when determining the level of occupational exposure to ultrasound and the potential for hazard is the power output of the industrial equipment or medical device. Again, Chapter VIII lists a wide variety of equipment by type and manufacturer and provides ranges for their power outputs and frequencies. Table II-3 gives some representative power values as measured at the face of the ultrasonic transducer or applicator [US0116,US0630,US0631,US0656,US0672,US0676, US0744]. A graphic representation of the correlation between power level, frequency, and use is given in Figure II-1.

TABLE II-3

OUTPUT POWER OF ULTRASONIC EQUIPMENT

Type and Application	Power Output (W)*
Cleaners	
Cleaning and degreasing	50-1,000
Industrial equipment	
Machining, cutting, and grinding	100-1,000
Scaling	250-600
Bonding and welding	5,000
Plastic welding	500-1,000
Defoaming and deaerating	100
Drilling	2,000
Soldering	100
Fatigue testing and flaw detection	100
Nondestructive testing	
Flaw detection, weld inspection, and hardness and thickness measurement	0.001-0.1
Medical devices	
Diathermy	2-20
Diagnosis	0.001-0.5
Miscellaneous equipment	
Sonar	0.5-600
Burglar alarms	0.001-0.8
Measuring and controlling liquid levels	10**
Biological research (cell disruption)	150

*Range or maximum value
**Input power

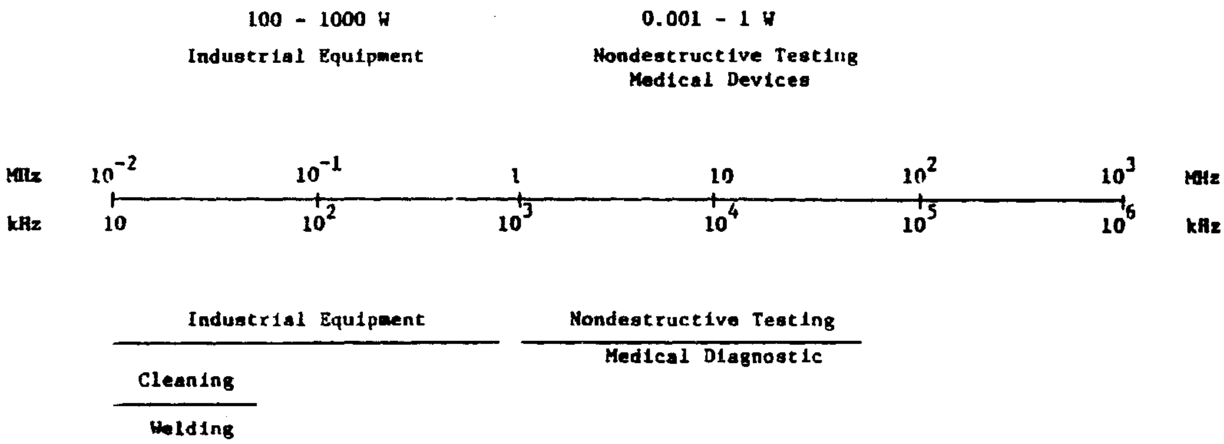

FIGURE II-1. FREQUENCY AND POWER OUTPUT OF VARIOUS TYPES OF ULTRASONIC EQUIPMENT

It is evident from Table II-3 that most ultrasonic equipment operates at output power levels that range from as low as 1 mW up to as high as 5 kW [US0444]. The majority of applications, and hence occupational exposure situations, involve output powers of less than 1 kW and power densities of less than 0.01 W/cm^2 (see Figure II-2). Information on actual occupational exposures is not as readily available. Parrack [US0116] and Hill [US1134] published the results of measurements made of power intensities at various operator positions for several industrial and medical applications of ultrasound. These indicated that typical exposures are to intensities of less than 1 $\mu W/cm^2$.

The limited data available from other occupational surveys generally agree with these figures. Parrack [US0134] reported in 1952 that turbojet aircraft engines produce intensities of less than 1 $\mu W/cm^2$ at ultrasonic frequencies. The intensities emitted by ultrasonic washers at frequencies between 20 and 40 kHz were found by Acton and Carson [US0100], Bakalar [US1075], Skillern [US0444], and Pazderova-Vejlupkova et al [US0203] not to exceed 10 $\mu W/cm^2$ (sound pressure of 110 dB). These values were measured at head height at the operator's customary work position and, in the case of the first two reports, with the covers open. Enclosing the washers decreased the intensity by two to three orders of magnitude. Dobroserdov [US0793] and Bakalar [US1075] reported that industrial lathes produced, at the operator's position, ultrasonic intensities at a frequency of 20 kHz ranging from 0.3 to 20 $\mu W/cm^2$ (95-114 dB) at ear height (1.7 m above the floor) and from 10 to 40 $\mu W/cm^2$ (109-116 dB) at hand height (1.4 m above

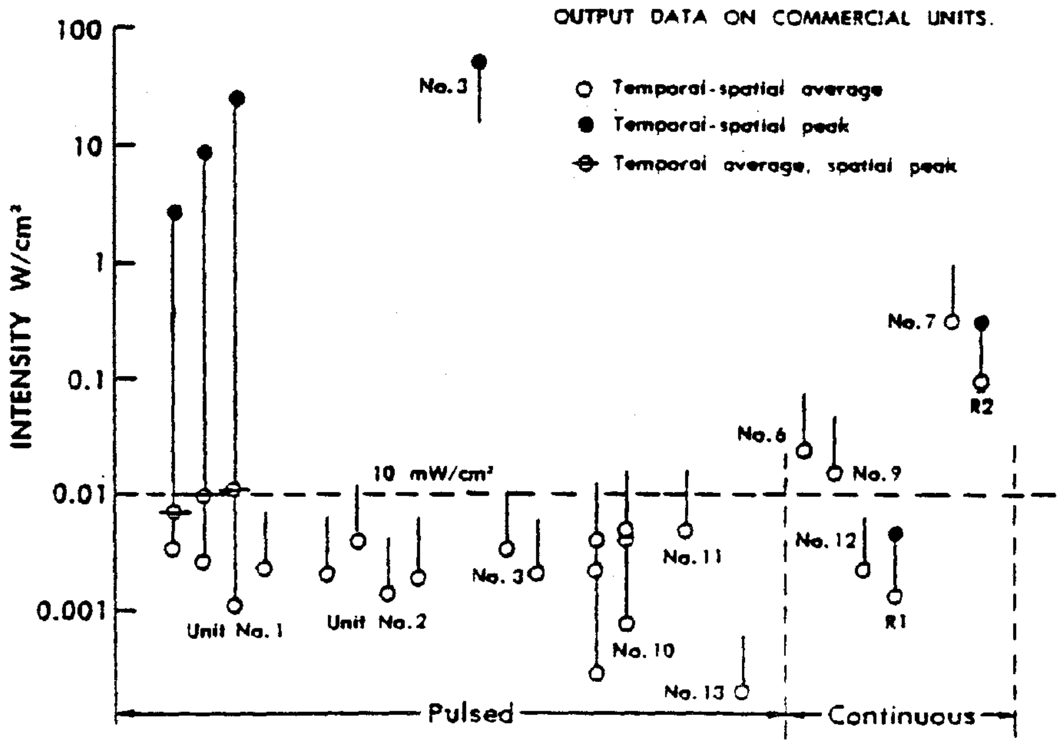

FIGURE II-2. REPRESENTATIVE DATA ON INTENSITY LEVELS GENERATED BY COMMERCIAL INSTRUMENTS

Taken from reference US0629

the floor). Near several installations used for processing ceramics and alloys and for welding, Ashbel [US0143] measured total sound pressure levels of 95-117 dB, corresponding to intensities of 0.3-50 $\mu W/cm^2$, for the frequency band from 16 to 31 kHz.

Surveys of a wider variety of equipment have also been published. In 1965, Ashbel [US0228] noted that, at a frequency of 31.5 kHz, the maximum intensities measured at operator position for four different industrial applications were as follows:

Cleaning and degreasing	4 $\mu W/cm^2$	(106 dB)
Processing of ceramics and alloys	10/$\mu W/cm^2$	(110 dB)
Dispersion	1 $\mu W/cm^2$	(101 dB)
Welding	2.5 $\mu W/cm^2$	(104 dB)

The results of similar surveys by Skillern [US0444] in 1965 and Acton and Carson [US0100] in 1967 are presented in Table II-4. Only one ultrasonic device was found to produce ultrasonic intensities above 1 $\mu W/cm^2$; the remainder radiated ultrasonic energy at intensities as low as 0.1 nW/cm^2. Although Reinhold et al [US0331] asserted that spinning machines produce measurable levels of ultrasonic energy at frequencies of 10 kHz and above, they were able to measure total sound pressure levels of 94-97 dB (0.025-0.05 $\mu W/cm^2$) over only the frequency range from 20 Hz to 20 kHz. It should be noted that these figures represent a small number of ultrasonic devices and measurements made for only a small range of frequencies; thus, any

TABLE II-4

RANGE OF ULTRASONIC INTENSITY LEVELS AT
OPERATOR POSITION FOR VARIOUS INSTRUMENTS

	Intensity at Midpoint Frequency, Given in kHz ($\mu W/cm^2$)*			
Type**	20	25	31.5	40
Drill (3)	0.0002-0.3 (64-95)	0.003-6 (75-107.5)	0.0025-0.025 (74-84)	0.2 (93)
Welder (1)	0.2 (93)	0.002 (73)	0.001 (69)	—
Cleaner (7)	0.005-0.4 (77-96)	0.0003-0.03 (65.5-85)	0.0001-0.03 (61-85)	—
Cleaner (1)	2,000 (133)	2,000 (133.5)	10 (110)	—

*Numbers in parentheses are actual measured ultrasonic pressure levels, given in decibels (dB).
**Number of instruments surveyed is given in parentheses.

correlation with the reported output powers for the complete range of ultrasonic equipment is slight.

A comprehensive analysis of the output power and intensity produced at the transducer face of 23 medical diagnostic units equipped with 44 different transducers was published by Carson et al [US0274] in 1978. The results, which have been summarized in Table II-5, indicate that the range in values is large for the four general classes of devices. It should be noted that the first group listed in the table were all pulsed-wave (PW) units that operated at pulse repetition rates of 520-2,600 pulses per

TABLE II-5

RANGE IN MEASURED ULTRASONIC POWER AND INTENSITY
FOR VARIOUS MEDICAL DIAGNOSTIC DEVICES

Type of Device*	Operating Frequency (MHz)	Output Power (mW)	Average Intensity (mW/cm^2)
Pulse echo scanning and echocardiography (29)	1-5	0.5-14.4	0.36-6
Obstetrical Doppler (8)	2.2-2.25	0.95-37	0.24-20
Peripheral vascular Doppler (5)	7.5-9.3	5.7-36	38-375
Ophthalmic (2)	8-10	0.06-0.61	0.21-4.9

*Number of transducers measured in each group is indicated in parentheses.

second (pps); thus, the peak intensities were four to six orders of magnitude greater. Nevertheless, the intensities are, in general, low at the transducer face and would be obviously much lower at the operator's position.

Several of the reports mentioned above also discussed the subjective responses of and physiologic effects observed in workers using ultrasonic equipment. Some of the characteristics of the so-called ultrasonic sick ness then thought to result from exposure to jet engine noise, ie, nausea, vomiting, fatigue, headache, dizziness, disturbance of neuromuscular coordination, tinnitus, and temporary hearing loss, were mentioned by Parrack [US0134] in 1952. But, as Pharris [US0084], Dickson and Chadwick [US0984], Parrack again [US0116], and Hill [US0146] pointed out, the attribution of such effects to the ultrasonic components of aircraft noise was questionable (see Chapter IV).

Similar subjective effects were reported to Skillern [US0444] by workers operating ultrasonic drills, cleaners, and a welder and to Acton and Carson [US0100] by operators of ultrasonic drills and workers standing 3.6 m from a bank of ultrasonic washers. Intensities above approximately 0.01 $\mu W/cm^2$ (78-79 dB) were uncomfortable, according to Skillern. Sonic and ultrasonic pressure levels were measured in both of these studies as well as in several of the others mentioned above. Acton and Carson, comparing the reported subjective effects with those produced by equipment emitting only higher frequency audible sound at high intensity, stated that the sonic components of the spectrum (near 16 kHz) were responsible. This point had been made by Davis et al [US0049] in 1949.

Tests of hearing level and temporary threshold shift were also performed on the affected workers by Acton and Carson [US0100]. They could find no significant differences in a comparison with a control group and no differences that could not be attributed to exposure to noise (sonic frequencies). In contrast, statistically significant reductions in auditory sensitivity in 25 workers operating ultrasonic lathes were reported by Dobroserdov [US0793] to result from exposure to both sonic and ultrasonic frequencies. He also reported statistically significant disturbances in stability due to alteration of the vestibular apparatus and inhibition of motor reactions to light and sound. Audiometric, stabilographic, and dynamometric studies in factory workers operating ultrasonic cleaners, welders, emulsifiers, and ceramic and alloy processors, described by Ashbel [US0228] in 1965, also revealed deteriorations in function following exposure to the sonic and ultrasonic frequencies emitted by the devices. An ultrasonically induced decrease in blood sugar level was considered to be the cause of the familiar subjective complaints listed by Ashbel. As described previously, however, Pazderova-Vejlupkova et al [US0203] reported no significant deviations in a variety of physiologic, gynecologic, neurologic, and otorhinolaryngologic variables in a comparison of operators of ultrasonic washers and lathes with a group of nonexposed workers.

As is the case for occupational exposure levels, the amount of available data on occupational hazards is limited. The information that is available does not permit definite conclusions concerning whether the ultrasonic or subharmonic sonic components of the sound energy emitted by ultrasonic devices are responsible for the subjective and biologic effects noted nor even whether such effects do occur.

With regard to actual occupational exposures to ultrasound, the Occupational Safety and Health Administration (OSHA) Management Information System data on OSHA inspections performed between 1972 and 1980 also provide only limited information. Table II-6 indicates that, of the 21 inspections for ultrasound performed at 19 establishments, four citations were issued for violations of the noise (sound) exposure standard. The establishments ranged from small to large (5-11,000 employees), and the

TABLE II-6

OSHA INSPECTIONS OF ULTRASONIC HAZARDS*

Type of Inspection	Total No. of Employees	No. of Employees Affected	No. of Samples or Readings Taken	Severity**	Section Violated/Type of Citation Issued***
General	156	28	44	0	—
General	550	8	1	1	—
General	543	2	5	0	—
General	185	1	2	0	—
General	175	3	6	1	.095/00101
General	152	30	140	1	.095/S0101
General	152	30	1	1	.095/S0101
General	306	15	10	0	—
General	155	8	15	0	—
General	30	1	1	0	—
General	46	4	3	2	.095/00104
Complaint	210	1	1	0	—
Complaint	5,300	2	2	0	—
Complaint	150	1	1	0	—
Complaint	130	7	6	0	—
Complaint	130	7	5	1	--
Complaint	245	5	43	0	—
Complaint	11,000	5	1	0	—
Complaint	135	6	72	0	—
Complaint	208	50	4	0	--
Followup	234	2	3	0	1

*Each entry signifies a single plant inspection.

**Severity is expressed as follows: 0 = at or below standard; 1 = level measured was between one and two times standard; 2 = level was between two to three times standard. Standard in this case presumably refers to OSHA noise standard.

***Section of Occupational Safety and Health Act (29 CFR 1910) violated was one dealing with noise exposure. First letter of citation refers to type of violation: S = serious; O = other.

number of workers presumably affected ranged from 1 to 50. A total of 37 out of 179 presumably affected and 19,910 plant employees had been exposed at citable levels. The fact that this information involves essentially noise (the OSHA standard applies to exposure to frequencies up to 20 kHz, whereas the American Council of Governmental Industrial Hygienists [ACGIH] standard applies only up to 56.2 kHz) renders these data useless for consideration of presumed ultrasound hazards.

A survey of health hazard evaluations performed by NIOSH revealed that 13 dealt with noise; none concerned ultrasound. One US Air Force report, produced for the Air National Guard at McClellan Air Force Base, California, mentioned a potential health hazard from ultrasonic degreasing in the pneudraulics shop [US0238], although no measurements were made.

A search of popular press literature on ultrasound over the last 4 years revealed only 2 of 21 articles that cautioned against its use. Both of these dealt with fetal monitoring, for which, as the reviews in Chapters IV and XIII show, concern is unwarranted. The remaining articles focused on the varied nature of its technologic applications. These concerned nondestructive uses; the potentially more harmful uses of low-frequency, high-intensity ultrasound have not been addressed in the press.

Secondary Hazards Associated with Use of Ultrasound

The use of ultrasound may expose workers to other hazards that do not involve the absorption of sound energy. One example of such secondary hazards has been and will be mentioned repeatedly, ie, audible sound generated as subharmonics of ultrasonic frequencies. Others include aerosols, vibration, and electric currents on fields.

The problems or potential hazards that any of these agents may present vary. Noise exposures are already limited (see Chapter III) by an OSHA standard covering frequencies between 20 Hz and 20 kHz. This should suffice to protect a worker from exposures to subharmonics. The noise levels detected near ultrasonic equipment have been below the current standard; furthermore, the contribution of audible subharmonics to the various subjective and physiologic complaints voiced by workers operating ultrasonic equipment is far from resolved, as the preceding discussion and Chapters VI and VII show.

Electric fields or currents that range throughout the so-called low- to ultrahigh-frequency bands may be produced by ultrasonic generators. A NIOSH occupational hazard assessment dealing with exposures to radiofrequency and microwave (RF/MW) radiation from 300 kHz to 300 GHz is nearly completed. This document suggests a frequency-dependent exposure limit, which decreases with the square of the frequency up to 10 MHz. Since the power output of most ultrasound equipment in use also decreases with frequency, as noted above, the suggested RF/MW limits would appear to apply.

It is questionable whether concern for exposures to electromagnetic fields is warranted. As the RF/MW document shows, the amount of RF energy absorbed below approximately 1 MHz is negligible and the power outputs of ultrasound generators are two to three orders of magnitude below those for RF/MW equipment. The only potential hazard is electric shock.

Whole- or partial-body vibration is possible when ultrasonic equipment is being used. This is especially true for small, handheld inspection equipment; however, since such equipment usually operates at high frequencies and low power, the probability of harm is low. Whole-body vibrations from resonating supports or enclosures for the ultrasonic equipment are also unlikely because such structures will dissipate much of the available energy quickly. Such exposure situations will undoubtedly be covered in the document on vibration currently being prepared by NIOSH.

The only potential problem with the use of ultrasound that may involve significant hazards is exposure to aerosols or mists. These may be produced, for example, during the transmission of ultrasound through oil baths used in some cleaning operations or for grinding and during defoaming or emulsification procedures. As experiments with ultrasonically generated aerosols have shown [US0865,US0866], these exposures are potentially harmful to the lungs. Since most of the ultrasonic equipment used for the operations mentioned above is enclosed, the problem is unlikely to occur. In fact, enclosure of equipment solves all of the potential problems discussed in this section.

Measurement Techniques

In determining the exposure of an individual to any physical or chemical agent, it is necessary to relate the values of certain physical variables describing the existence of that agent with the extent or likelihood of occurrence of a specific biologically significant effect. There are essentially two ways to present values for those physical variables: in terms of the dose, which refers generally to the amount of the agent absorbed by a mass of tissue or organism, or in terms of the concentration or density of the agent in a region of free space. With a physical agent, such as ultrasound, quantity is usually expressed as energy or power, which is the energy transferred past some point per unit time. Thus, the dose of ultrasound delivered to or absorbed by tissue is expressed in terms of energy per unit mass, ie, joules per kilogram or ergs per gram. This measurement is difficult to make because of the uncertainty of correlating temperature increases in a tissue with the amount of heat generated and energy absorbed and because of the complexity of making measurements of incident, reflected, and transmitted energies. Describing the ultrasonic field is more direct and reliable.

Since sonic (and ultrasonic) energy is transmitted only through a medium, as opposed to electromagnetic energy, which can propagate through a vacuum, the field can be described by measuring the effects of the ultrasonic energy on the medium. Here the displacement, velocity, acceleration, velocity gradient, or pressure of the particles of the medium can be measured. An ultrasound detector (also referred to as a probe) responds to and physically measures one or more of these five variables but, for the most part, integrates the measurement over its dimensions and expresses its results in terms of intensity, ie, power per unit area or watts per square meter. This is true for propagating (or radiating) plane-wave fields; for standing waves, ultrasonic detectors measure the energy density.

The techniques for measuring ultrasonic power levels can be grouped into four categories based on the type of measurement made: radiation force, thermal, optical, and electromagnetic. The methods and theories of operation of various probe designs have been reviewed by Mattiat [US0732], Kossoff [US0846], Lloyd [US0765], Beyer and Letcher [US0655], Hill [US0938], and Stewart [US0714]. Short descriptions of the detectors available and their relative utility for occupational exposure measurements are given in Chapter XII. As that chapter indicates, there is no single ultrasonic monitor preferable for occupational exposure measurements. In fact, none of the designs are acceptable for routine monitoring use.

<u>Control of Exposure</u>

At present, there are no specialized techniques or equipment for controlling exposure of workers to ultrasound. No doubt this lack is due to the perception, pervasive in the industry, that ultrasound is not hazardous. Enclosure of ultrasonic washers was mentioned above [US0100, US0203,US0444,US1075] as capable of reducing incident intensities by two to three orders of magnitude. Where practical, this approach would seem to offer a simple, efficient means for limiting exposures. However, environmental enclosures or sound-attenuating curtains, such as are available from several manufacturers [US0252,US1146,US1155], are useful only for the audible frequencies and produce significant attenuation only up to frequencies of 5 kHz. Furthermore, as Chapters IV, VIII, and XI show, they would prove superfluous for the control of airborne ultrasound, which is already subject to large absorption by air.

Administrative controls and proscribed work practices are also nonexistent for occupational uses of ultrasound. They would have limited effectiveness except for controlling direct contact or coupled exposures, as Chapters IV and V will show.

Conclusions

The total population of workers potentially subject to occupational exposure to ultrasound can be estimated to be 500,000 or more in 1980. For the estimated 650,000 industrial, scientific, and medical ultrasound devices in use in 1980, producing output powers from approximately 1 mW to 10 kW at frequencies from 20 kHz to 50 MHz, usage figures suggest that there is no preponderance of exposure to any specific range of intensity or frequency. Furthermore, it can be generalized that low-frequency ultrasound is commonly used at high intensities, eg, for cleaning, whereas high-frequency ultrasound is used at low intensities, eg, for nondestructive testing and medical diagnosis. Thus, since the absorption of ultrasonic energy is known to increase with frequency, the amount of energy delivered to a tissue and absorbed may be roughly the same at each frequency, and every specific incidence of occupational exposure to ultrasound may involve the absorption of a constant amount of energy. Hence, no single population of workers is at excessive risk of exposure to a hazardous level of ultrasound.

Determination of the relative hazard is dependent on relating absorbed dose to incident intensity and the extent or incidence of a biologic effect to dose. That dose, once known, can be compared with the dose expected for an occupational exposure (as described above) to determine whether a hazard is likely to exist. Chapter IV presents information on the range of intensities found through observation and experimentation to produce a variety of effects. It is evident that the incident ultrasonic intensity estimates made in the present chapter were based on limited data. Also, exposure standards for ultrasound are nonexistent; thus, guidelines for estimating the degree of risk are lacking. It may be concluded that occupational exposures require further investigation before the extent of the ultrasound hazard can be known.

III. EXPOSURE STANDARDS AND FEDERAL AGENCY ACTIVITIES

Two types of standards apply to the limiting of occupational exposure to ultrasound: performance or emission standards and exposure standards. An example of the first is the Radiation Control for Health and Safety (RCHS) Act of 1968 (Public Law 90-602) and the regulations for administration and enforcement of the performance standards [US0665] by BRH. The second is exemplified by the 1976 ACGIH threshold limit values (TLV's) for airborne upper sonic and ultrasonic acoustic radiation [US0120]. However, there are limitations to both of these standards.

In 1956, the American National Standards Institute (ANSI) published the first consensus standard dealing with the performance of ultrasonic therapeutic devices [US1178]. The RCHS Act discussed the need for protecting individuals from electronic product radiation, which included ionizing and nonionizing electromagnetic radiation as well as acoustic radiation in the infrasonic, sonic, and ultrasonic ranges [US0780]. At the present time, BRH regulations on ultrasound apply only to the performance of ultrasonic therapy devices [US0665,US0953]. They specify that the operating conditions of the devices, eg, power and intensity, pulse duration and repetition rate, and frequency, need only remain within certain specified limits. Maximum emission levels were not set.

Sperber [US0220] has discussed the role of several other regulatory agencies in controlling emissions from ultrasonic devices. As with proposed drugs, the Food and Drug Administration provides means for obtaining premarket approval for the development of ultrasonic surgical devices (Federal Food, Drug and Cosmetic Act, Sections 515c and 515f). Diagnostic and therapeutic devices need only show that they are safe and efficacious (Sections 513a and 1B). The Consumer Product Safety Commission has not promulgated any ultrasonic performance standards, whereas the Federal Communications Commission requires that ultrasonic equipment produce no electromagnetic radiation within the frequency range of the so-called ISM bands unless shielding and filters are applied to the equipment. In effect, ultrasound emission limits for industrial, medical, and scientific equipment do not exist.

The same situation also obtains for exposure standards. The OSHA standard for noise exposure (29 CFR 1910.095) is limited to essentially audible frequencies (10 Hz - 20 kHz) and sets the permissible 8-hour exposure at an equivalent A-scale-weighted sound level of 90 dB, or 0.1 $\mu W/cm^2$ [US0982]. A limit of 85 dB is being suggested in the proposed revision to the US Air Force standard (AF Regulation 161-35) on noise exposure [US0991]. This regulation only applies to audible sound. The aforementioned ACGIH standard [US0120] covers frequencies from 8.9 to 56.2 kHz inclusive and provides for the TLV's given in Table III-1. It should be noted that ACGIH suggested these limits to prevent possible hearing losses from subharmonics of the ultrasonic frequencies in the audible (sound) range.

TABLE III-1

ACGIH THRESHOLD LIMIT VALUES FOR AIRBORNE ULTRASONIC RADIATION

Frequency Range of Third-Octave Band (kHz)*	Permissible Exposure Level ($\mu W/cm^2$)**
17.8-22.4 (20)	3 (105)
22.4-28.2 (25)	10 (110)
28.2-35.5 (31.5)	30 (115)
35.5-44.7 (40)	30 (115)
44.7-56.2 (50)	30 (115)

*Midfrequency of band is given in parentheses.
**Actual sound pressure levels expressed in decibels are given in parentheses. These are referenced to an initial sound pressure of $2x10^{-4}$ dynes/cm^2 and intensity of $1x10^{-16}$ W/cm^2.

For Great Britain, Acton [US0101,US0382,US0678] has proposed that the permitted level of exposure for the third-octave bands centered on frequencies of 25 and 31.5 kHz be 110 dB, or 10 $\mu W/cm^2$, but that the level for the band centered at 20 kHz be 75 dB, or 0.003 $\mu W/cm^2$. He based his proposal on limited evidence for the production of auditory damage and subjective effects [US0101,US0678] by low-frequency ultrasound as well as high-frequency audible sound. As early as 1950, ANSI had considered the possibility that exposures to such frequencies might contribute to hearing loss [US0996]. Grigoreva [US0990] had proposed similar exposure limits for the USSR on the basis of similar criteria. Auditory effects were cited by Gorshkov and Roshchin [US0372] as sufficient to limit permissible ultrasound exposure levels under industrial conditions to 100 dB, or 1 $\mu W/cm^2$. The lack of sufficient, reproducible data was mentioned by all

of the above authors, as well as by Suess [US1160] in a recommendation for a World Health Organization program to determine the health hazards associated with ultrasonic and other nonionizing radiation, as responsible for their caution in proposing exposure standards. All were uncertain whether ultrasound presented an occupational hazard.

IV. HEALTH EFFECTS OF EXPOSURE TO ULTRASOUND

As stated in Chapter I, ultrasound has been found to have definite effects on animals and plants, tissues, cells, and microorganisms [US0038]. Those effects of particular relevance to the potential problem of human exposure under occupational settings are reviewed fully in Chapter XIII, where approximately 200 reports have been discussed and evaluated and their results tabulated. This chapter summarizes the information presented in that chapter on human and animal effects and correlates the data on ultrasonic dose with response.

Effects on the reproductive system, including teratogenic and mutagenic effects, are discussed in a separate section, since the results of animal and human studies are uniformly negative. Finally, thresholds for various effects are determined, and the potential for industrial exposures to attain such doses is estimated. The relative harm of such effects to the individual is then discussed, so that the hazard of ultrasound can be assessed realistically.

It should be noted that the term "dose" has been applied here, as it is by most scientists working in the field of ultrasound, to indicate the product of the intensity and the duration of exposure, which is expressed in terms of energy per unit area. Although this usage is strictly incorrect (see Chapter II) and the term "fluence" is preferred, the product of power density (so-called intensity) and duration represents the most convenient way to state the exposure of an organism.

Subjective and Biologic Effects on Humans

Chapter II has already presented some data on the generalized effects associated with occupational exposure to ultrasound. Ultrasonic sickness, characterized by subjective complaints of fatigue, nausea, headache, loss of coordination, etc, was described by Parrack [US0116], Pazderova-Vejlupkova et al [US0203], Knight [US0284], Bohanes and Kratochvil [US0374], Lisichkina [US0532], Dickson and Watson [US0983], and Dickson and Chadwick [US0984]. Estimates of ultrasonic intensities were not made in these studies, but because the exposures involved airborne ultrasound at frequencies of 88 kHz and below, the levels can be assumed not to have exceeded the range of microwatts per square centimeter (see Chapters II and V). Furthermore, as has already been pointed out [US0084,US0100, US0116,US0134,US0146,US0444], it is more probable that any subjective effects reported can be attributed to exposure to high-frequency sound rather than to ultrasound, if such effects exist at all.

The same may be said for the production of biologic effects in workers. Reports of changes in electrocardiogram, blood pressure, and heart rate by Yazburskis [US0605], blood sugar level by Ashbel [US0143], and secretion of catecholamines by Gerasimova [US0215] involved exposures to high-frequency audible sound (8-18 kHz) only, emitted by cleaners, welders, drills, and other industrial processing equipment. No correlation existed between exposure to ultrasound and alterations in several physiologic variables, such as blood pressure, temperature, blood cell count, liver function, and blood enzyme levels, in workers using ultrasonic cleaners, welders, and other equipment, according to Lisichkina [US0532], Parrack [US0116], and Pazderova-Vejlupkova et al [US0203]. Differences in hearing, balance, motor function, and psychologic response, such as reported by Acton and Carson [US0100], Ashbel [US0228], Knight [US0284], and Dobroserdov [US0793], also have not been definitively attributed to ultrasonic exposure.

Workers operating handheld inspection equipment, producing intensities of up to 1 W/cm^2 at frequencies of 0.5-5 MHz, have been found to suffer from minor microcirculatory disorders of the anterior of the eye [US1041] and skin of the hand [US0387,US0556]. Hemorrhagic skin rashes and edema also have been observed in medical technicians operating handheld therapeutic ultrasound devices [US0387]. No major pathologic changes were noted in the studies, and the condition of the eye and skin returned to normal after use of the equipment was halted.

The perception of ultrasound, apparently a subjective response, may be of some significance to worker function and safety, since, if the ultrasonic noise becomes obtrusive, it may be irritating and interfere with job performance. Studies on perception have indicated that levels of 4 mW/cm^2 down to 30 nW/cm^2 can be detected as percussive noises [US0388,US0555, US0769,US0789,US0820,US0884]. The experiments involved exposures to frequencies ranging from 20 to 100 kHz, and direct contact with the skull was maintained in all the studies except one [US0719]. The fact that the perception threshold was frequency dependent, that some deaf individuals could perceive ultrasound, and that the occipital region of the head was most sensitive to ultrasound suggests that the ear is not responsible for the effect. Whether bone conduction, stimulation of the auditory nerve, or some indirect effect on the inner ear is responsible has not been determined; nevertheless, ultrasonic hearing appears to be possible in controlled laboratory situations. The sound reportedly heard in industrial environments by workers using ultrasonic equipment has been determined to be high-frequency audible sound [US0049,US0100,US0444]; thus, whether ultrasonic perception can occur in occupational settings is questionable.

In summary, no harmful biologic or subjective effects have been discovered to follow occupational exposure of humans to ultrasound in the industrial environment. The single long-term study by Pazderova-Vejlupkova et al [US0203], in which workers operating industrial cleaners for an average of over 3 years were examined, revealed no statistically significant differences between these workers and a control group in 21 biochemical and physiologic variables nor in the results of five anatomic examinations.

Results of experiments and case observations have been more positive. Figure IV-1 shows a distribution of reported effects in humans at various

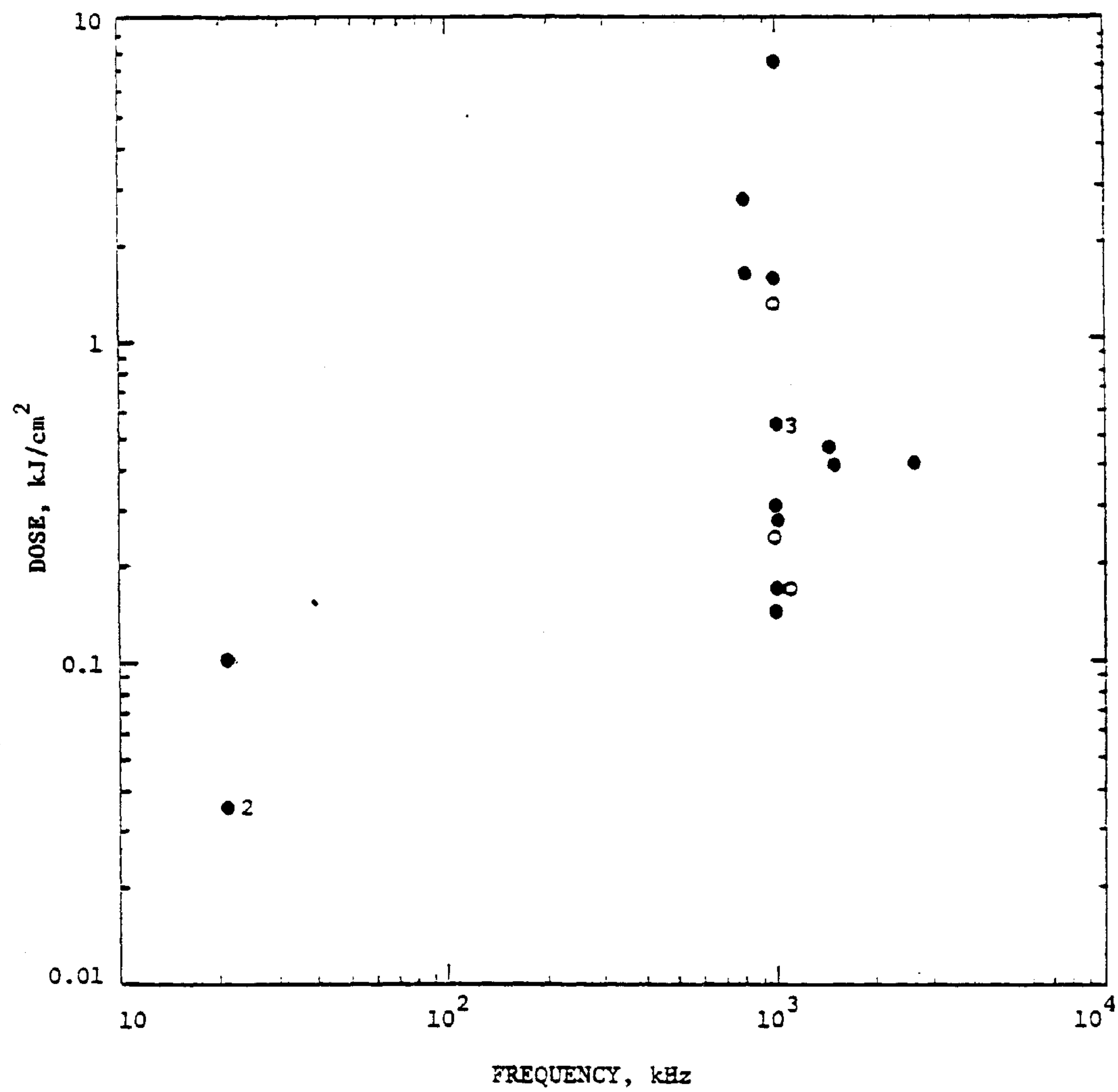

FIGURE IV-1. DOSES AT WHICH BIOLOGIC EFFECTS HAVE BEEN REPORTED IN HUMANS. SOLID CIRCLES INDICATE DEFINITE RESULTS; OPEN CIRCLES INDICATE RESULTS AT THAT DOSE. NUMBERS REFER TO THE NUMBER OF EXPERIMENTS REPORTING RESULTS AT THAT DOSE.

doses and frequencies. These data have been compiled from Tables XIII-2 and XIII-4 and the text of Chapter XIII.

Temporary shifts in hearing threshold and tinnitus were mentioned by Grigoreva [US0990] and Moller et al [US0424] to follow exposures of 1 and 0.5 hours, respectively, to 20- to 42-kHz ultrasound. The intensities reported ranged from 10 to 20 $\mu W/cm^2$, corresponding to a maximum dose of 36 J/cm^2. Smith [US0998] reported neither of these effects following exposure to a maximum intensity of 1 $\mu W/cm^2$. The temporary nature of these changes, as well as the lack of longer term studies that could determine if permanent effects follow chronic exposure, leaves the question of potential harm to hearing due to low-level exposure unanswered. Higher doses have been reported to lead to histologic changes in the labyrinth 2 years postexposure: exposure at intensities of 9-15 W/cm^2 [US0476] and 10- and 15-minute exposures at 3 and 5.6 W/cm^2, corresponding to doses of 1.8 and 8.4 kJ/cm^2 [US0317]. These alterations could affect hearing.

The only reported effects of ultrasound on the human eye have involved those observed following insertion of an ultrasonic probe into the lens [US0164,US0188,US0208,US0214,US0218,US0575]. The process is a surgical procedure, called phacoemulsification, used to remove cataracts, and no information on dose is available. Considering the extensive degenerative changes in the eye found to accompany such surgery, eg, corneal edema, iritis, retinal detachment, capsular opacification, and endothelial loss, it would seem that contact of the eye with an ultrasonic probe can be considered definitely harmful.

Swelling, blistering, and edema of the skin have also been reported to follow contact exposure to ultrasound at several frequencies between 20 kHz and 9.5 MHz. However, as Wittenyellner [US0224], Lehmann et al [US0294], Filipczynski [US0501], Chieppo [US0784], and Block [US0773] pointed out, the effects were temporary and led to no permanent damage, even for exposures at intensities as high as 1.33 W/cm^2. Temporary increases in tissue temperature and blood flow were noted in similar experiments reported by Bickford and Duff [US0880], Abramson et al [US0368], and Lota [US0410]. These involved doses of 1.8-3.15 kJ/cm^2 at frequencies of 0.8 and 1 mHz. Negative effects on blood flow were observed by Grigoreva [US0990] for 20-kHz ultrasound at doses of 36-108 J/cm^2 and by Lota [US0410] for 1-MHz ultrasound at 150-225 J/cm^2. In addition, Buchanan et al [US0782] showed that destruction of muscle tissue did not follow exposure at a dose of 1.08 kJ/cm^2. Thus, according to human studies, any effects on the skin and muscle tissue are minor and transitory. Increases in the concentrations of glucocorticoids and histamine were observed following ultrasonic therapy by Aniskova et al [US1014], but the one experimental study dealing with the neuroendocrine system, by Muggeo et al [US0425], measured no changes in secretion of pituitary growth hormone following exposure to 3-MHz ultrasound at doses of 38-58 kJ/cm^2.

Ultrasound has also been used during brain surgery. As will be discussed in the next section, small, localized lesions can be produced in brain tissue by highly focused ultrasound. According to case reports by Nilson et al [US0544] and Oka et al [US0083], short pulses of high-intensity ultrasound producing doses from 0.51 to 8.4 kJ/cm^2 were effective at frequencies of 1 and 1.46 MHz. Garg and Taylor [US0704] noted that less intense ultrasound, at a dose of 3.6 J/cm^2, was ineffective in producing lesions, edema, hemorrhage, and nerve degeneration or in altering brain enzyme levels, cerebrospinal fluid, or the electroencephalogram. With regard to the peripheral nervous system, nerve conduction has been found to be altered during contact of an ultrasonic transducer with the skin. Lehmann et al [US0850], Madsen and Gersten [US0537], Zankel [US0362], Edel and Bergmann [US1027], Esmat [US0165], and Currier et al [US0161] applied ultrasound at frequencies of 0.8 and 1.5 MHz at doses varying between 0.15 and 0.6 kJ/cm^2 and reported variable results. The induction of tactile, temperature, and pain sensations in the skin by ultrasound was analyzed by Makarov [US0305] and Gavrilov and coworkers [US0807,US1092,US1093]. The threshold for inducing the sensations was found to increase as the frequency of the pulsed ultrasound was increased and the pulse width was decreased. Doses ranging from 0.13 to 100 J/cm^2 were investigated. The relative harmful nature of such effects on the nervous system is low, since the effects appear to be transitory. Whether they are irritating or could interfere with performance and, consequently, regard for safety is unclear.

As this discussion and Figure IV-1 show, the apparent threshold dose observed for producing various effects in humans is approximately 0.1 kJ/cm^2. Furthermore, most of the effects reported in human studies appear to be minor and of no lasting consequence. Final judgment should be reserved, however, until the results of extensive animal studies have been analyzed. What should be noted is that nearly all of the reports concerning human exposure involved experiments or observations of effects from direct or coupled contact exposure to ultrasound. Under such conditions coupling can be assumed to be nearly complete, and airborne exposures that deliver similar doses to the tissue can be considered to lead to similar results.

Biologic Effects on Animals

The range of effects observed in animal experiments resembles that for human studies, as Chapter XIII and Tables XIII-5 to XIII-13 show. So, also, does the distribution of effects as a function of dose and frequency (see Figure IV-2). However, in considering the animal effects data, it must be continually emphasized that several factors limit the usefulness of the data:

(1) With few exceptions, all of the reports deal with contact exposures.

(2) The fur or hair on an animal acts to allow much greater transmission of ultrasonic energy into the body, ie, as an impedance-matching device, than would normally occur under air/skin or transducer/skin interface conditions.

(3) The ratio of surface area to body mass is much greater in animals than in humans.

(4) The lower ultrasonic frequencies are audible to animals.

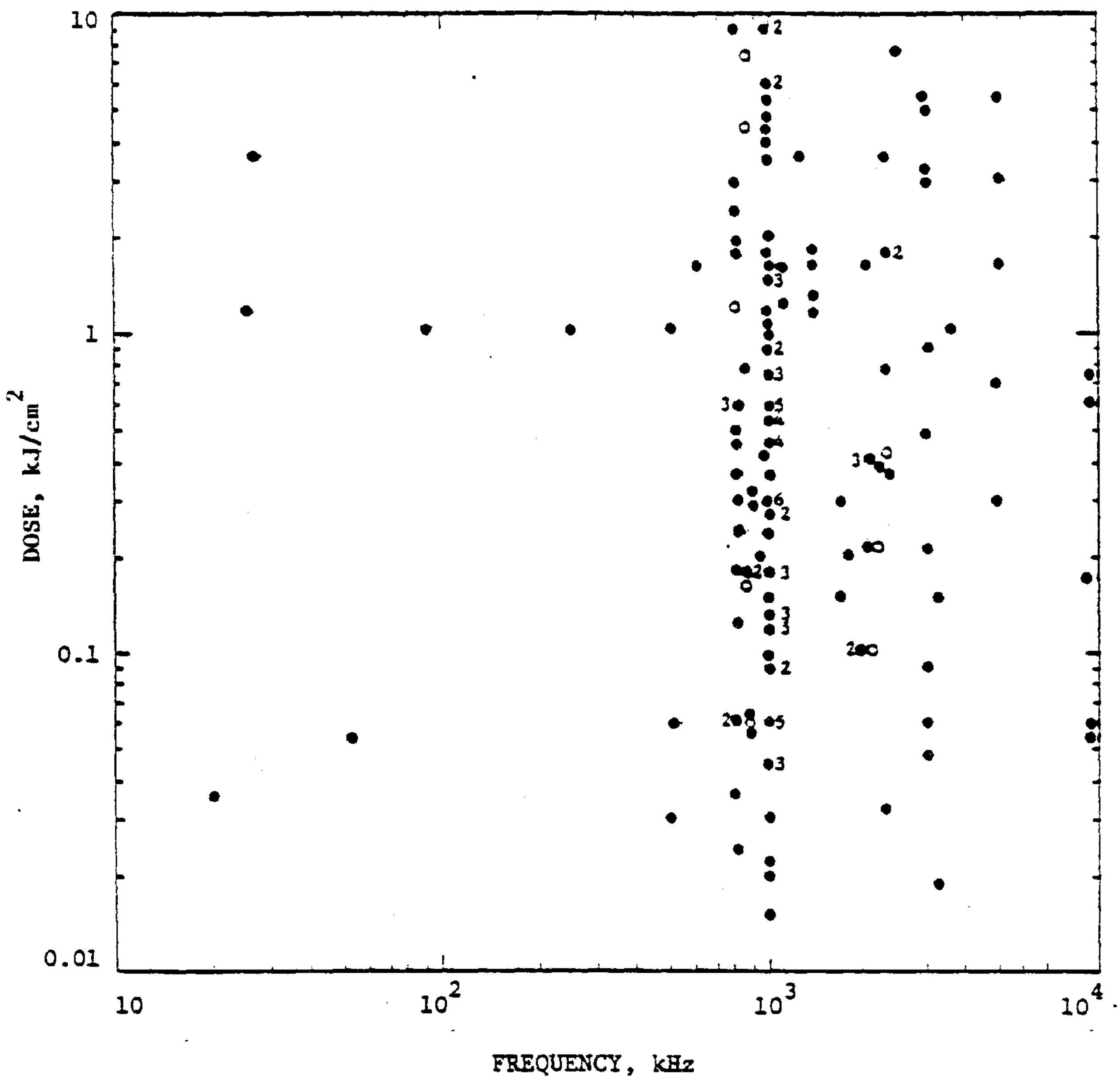

FIGURE IV-2. DOSES AT WHICH BIOLOGIC EFFECTS HAVE BEEN REPORTED IN ANIMALS. SOLID CIRCLES INDICATE DEFINITE RESULTS; OPEN CIRCLES INDICATE NEGATIVE RESULTS AT THAT DOSE. NUMBERS REFER TO THE NUMBER OF EXPERIMENTS REPORTING RESULTS AT THAT DOSE.

The second and third factors mean that, first, more heat will be generated in the body of an animal than in that of a human and, second, an animal will have more difficulty in dissipating that heat than a human will.

These problems become immediately obvious when the lethality data are considered. An intensity of 10 W/cm^2 was found by Southern et al [US1009] to be lethal within 25 or 6.8 minutes when ultrasound at frequencies of 0.5 or 3.8 MHz was coupled to the abdomens of mice. These figures correspond to doses of only 15 and 4.08 kJ/cm^2, respectively. Doses one-tenth as small, produced by an intensity of 1 W/cm^2, were found to be ineffective. In contrast, Fry and coworkers [US0194,US0641] found doses of 356 and 536 J/cm^2 to be lethal to mice when high-intensity 1-MHz pulses were coupled to their gonads, and Cowden and Abell [US0048] reported that doses of 0.18-1.2 kJ/cm^2 were lethal to rats under low-intensity irradiation. Airborne 19-kHz ultrasound was also found to produce death within 15 minutes at doses of 60-90 J/cm^2, according to Frings et al [US0261]. The last report mentioned that body temperature reached 43 C during irradiation. Death due to hyperthermia is implicated in all of these studies.

Dose-dependent alterations to the ear have been observed in several animal species. These have involved epithelial changes, hyperplasia, edema, vascular damage, necrosis, and degeneration, with the minor effects observed at doses of 0.3 and 9 kJ/cm^2 and the more extensive damage beginning to occur at doses between 1.62 and 9 kJ/cm^2. Various frequencies ranging from 1 to 5 MHz were used in the studies. Destruction of the labyrinth, such as described by Lundquist et al [US0412], Arslan and Sala

[US1106], Brain et al [US0489], and James et al [US0522], was observed to predominate over other effects. Exposure to the ultrasonic energy emitted from a small probe in contact with the inner ear was direct in these and other experiments [US0221,US0412,US0475,US0489,US0491,US0503,US0522, US0536,US0718,US1171], which makes extrapolation of the data to occupational exposures difficult.

The same point can be made with regard to studies on the effects of ultrasound on the eye. Damage to the retina was observed by Marmur and Plevinskis [US0198] to begin at doses of 0.6-3 kJ/cm^2 with 880-kHz ultrasound, whereas definite lesions in the retina, as well as choroid and sclera, appeared at doses near 24-30 kJ/cm^2 with 2.07- and 9.8-MHz ultrasound, according to Moiseyeva and Gavrilov [US0201] and Lizzi et al [US1103], respectively. Among other effects, conjunctiva and corneal opacities, hypertony, burning and epilation of the skin, hemorrhage, edema of the iris, and inflammation were observed by Baum [US0240] to follow exposure to 1-MHz ultrasound at doses between 0.45 and 0.9 kJ/cm^2. Zaiko and Mints [US0468] and Marmur [US0419] mentioned increases in permeability of various tissues in the eye to ^{32}P and ^{35}S following exposure at doses between 24 and 120 J/cm^2. Lower doses, between 45 and 60 J/cm^2, led to superficial corneal defects and lesions in the ciliar body, according to Jankowiak et al [US0379], Preisova et al [US0551], Rosenberg and Purnell [US0334], and Polack [US0183]. Cataracts have been reported to occur by Bernat et al [US0582], Torchia et al [US0351], and Lizzi et al [US0174] at doses ranging from 0.055 to 2.7 kJ/cm^2. Some of the disparity in these results can be attributed to variation in exposure conditions: in general, the dose required progressively increased as the intensity of exposure decreased. This trend can also be noted for the production of corneal defects mentioned above [US0379] and of damage to the optic nerve [US0584] and retina, observed by Purnell et al [US0434] and Jankowiak and Majewski [US0071] to occur at doses of 2-60 J/cm^2. A similar variable response will be evident for other tissues. The rabbit eye, the subject of all of the above studies, is considered to closely resemble, both physiologically and anatomically, the human eye; nevertheless, the lack of reported effects from airborne exposures leaves the potential for occupational hazard unclear.

Studies on the skin have revealed that progressive damage can occur. Ultrasound-induced heating of the subcutaneous layer was noted by Gersten [US0808] and of the skin surface by Godfrey et al [US0614] at doses between 0.06 and 2.16 kJ/cm^2. Chirkina [US0247] described inflammation and degeneration of the skin following irradiation with 830-kHz ultrasound at doses of 0.24 and 0.72 kJ/cm^2. Phonophoresis, ie, transmission of drugs across the skin, occurred in rabbits and pigs following exposures at doses of 0.06-1.02 kJ/cm^2, according to Novak [US0872] and Griffin and Touchstone [US0622,US0815,US0816], and in rabbits and dogs at doses of 0.48-0.6 kJ/cm^2, according to Dohnalek et al [US0141]. Finally, Argyris and Bell [US0474,US0756] observed ulceration at a dose of 10.8 J/cm^2. Only the last noted effect can be considered to have significance to human exposures.

A variety of effects in the soft tissues have also been reported at doses between 0.06 and 3 kJ/cm^2. These include, in order of increasing dose, dose-dependent disruption of mast cells in the mesentery [US0352], induction of uterine contractions [US1147], increased absorption of gastric mucosa [US0375], decreased acid secretion and ulceration of the gastric mucosa [US0340], and retardation in larynx growth [US0397]. None but the last two effects, which occurred at doses above 1.5 kJ/cm^2, appear to be harmful.

The skeletal system has been the subject of extensive study because of its abnormally high ultrasonic absorption coefficient (see Chapter XI). Herrick [US0763] and Lehmann et al [US0293,US0849] observed preferential heating of the cortex of the bone at doses of 0.12 and 0.45 kJ/cm^2. Dose-dependent effects were described by Ardan et al [US0697], Janes et al [US0523], and Payton et al [US0324] at doses ranging from 0.09 to 15 kJ/cm^2. These included inhibition of new bone growth as well as healing, fibrosis, hemorrhage, eburnation, discoloration, embrittlement and fracturing, rarefaction and periosteal reaction of the bone, necrosis and avascularization of the cortex, and changes in the marrow. The studies involved frequencies between 0.8 and 1 MHz. However, a lack of effects on the bone and marrow was reported by Janes et al [US0620] and Payton et al [US0324] at doses of 0.36-7.5 kJ/cm^2. Temporary inhibition of bone mineral metabolism, measured by ^{45}Ca uptake, was observed to follow irradiation at 1.225 kJ/cm^2. Although the ultrasound-induced changes in bone appear harmful, the variable nature of the results at lower doses, as well as the lack of data from exposures to short pulses of high intensity, hinders determination of a threshold for production of the effects.

Several of the points made above concerning exposure conditions apply to the results of experiments on the circulatory system. Changes in enzyme activities and the concentrations of various biochemicals in the heart and bloodstream were reported by Zimny and Head [US0469], Maneva and Beleva-Staikova [US1119], Straburzynski et al [US0580], and Bernat et al [US0583]. These occurred at doses of 0.06-2.4 kJ/cm^2 and frequencies of 0.8 and 1 MHz, although one report [US0190] noted negative results, on the porphyrin content of the blood, at doses up to 0.3 kJ/cm^2. The hazardous nature of these alterations is questionable. Lesions of the heart valves, heart failure, induction of heart murmur, and necrosis and degeneration of the arteries have been observed. Reeves et al [US0436] and Fallon et al [US0798,US1087] reported that doses ranging from 0.15 to 6 kJ/cm^2 were effective but that the changes at lower doses occurred only when high-intensity pulses were used.

With regard to other internal organs, including the neuroendocrine glands, the pattern of response is similar to that noticed for the heart. At lower doses, namely, 0.036-0.9 kJ/cm^2, alterations in enzyme activities and biochemical concentrations were observed by Keller and Tanka [US0197], Beleva-Staikova and Maneva [US1076], Shchereva [US1166], and Vibe et al [US0464]. Glick et al [US0792] reported no changes in the concentrations of cyclic adenosine monophosphate, cyclic guanosine monophosphate, and histamine in the skin, lungs, and peritoneal cells after irradiation with 2-MHz ultrasound at doses of 0.1-0.2 kJ/cm^2. They suggested that these negative results indicated that the cell membrane had remained intact during irradiation. Minor damage to the organs appeared on exposure at higher doses. This dose-dependent damage included changes in organ weight, such as reported by Longo et al [US0407] at 0.27-0.45 kJ/cm^2, and vascular occlusion, congestion, fragmentation, and necrosis of the liver and vacuolization of its parenchymal cells, such as observed at doses of 0.12-9 kJ/cm^2 by Bell [US0768], Curtis [US1021], Majewski et al [US0857], Cowden and Abell [US0048], and Jankowiak et al [US0258]. At doses of 0.3 and 0.6 kJ/cm^2, Hrazdir and Konecny [US0273] observed decreases in the uptake of ^{131}I by the thyroid; Gorshkov et al [US0063] reported increases in uptake at higher doses, ie, 1.08-3.24 kJ/cm^2. These variable changes were temporary. Exposures at the highest doses, ie, 3-18 kJ/cm^2, led to the production of focal lesions in the liver and kidney, such as observed by Taylor and Connolly [US0155] and Frizzell et al [US1145], and cellular damage, such as that observed by Jankowiak et al [US0258] in the adrenals, by Bernstine and Dickson [US0925] in the kidneys, and by Kremkau and Witcofski [US0288] in the liver.

In all of the above experiments, the transducer was placed in contact with the body of the animal, and the application of ultrasonic energy was limited to a small area on the skin surface above the affected organ. Nevertheless, damage of significance to the problem of potential hazard was not observed to occur below an approximate dose of 120 J/cm^2.

By far, the greatest amount of experimentation with ultrasound has involved the nervous system. Lesions have been produced in the brain and spinal cord using focused ultrasound at low-intensity doses ranging from 0.12 to 12 kJ/cm^2 [US0069,US0125,US0484,US0509] and at high-intensity doses from 0.125 to 67.5 kJ/cm^2 [US0003,US0009,US0125,US0077,US0095, US0337,US0477,US0480,US0543,US0633,US0706]. The use of convex reflectors outside the skull or small probes to localize the damage in these experiments renders them interesting examples of the development of surgical technique but of no significance to potentially hazardous exposures of humans in occupational settings. Other experimental results, such as heating, hemorrhage, and necrosis of the spinal cord, reported by Fry and Dunn [US0010], Taylor [US0156], and Anderson et al [US0103] to occur at doses of 0.015-0.416 kJ/cm^2, and degeneration of the peripheral nerves, reported by Anderson et al [US0103] and Voskoboinikov [US0465] to occur at 0.15-3 kJ/cm^2, involved placement of a flat ultrasound transducer onto the lumbar region of the animal. They are of limited significance to occupational exposures because of this fact. Although such degenerative changes are potentially harmful, this cannot be unequivocally said of changes in hydroxyindoleacetic acid secretion reported by Jankowiak et al [US0070], presumed damage to the blood-brain barrier observed by Bakay et al [US0124,US0478], and changes in the electrical activity of the cortex measured by Battista and Quint [US0332]. These effects were observed to follow irradiation at doses of 0.85-2.7 kJ/cm^2.

The negative results of experiments on learning and conditioned response [US0978] performed by Gilbert and Gawain [US1003] and Smyth [US0660] with doses up to 72 J/cm^2 contradict the one positive effect on behavior reported by Shipacheva [US0441] at a dose of 54 J/cm^2. Thus, animal experiments on learned behavior are inconclusive. It would seem that the large number of experiments on the nervous system are of limited use to the determination of human hazard potential.

Effects on Reproduction

Discussion of reproductive effects, including teratogenesis and mutagenesis, has been separated from that of the other effects for two reasons: (1) effects on reproduction are of immediate concern, and (2) results from both nearly 20 years of clinical experience and extensive animal experimentation have been negative. Figure IV-3 presents another distribution of results as a function of dose and frequency. Here, however, the negative results have been displayed for humans and animals.

Reports of a lack of effect in humans on the incidence of fetal abnormalities [US0100,US0145,US0242,US0888,US0951,US1134], neonatal development [US0616,US0652,US0842], and the rate and type of chromosomal aberrations [US0301,US0398,US0858,US0900] have all concerned observations made on pregnant females subjected to obstetric examinations. Improvements in ovarian function and regulation of menstruation have been observed following therapy [US1032,US1066]. The ultrasonic equipment used for such purposes has been determined to produce very low intensity ultrasonic energy, but the doses involved over a long period of can be estimated to range between 0.018 and 0.54 kJ/cm^2 for diagnostic examination and from 0.144 to 0.6 kJ/cm^2 up to 18 kJ/cm^2 throughout therapy.

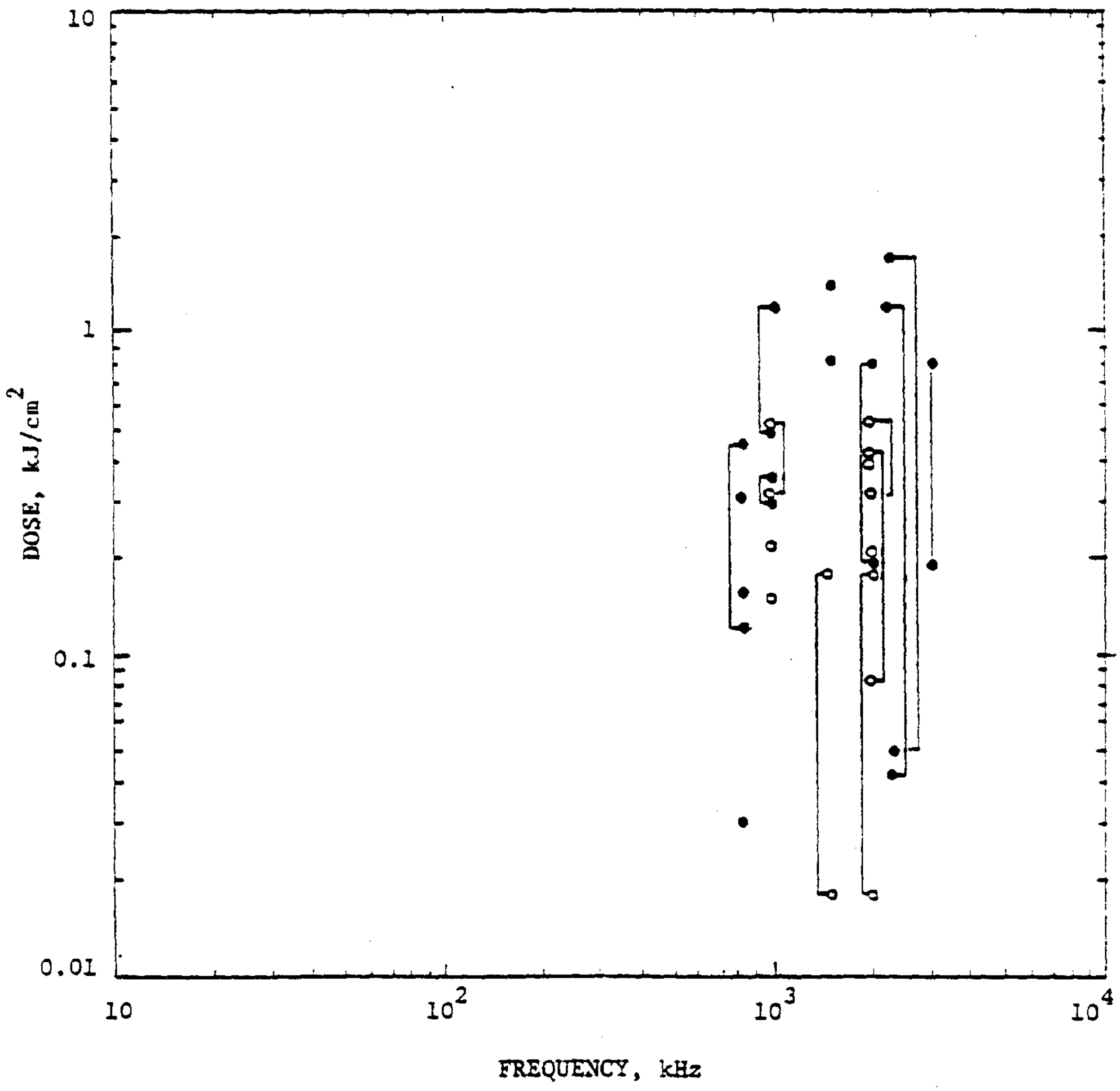

FIGURE IV-3. DOSES AT WHICH NEGATIVE EFFECTS HAVE BEEN REPORTED ON THE REPRODUCTIVE SYSTEM. SOLID CIRCLES DENOTE HUMAN STUDIES; OPEN CIRCLES DENOTE ANIMAL STUDIES. BRACKETS INDICATE RANGE OF DOSES OVER WHICH EXPERIMENT WAS PERFORMED.

Initial experiments with mice and rats, described by Woodward et al [US0097], Warwick et al [US0157], Mannor et al [US0307], McClain et al [US0303], Pizzarello et al [US0181], Stolzenberg, Edmunds, Torbit, and coworkers [US0530,US1126], Martelli et al [US0420], and Sikov et al [US0219], indicated no effects on fetal resorption, abnormalities, weight, and survival. These experiments were all performed, except for the last [US0219], at low intensities and using doses of 1.76 kJ/cm^2 or below.

More recent papers describing experiments on mouse and rat fetuses have provided contradictory results. Dose-dependent increases in body and organ weight were measured by Stratmeyer et al [US0643] for doses of 30 and 96 J/cm^2, and minor alterations in fetal development were observed by Torbit et al [US1162] at doses of 0.2 and 0.4 kJ/cm^2. Shoji and coworkers [US0442,US0887,US1120] and Rugh and McManaway [US0638] reported increases in the incidence of specialized abnormalities, such as exencephaly, dysraphe, and extra digits, at doses of 0.32-1.8 kJ/cm^2, whereas Muranaka, Tachibana, and coworkers [US1111,US1112,US1127] stated that the incidence of such abnormalities at doses up to 1.26 kJ/cm^2 was not statistically significant.

An increased incidence of fètal malformations owing to the production of temperature increases of 11-15 C in the uteruses of pregnant mice was noted by Mannor et al [US0307] at a dose of 3.79 kJ/cm^2. Fry et al [US0641] stated that doses between 1.18 and 1.875 kJ/cm^2 led to a 50% decrease in litter size of mice, and Sikov et al [US0219] determined the 50% lethal dose for rat fetuses to be 5.52 kJ/cm^2. Both of these results can be attributed to excessive heating of the uterus by high-intensity ultrasound, whereas the cause for the increase in postpartum mortality reported by Curto [US0712] for doses of 22-90 J/cm^2 is unclear.

Reported effects on the reproductive system are also contradictory. Stolzenberg, Torbit, and coworkers [US1126,US1162] observed microscopic changes in the ovarian, corpus lutean, and placental tissues of pregnant mice at doses of 0.1-0.4 kJ/cm^2. Disruption of spermatocytes and spermatids, reported by Andrianov [US0226] at doses of 0.06-0.6 kJ/cm^2, and variable changes in testicular electrolyte concentrations, observed by Fahim et al [US0497] at 0.9 kJ/cm^2, were found to be temporary. O'Brien et al [US0637,US1153], Cowden and Abell [US0048], Fahim et al [US0256], Pourhadi et al [US0550], and Dumontier et al [US0696] described degeneration of the testes, a long-term decrease in spermatogenesis, and disruption of spermatocytes and spermatids after exposure of mouse testes to doses of 0.3-1.2 kJ/cm^2. The loss of reproductive capacity associated by the last two groups with alterations in spermatogenesis was not observed, however, in mice by Lyon and Simpson [US0302] and by Kirsten [US0720] for doses ranging between 0.3 and 1.44 kJ/cm^2 nor in rabbits by Hahn and Foote [US0609] for a dose of 0.6 J/cm^2. Chromosomal damage was absent in all reported exposures between 0.03 and 0.45 kJ/cm^2, according to Galperin-Lemaitre et al [US0264], Levi et al [US0297], and Harkanyi et al [US1133].

Hence, the overall impression to be gained from human studies and experimental results is that ultrasound has no effect on the reproductive system. The one exception to this statement occurs when excessive heat is produced in the uterus, which occurs at doses above 1.18 kJ/cm^2 in the mouse.

Thresholds for Effects and Potential for Hazards

As the discussions of biologic affects in Chapter I and this chapter and the review of literature in Chapter XIII have implicated, exposure to ultrasound can cause various subjective and physiologic effects in humans and other animal species. Before any conclusions as to relative hazard of such exposure can be made, however, the thresholds for the effects must be determined, the relative harm of any or all of the effects should be ascertained, and the potential for and likelihood of occupational exposure at harmful thresholds need to be assessed.

Much of the preceding discussion has emphasized the levels of exposure responsible for three basic responses to ultrasound: (1) temporary effects of little or no significance to humans, (2) minor effects to the structure or function, or both, of the body, and (3) damage that may be harmful. Examples of each are given in Table IV-1. Underlying this analysis has been the determination of exposure levels below which no effects were observed. Figures IV-1 and IV-2 indicated that, for humans and animals, the threshold dose for the production of effects has been approximately 50 and 25 J/cm^2, respectively. Nyborg [US0629] came to a similar conclusion in his comprehensive analysis of data from studies on a

TABLE IV-1

TYPES OF EFFECTS IN HUMANS AND ANIMALS

Category	Effect
Temporary	Perception of ultrasound (hearing and feeling); temporary shifts in hearing threshold; increases in skin and muscle tissue temperature; increased blood flow; alterations in nerve conduction; heating of bone and nervous tissues; alteration in secretion by gastric mucosa; uterine contractions; mast cell disruption; alterations in enzyme activities and neuroendocrine concentrations
Minor	Phonophoresis; alterations in bone growth and structure; changes in organ weight; congestion, fragmentation, and occlusion of liver; degeneration of arteries and nerves
Damage	Degeneration of labyrinth of the ear; damage to the cornea, ciliary body, and retina of eye; necrosis, hemorrhage, and avascularization of bone; lesions in heart, organs, and neuroendocrine glands; congestive failure of heart and liver; brain lesions

variety of mammalian tissues, and this point has been corroborated by, among others, Acton [US0678], Baker and Dalrymple [US0189], Dunn and Fry [US0253], Hill [US0136,US0710], Lele [US0404], and Parrack [US0116].

A trend for higher intensity (over 1 W/cm^2) ultrasound to require lower doses, ie, shorter exposures, to produce an effect has been mentioned above. This tendency has been observed to describe the production of focal lesions in brain and neuroendocrine tissues [US0017,US0404,US0678,US0710]. The information available from the experimental studies of Chapter XIII, however, is insufficient to ascertain the exact intensity above which such

an effect occurs, although, as suggested by Nyborg [US0629], a value of 0.1 W/cm^2 appears to be a reasonable estimate.

With regard to the three categories of response induced in humans by ultrasound, nearly all reported effects can be placed in the first. This applies to the so-called perception of ultrasound, temporary shifts in hearing (audible sound) threshold, increases in temperature and blood flow in the skin and muscle tissue, and the induction of various sensations in and the alteration of electrical conduction by the nervous tissue. These effects have been reported to occur following exposure to doses ranging from 36 to 600 J/cm^2. Degeneration of the labyrinth of the ear, large increases in tissue temperature and blood flow, and localized brain lesions, mentioned in three reports, occurred when the doses reached 1.8-8.4 kJ/cm^2. These figures represent legitimate thresholds except for the fact that, as with the damage to the eye associated with phacoemulsification, an ultrasonic probe was in direct contact with the affected tissue in the case of the first and third effects.

It can be assumed that, if the dose of ultrasonic energy incident on these tissues reaches a level of approximately 2 kJ/cm^2, whether the ultrasound is coupled or in direct contact with the tissue will not matter to the production of an effect. Although this conclusion refers to human studies, a similar point can be made as well for animal studies. Minor effects were induced in animal ears and eyes by doses exceeding 300 J/cm^2 and approximately 45-60 J/cm^2, respectively; more extensive damage occurred at doses over 1.62 and 0.45 kJ/cm^2, respectively. Localized brain lesions have been produced in animals at doses of 120 J/cm^2 and above.

Thus, the thresholds for producing damage to the ear, eye, and brain of the human appears to be roughly 10 times as great as that required in other animal species. The relative dearth of human data is partly responsible for this disparity in results. The thresholds determined in the animal studies are probably accurate for two additional reasons. The exposure conditions in both animal and human studies were similar. Furthermore, animal experiments dealing with these three tissues were not subject to the four limitations described at the beginning of the section on animal effects, ie, those dealing with differential impedance matching and heat dissipation.

These limitations do, however, apply to the results of the remaining animal studies. Transitory effects, such as heating of the skin, subcutaneous, and muscle tissues, heating and discoloration of the cortex of the bone, heating of nervous tissue, alterations in secretion and absorption by the gastric mucosa, uterine contractions, mast cell disruption, and alterations in enzyme activities and biochemical concentrations in the circulatory and neuroendocrine systems, were all observed to begin at doses of approximately 60 J/cm^2. These would appear to be of little significance. Minor effects, such as phonophoresis, alterations in bone growth and structure, changes in organ weight, congestion, fragmentation, and vascular occlusion of the liver, and degeneration of the arteries and peripheral nerves, have been found following exposure at doses above approximately 150 J/cm^2. Their long-term effects on the organism have not been studied, and, as would be expected, the extent of such minor damage is dose dependent.

In some cases, negative evidence makes a precise determination of the threshold for such effects difficult, eg, in the case of the bone, neuroendocrine glands, and the nervous system. It is possible, on the other hand, to state that above a threshold dose of approximately 1 kJ/cm^2 irreversible damage to various tissues occurs. This includes necrosis, hemorrhage, and avascularization of the bone, production of lesions in the heart and neuroendocrine glands, and congestive failure of the heart and liver. Again, some negative evidence for such effects exists, eg, for alterations in bone at doses up to 7.5 kJ/cm^2. The lack of effect on behavior and, in general, reproduction at doses up to approximately 2 kJ/cm^2 should also be kept in mind in deciding whether a threshold for extensive damage exists.

This decision is made more difficult by the apparent anomaly of lethality to animals. Ultrasonic doses ranging from 0.35 to 4.08 kJ/cm^2 were found to lead to immediate death in mice and rats, whereas doses between 0.18 and 1.2 kJ/cm^2 were lethal within 24 hours. The lower doses are below those found to be ineffective for producing some types of irreversible damage described above. Just as with ultrasound-induced teratogenesis, which appears to have a threshold of 5 kJ/cm^2, death probably can be attributed to hyperthermia. The inefficient dissipation of heat by small animals (see previous section on animal effects), relative to humans, especially under conditions of water or oil coupling, accounts for the low lethal doses.

Furthermore, as noted above, the fur of animals acts as a device to more efficiently couple ultrasonic energy to the body. Thus, threshold doses, estimated by using intensities measured at the transducer face, are expected to be less for animals than for the human. The exact numerical advantage such enhanced impedance matching provides is not known, although Acton [US0678] has estimated from comparisons of ultrasound-induced temperature rises in hairless and normal mice that fur may lower the threshold intensity (and dose) for an effect by slightly more than one order of magnitude. This figure, when considered with the difference in heat dissipation, is similar to the difference in thresholds noted between the human and animals. Threshold doses and intensities for the production of the three categories of effects in humans and animals are compiled in Table IV-2.

In relating the threshold doses with the potential for hazards, several factors ought to be considered. First, as was noted in the discussions accompanying Figures IV-1, IV-2, and IV-3, most of the experimental results involve irradiation at frequencies between 1 and 10 MHz. These data must be extrapolated to both lower and higher frequencies if the entire ultrasonic frequency range at which potential occupational exposures may occur is to be considered. Such extrapolation is valid on mechanistic grounds. Cavitation is a high-frequency (low-wavelength) phenomenon that, as Chapter I indicates, is unlikely to occur in vivo. Of

TABLE IV-2

THRESHOLDS FOR PRODUCTION OF EFFECTS

Type of Effect	Human		Animal	
	Dose (kJ/cm^2)	Intensity* (W/cm^2)	Dose (kJ/cm^2)	Intensity* (W/cm^2)
Temporary	0.036-0.6	0.1-1.33	0.045-0.06	0.05
Minor	—	—	0.15	0.1
Damage	1.8-8.4	2-170	1-2	1.5

*Some effects have been observed following irradiation with low intensities ($\mu W/cm^2$ range) for long periods or with high intensities (kW/cm^2 range) for short periods (millisecond range).

the other possible mechanisms responsible for producing biologic effects, thermal factors are independent of frequency and the frequency dependence of mechanical forces is negligible in the frequency range of ultrasonic equipment, 20 kHz and 10 GHz. Thus, it may be assumed that the threshold data apply over the range presented in Figures IV-1 to IV-3, ie, 20 kHz to 10 MHz. Another factor discussed later in this section controls the potential for hazardous exposures to higher frequency (1 MHz and above) ultrasound.

Second, it was emphasized above that the thresholds were determined from experiments in which the ultrasonic energy was applied either directly or through a thin layer of coupling agent to the body or tissue surface. Whether such thresholds are valid for airborne exposures is questionable, since transmission of ultrasonic energy across transducer/tissue or coupler/tissue interfaces is not equal to that at air/tissue interfaces. Chapters I, VII, and XI imply that, since reflection and transmission of energy depend on the relative impedances (which depend, in turn, on densities), transmission would be smaller at air/tissue interfaces. Thus, the threshold incident intensity (or dose) necessary to produce an effect would be greater for airborne than for contact or coupled ultrasound.

There are no exact figures available for estimating the extent of this effect. In Table XI-3, the reflection coefficient for an air/muscle interface implies that only 0.02% of the incident ultrasonic energy is transmitted from air into muscle. No values for transducer/muscle interfaces are available for comparison, although the coefficient for muscle/fat interfaces may be of some use. Oils have been used as coupling agents (mineral oil, since it has a density approximately equal to that of water, cannot be included here), and they resemble fats in density and impedance. Hence, it can be estimated from Table XI-3 that transmission of oil-coupled ultrasound is 5,000 times more efficient than that of airborne ultrasound. The difference in impedances (and densities) between a metal ultrasonic transducer and a tissue is intermediate between that for air/tissue and oil/tissue interfaces. Thresholds for the production of an effect by a given incident intensity of airborne ultrasound may vary from one to three orders of magnitude greater than that for ultrasonic energy directly applied to the body. Again, these estimates are only of limited predictive value but do indicate a trend.

A third factor that must be considered in deciding the potential for the existence of an occupational hazard is the absorption of ultrasonic energy by tissues and air. The absorption coefficients given in Table XI-1, which describe the relative loss in ultrasonic intensity per thickness of absorbing material, were used to calculate the decrease in intensity as a function of distance for various tissues, water, and air. The results are presented in Figure IV-4. Note the huge difference in absorption between water and air; this explains the use of water to transmit ultrasonic energy in cleaning baths. The figure also illustrates the large difference in penetration of ultrasonic energy into various tissues that was brought out in Chapter I and Table XI-2.

Air has a relatively large absorption coefficient for ultrasound. According to Figure IV-4, the intensity of 1-MHz ultrasound would be decreased by four orders of magnitude, ie, reduced by 99.99%, in traveling 30 cm (1 ft) in air. Schilling et al [US0972], Sivian [US0973], and Verma [US0753] have pointed out that absorption is frequency dependent (see Table XI-1). For air, the absorption coefficient increases with the square of the frequency. Absorption coefficients were, thus, calculated for several frequencies ranging from 20 kHz to 1 MHz; above 1 MHz, Figure IV-4 indicates that transmission of ultrasonic energy by air is negligible. Using these calculated values, the decrease in intensity of ultrasound as a function of distance from the source was calculated (Figure IV-5). The plots indicate that the ultrasonic intensity is, for frequencies of 1,000, 300, 100, and 30 kHz, 1% of its initial value at distances at 0.15, 1.5, 15, and 150 m, respectively. In other words,

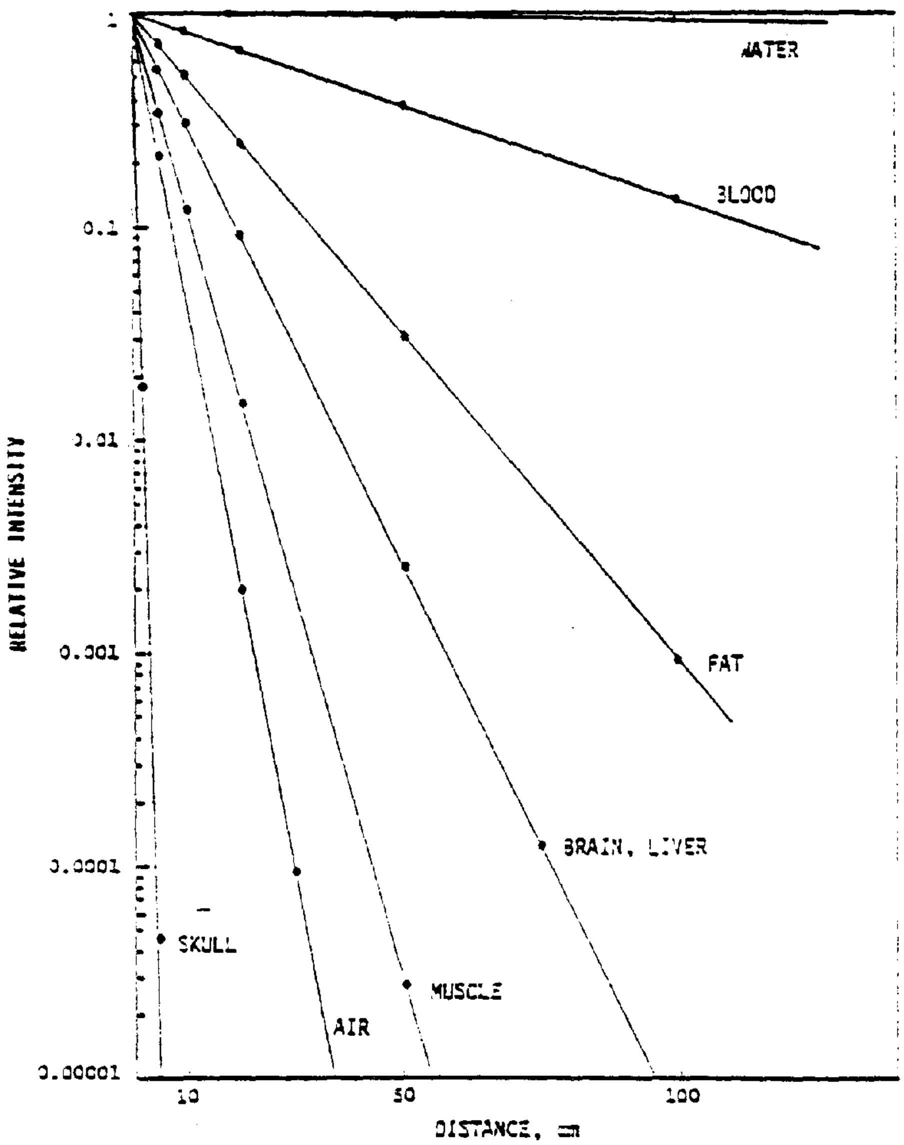

FIGURE IV-4. RELATIVE ULTRASONIC INTENSITY AS A FUNCTION OF THICKNESS FOR VARIOUS TISSUES AND MEDIA. VALUES ARE CALCULATED FROM EXPRESSIONS OF CHAPTER VII:

$$\frac{I}{I_o} = (x)^{-\alpha}$$

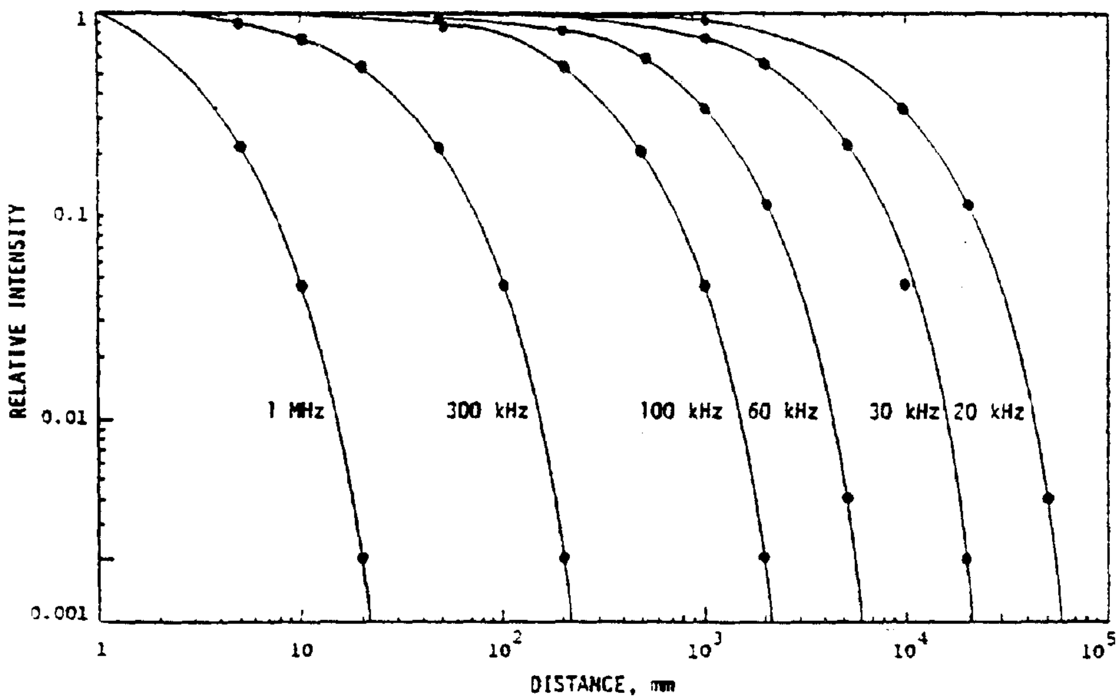

FIGURE IV-5. RELATIVE ULTRASONIC INTENSITY IN AIR AS A FUNCTION OF DISTANCE FROM A RADIATING SOURCE. VALUES ARE CALCULATED FROM EXPRESSIONS GIVEN IN CHAPTER VII:

$$\frac{I}{I_o} = (x)^{-\alpha}$$

absorption by air is lower at lower frequencies: two orders of magnitude less for every order of magnitude less in frequency. In contrast to the situation with airborne ultrasound, propagation of ultrasonic radiation through liquids and solids is more efficient. Table IV-3 shows that, since the absorption coefficients for water and solids are approximately three orders of magnitude smaller than that for air, ultrasound will penetrate up to 1,000 times as far. That is, the intensity emitted at the transducer face will be decreased to the same extent after propagating for distances 1,000 times as great in water and solids as in air.

TABLE IV-3

ABSORPTION AND PENETRATION OF ULTRASOUND

Medium	Absorption Coefficient ($dB\ cm^{-1}\ s^2$)	Relative Absorption	Relative Penetration
Dry air	1.61×10^{-12}	4,639.8	1
Carbon tetrachloride	4.69×10^{-14}	135.2	34
Acetone	4.69×10^{-15}	13.52	343
Ethanol	4.52×10^{-15}	13.03	356
Distilled water	2.17×10^{-15}	6.25	742
Glass	1.74×10^{-15}	5	928
Aluminum	3.47×10^{-16}	1	4,640

The decrease in intensity owing to geometric factors, described in Chapters I and VII, has not been taken into account here because there is no consistent way to estimate their contribution. Most sources of ultrasound are unfocused; thus, the wave will spread as it radiates from the source. The effect of such spreading is to decrease the intensity, or power per unit area, at increasing distances from the source. In contrast to the variation of absorption and reflection properties, the small, variable frequency dependence of this effect in air can be ignored.

All of the factors mentioned above will contribute to reducing the ultrasonic intensity delivered to an individual, with regard to both the actual energy incident on the body of that worker as he or she stands or sits some distance from the source as well as the fraction of that incident energy absorbed. Estimates of the size of this reduction are presented for representative devices in Table IV-4, where data from Table II-3, Figure IV-5, and Table I-1 have been combined and the reduction factors calculated. Exposures to ultrasound generated by industrial and cleaning equipment, which operate at lower frequencies and higher power outputs, are least affected by absorption and reflection. However, since the transducers of such equipment (cleaning, scaling, or defoaming) or the areas to which the power is delivered (in bonding two surfaces, grinding, or drilling) are large, ie, at least 100 cm^2, the intensity available at the radiating source will range from 0.5 to 10 W/cm^2. Reductions at a distance of 1 m to 10^{-4}-10^{-6} of the emitted intensity would lower the absorbed intensity to the microwatt per square centimeter range. As Table IV-4 shows, low-power, high-frequency devices are capable of delivering

TABLE IV-4

REDUCTION OF POWER OF AIRBORNE ULTRASOUND

Device or Application	Power Output (W)	Frequency* (kHz)	Reduction Factor: Absorption by Air**	Reduction Factor: Reflection	Reduction Factor: Total
Cleaning (bath)	1,000*** 50	15-50	0.97 (30 kHz)	10^{-6}	$9.7x10^{-7}$
Industrial equipment****	5,000 100	20-60	0.89 (60 kHz)	$2x10^{-4}$	$1.78x10^{-4}$
Nondestructive testing	0.1 0.0001	1-30 MHz	10^{-14} (1 MHz)	"	$2x10^{-18}$
Medical diathermy	20 2	80 kHz - 1 MHz	0.73-0.045 (0.1-0.3 MHz)	"	$1.46x10^{-4}$ - $9x10^{-6}$

*Except where noted
**At distance of 1 m. Number in parentheses indicates frequency.
***Measurements have indicated that intensities at transducer are approximately 4-8 W/cm^2.
****Includes welding, drilling, machining, and soldering

ultrasonic energy to the body at no more than this intensity and, in the case of testing equipment, at much less. Chapter II and Table II-4 provide measured intensities that correspond closely to these estimates.

The threshold for producing minor damage to the human body has been estimated above to be approximately 1 kJ/cm^2. This figure corresponds to a 15-minute exposure to an intensity of 1 W/cm^2 or an 8-hour exposure to an intensity of 35 mW/cm^2. None of the equipment described above is capable of delivering such a dose except under conditions of direct contact with the transducer or the coupling medium. Chapter V will discusses the significance of both the observed health effects and the presumed exposure levels to the potential for hazardous exposure to ultrasound.

V. CONCLUSIONS AND RECOMMENDATIONS

To properly assess the potential occupational hazards associated with the varied industrial, scientific, and medical uses of ultrasound requires correlation of two types of information: health effects and exposure data. Chapter IV (see also Chapters VII, XI, and XIII) has reviewed and evaluated data on the biologic effects of exposure to ultrasound and, where possible, dose-response relationships have been established. Chapter II (see also Chapters VIII and XI) has described ultrasonic equipment and operations and discussed the extent and type of occupational exposures to be expected. Exposure levels have been estimated in Chapters II and IV, using the information presented in Chapters VII, VIII, and XI. This chapter addresses the current awareness of problems caused by ultrasound in occupational situations and reiterates conclusions reached in previous chapters.

Potential for Hazardous Exposure to Ultrasound

With a short-term exposure above a dose of approximately 1 kJ/cm^2, ultrasound can cause irreversible damage to the human and animal body through excessive heating of the tissues. The threshold for the production by ultrasound of biologic effects in animals is one to two orders of magnitude lower, 50 J/cm^2. The reported effects associated with the

absorption of ultrasonic energy between this threshold and the dose at which irreversible damage occurs appear to be inconsequential, minor, or transient and, in many cases, contradictory evidence exists. The threshold for the production of effects in the human is approximately 0.1 J/cm^2, but all of the reported effects entail minor or temporary changes in structure or function following short-term exposures. Extrapolation of data obtained in animal studies to human exposures must acknowledge the fact that, compared with the human, the thermoregulatory mechanisms of animals are less efficient and animals absorb a greater proportion of incident energy. Thus, higher doses as well as higher incident intensities would be required to produce similar effects in human tissue. The degree of augmentation has been estimated at approximately one order of magnitude, but too few data exist to make a definite conclusion. Furthermore, since short-term exposures were used in all of the available studies, decisions on the long-term effects to the worker of continuous occupational exposures at levels above the threshold but below the damage level cannot be reasonably made.

Analysis of the reported information on the extent of occupational exposure, as well as calculations of the potential exposure levels, indicates that exposures to harmful doses of ultrasound are improbable. This conclusion is especially valid for airborne ultrasound, for which large attenuation by air and large reflection at air/tissue interfaces limit the expected doses to negligible levels. Contact with liquid- or solidborne ultrasound has greater potential for being harmful, owing to less efficient absorption and reflection of ultrasonic energy. That is, not only is the intensity incident on the body greater than with air, but also the energy transmitted into the tissue is greater. For water and metal transmission, absorbed doses may be as high as 1,000 times greater than those for airborne ultrasound. However, compared with airborne ultrasound, the contribution of geometric factors to the attenuation of liquidborne ultrasonic energy will be large. With unfocused ultrasound, the reduction of intensity will follow the inverse of the square of the distance. For large bath cleaners, this means a decrease in incident intensities by 10^{-4} at a distance of 1 m, or to approximately 0.1 W/cm^2, the threshold intensity for the production of effects.

Evaluation of available data suggests that the only significant primary as well as secondary hazards expected from occupational exposures to ultrasound are those resulting from contact with the transducers or radiators of ultrasonic equipment and from exposure to aerosols. In the first case, the hazards are primarily safety hazards; the extent of the health hazard caused by the second is uncertain. Exposures to other secondary hazards, ie, noise, vibration, and electric fields, appear to be inconsequential, whereas exposures to airborne ultrasound are not expected to be significant except within distances of 10 cm to low-frequency (below 100 kHz) sources.

Analysis of Process-Related Hazards

Implicit to the discussion of occupational exposures has been the arbitrary distinction between low-frequency, high-intensity and high-frequency, low-intensity sources. This distinction reflects the division of ultrasound uses into basically processing and testing of materials. Cleaning, machining, welding, and other similar processes constitute the first category, whereas the second comprises nondestructive testing, inspection, and human diagnosis and therapy.

The hazards associated with large-scale industrial processing appear to be potentially more harmful than those expected from nondestructive use of ultrasound. However, since the application of ultrasonic energy represents a single step in an industrial process, eg, welding, soldering, defoaming, emulsifying, cleaning, impregnating, or drying, analysis of an industry or an entire process would seem to be irrelevant to assessing the problems of occupational exposure.

Evaluation of the potential hazards presented by each application or use would be a reasonable approach, except for the fact that the intensities used in each overlap to a large extent. The problems presented by exposures to ultrasound in bonding operations using output powers of 0.1-1 kW would resemble those presented by grinding or drilling at similar power outputs. So, also, would those presented by cleaners resemble those associated with foaming, aerating, or emulsifying. That is, the diversity in exposure conditions among the different applications is no more than that found within each type of application. Thus, neither of these approaches would be more advantageous than the present overall review of industrial ultrasound.

Plant Visits and Site Measurements

In general, lower frequency ultrasonic equipment operates at high intensities, whereas higher frequency equipment operates at low intensities. Since absorption by tissues is frequency dependent, ie, a larger fraction of the incident ultrasonic energy is absorbed at the higher frequencies, absorbed doses for similar output intensities will be similar at all frequencies. Differential attenuation by air will skew the overall distribution for absorption of ultrasonic energy to the lower frequencies for workers standing at similar distances from ultrasonic equipment; however, routine work practices need to be evaluated before this factor can be accurately considered.

At present, evaluation of available literature makes it impossible to determine the type or extent of hazards to worker safety associated with low-frequency, high-intensity ultrasonic processing. Observing work practices at industries that use ultrasound to process materials would help resolve whether potentially harmful contact exposures are commonplace or likely to occur.

Because of the low probability of danger from exposure to airborne ultrasound, measurements appear to be superfluous. One exception is the area within 0.5 m of industrial ultrasonic equipment. Monitoring could prove conclusively that potentially hazardous exposure levels do not exist there, as presumed. Measurements (using hydrophones) inside bath cleaners could also determine whether there is a hazard from liquidborne ultrasound. Either of these determinations could be rendered irrelevant by first observing that work practices do not involve worker activity in either of the areas.

Need for Document on Ultrasound

The preceding discussion has intended to convey that, for the most part, ultrasound is not hazardous to the worker. Those few cases for which potentially harmful exposure is likely have been addressed. Restricting the document to a review of these special cases would be antithetical to the goal of fully informing representatives of management, labor, and the occupational health community about the potential for hazardous occupational exposures to ultrasound. Neither would such a special hazard review explain why control measures and medical monitoring protocols are nonexistent and considered unnecessary.

A thorough analysis of occupational exposures is of value, especially to allay the concern of workers for their health or safety. The history of ultrasound begins more than 70 years ago, with discovery of its lethal effects on animals and microorganisms. With the advent of jet engines and ultrasound cleaners 35 years ago came the attribution of a so-called ultrasonic sickness or malaise to exposure to ultrahigh-frequency sound. However, it is the development 20 years ago of ultrasonic fetal monitors and therapeutic devices and the subsequent spread in their use that have introduced questions about the potential danger of ultrasound into the consciousness of the general public as well as the worker. As expected, the widespread belief in industry is that ultrasound is not dangerous.

This absence of concern is justified by the results of biologic experiments as well as the analysis of occupational exposures. The preparation of this document has involved the review and evaluation of 1,177 articles. Approximately 40% of these describe in vivo studies of human and animal exposures, and another 20% report various in vitro studies on tissues, cells, and microorganisms. Effects can be observed, but in the latter case the causative agent is cavitation in solution, which cannot occur in the intact body. In the former case, thresholds for lesion formation in organs apply only for direct contact or focused ultrasound, which is improbable under occupational situations. The majority of the remaining ultrasound-induced biologic effects are minor or transitory. Furthermore, the thresholds for producing potentially harmful effects are not exceeded in most occupational settings, as the analysis of the articles (15% of the total) dealing with occupational exposure levels has shown.

Thus, the following conclusions can be drawn:

(1) Threshold doses for production of biological effects in animals and the human are approximately 25 and 50 J/cm^2, respectively, corresponding to intensities of 0.05 and 0.1 W/cm^2.

(2) Output intensities (transducer face) of most commercial ultrasound equipment are below 10 mW/cm^2; measured intensities at common operator positions are below 1 $\mu W/cm^2$.

(3) Airborne ultrasound does not present a problem except under special exposure conditions.

(4) Direct contact with liquid- or solidborne ultrasound, such as is used in cleaning baths, welders, drillers, and other industrial sources, is potentially hazardous.

(5) The use of ultrasound in various industrial settings can result in exposures to potentially harmful levels of the secondary hazards aerosols, noise, and vibration.

A document that represents a comprehensive review of industrial ultrasound and reliably supports such conclusions could settle the issue of hazardous ultrasound exposures in present-day as well as future industrial settings. The analysis developed in the preceding chapters of this report has presented a threshold dose for presumably harmful effects and a protocol for deciding when or where occupational exposures might exceed that threshold. Both determinations are open ended so that, as new or additional biologic data become available, the threshold for harm can be adjusted or, as industrial or medical equipment is designed to either produce higher outputs or be used in novel ways, the probability for exposures at or above the threshold can be recalculated. Any occupational hazard assessment should be flexible enough to address not only the current hazards, which in the case of ultrasound are limited to safety problems associated with contact exposures, but also the potential for hazard in the future as the industries using ultrasound refine current or develop new applications and techniques.

Recommendations for proceeding to the next step of document development are as follows:

(1) Analysis of the potential for exposure to liquid- or solidborne ultrasound, airborne ultrasound generated within 0.5 m of low-frequency, high-intensity sources, and ultrasound-generated aerosols, noise, and vibration to determine the hazards to worker safety as well as health

(2) Preliminary plant observations to determine to what extent work practices or engineering and administrative controls limit the occurrence and the levels of such exposures

(3) Measurements of ultrasonic intensities in the areas described above and evaluation of the health effects resulting from exposure to aerosols, noise, and vibration, if plant observations indicate a potential for hazardous exposures

(4) Evaluation of data obtained and used by manufacturers of ultrasonic therapeutic and diagnostic equipment in determining safe operating levels

(5) Preparation of a special review of safety hazards possibly encountered in close proximity to or resulting from contact with high-intensity, low-frequency sources

(6) Development by NIOSH of an occupational hazard assessment for ultrasound that, as a comprehensive evaluation of the literature and industrial practices, distinguishes between hazardous and nonhazardous occupational exposure conditions

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VII. APPENDIX I

PHYSICS OF ULTRASOUND

Figure VII-1 depicts a longitudinal sound wave, in this case produced by a piston, as it propagates down a cylindrical tube. For the case of simple harmonic, that is, periodic, motion, the displacement of the molecules of the medium varies sinusoidally and the usual wave relationship applies:

$$c = \nu\lambda$$

where c is the speed of the wave, ν the frequency, and λ the wavelength. The motion of the molecules produces similar periodic variations in pressure, which are accompanied by variations in density, temperature, and particle velocity and acceleration (Figure VII-2).

The quantities that describe the wave are related in the following manner. For sound waves moving through a medium of density ρ with a speed c, the particle displacement A in the direction of propagation x can be described by

$$A = A_o \exp\left[i2\pi\nu(t - x/c)\right]$$

where A_o is the maximum displacement of the particle from its equilibrium position. Since the displacements are directly responsible for altering the pressure within the medium, the sinusoidal wave form can also be used

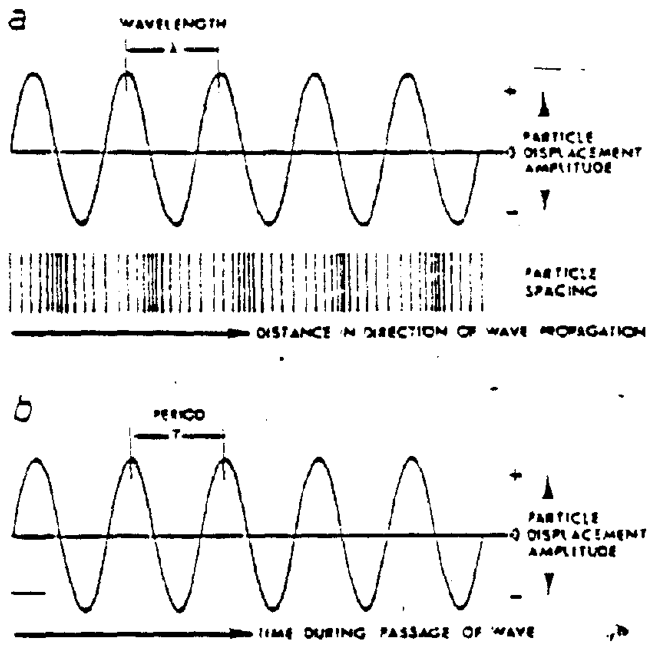


FIGURE VII-1. DIAGRAMS ILLUSTRATING LONGITUDINAL WAVE MOTION. (A) PARTICLE DISPLACEMENT AMPLITUDE AND PARTICLE SPACING AT A PARTICULAR INSTANT IN TIME IN THE ULTRASONIC FIELD: DISTRIBUTION OF THE WAVE IN SPACE. (B) DISPLACEMENT AT A PARTICULAR POINT IN SPACE: DISTRIBUTION OF THE WAVE IN TIME.

Taken from reference US0677

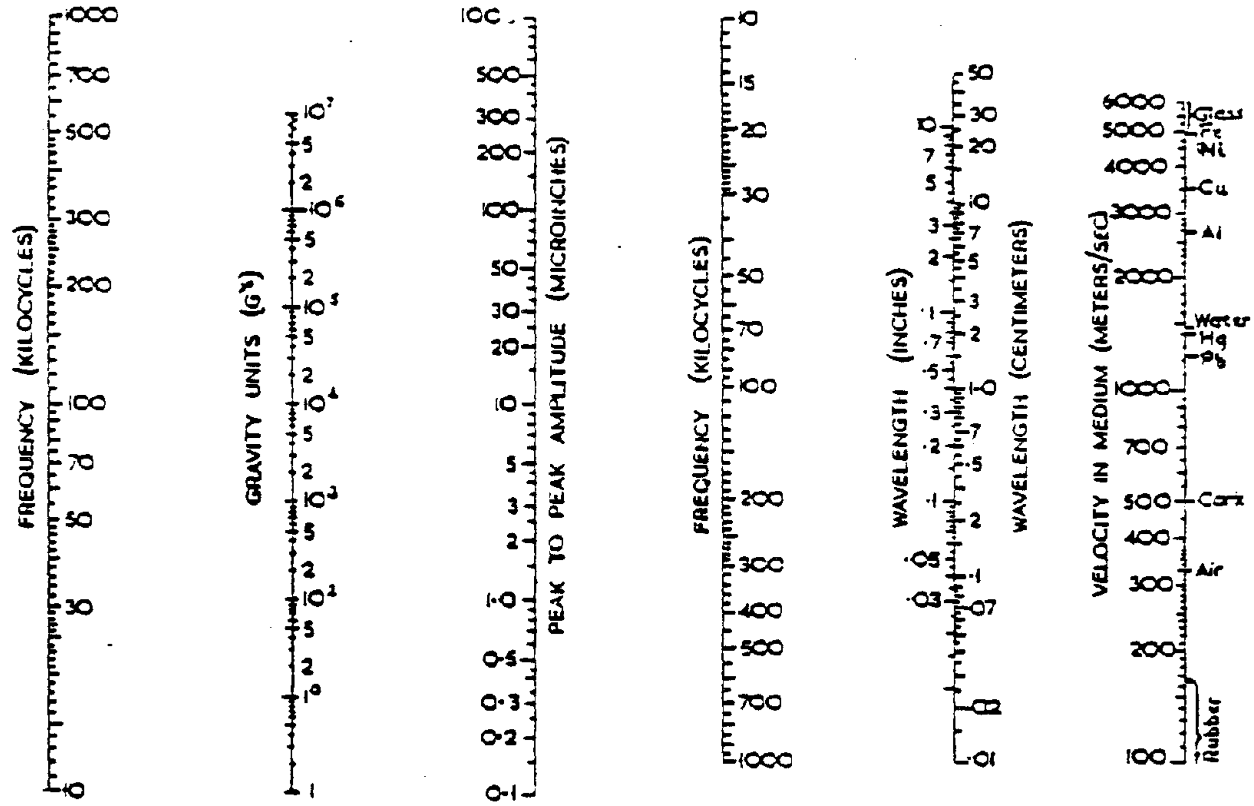


FIGURE VII-2. THE RELATIONSHIP OF FREQUENCY, ACCELERATION, AMPLITUDE, WAVELENGTH, AND VELOCITY OF PROPAGATION

Taken from reference US0694

to indicate changes in pressure. In many cases, it is more convenient to deal with these variations in describing a sound wave and in measuring its intensity. The instantaneous values of pressure and particle velocity at a point, p and v, respectively, are related to the impedance Z by

$$\frac{p}{v} = Z = \rho c$$

and the intensity of the wave, or rate of flow of energy across a unit of surface area normal to the direction of propagation, by

$$I = \tfrac{1}{2}\frac{(p_o)^2}{Z} = \tfrac{1}{2}\, p_o v_o$$

or

$$I = \tfrac{1}{2}\frac{(p_o)^2}{\rho c} = \tfrac{1}{2}\, v_o \rho c = \tfrac{1}{2}(2\pi\nu)^2 A^2 \rho c$$

where the subscript o refers to the maximum value.

As the sound wave propagates through the medium, eg, from point 1 to point 2, the intensity will decrease owing to geometric considerations and attenuation by the medium. The effect of the first factor can be illustrated most easily by considering the simplest shape for a source of sound energy: a sphere. As the wave spreads out in a spherical manner from that source, the constant amount of energy available will be dispersed over an increasingly larger surface area, given by $4\pi r^2$, and will decrease in proportion to the square of the distance from the source. Thus, the intensities at the two points are related by

$$\frac{I_1}{I_2} = \frac{r_2^{\,2}}{r_1^{\,2}}$$

The second factor relates to absorption of energy by a homogeneous medium, mainly in the form of heat. This takes the form of an exponential decrease in intensity or displacement amplitude:

$$I_2 = I_1 \exp[-2\alpha(x_2 - x_1)]$$

$$A_2 = A_1 \exp[-\alpha(x_2 - x_1)]$$

which can be expressed equivalently as

$$\ln \frac{I_2}{I_1} = -2\alpha(x_2 - x_1)$$

$$\ln \frac{A_2}{A_1} = -\alpha(x_2 - x_1)$$

where α is the absorption coefficient, or the loss in intensity or amplitude per unit distance. The above relationship implies that at any frequency this reduction in intensity of the wave is a constant fraction for a given thickness of material. A large absorption coefficient implies that more energy is deposited within a unit thickness of material and, thus, that the sound wave will not penetrate as far; ie, most of the energy will be absorbed close to the incident surface.

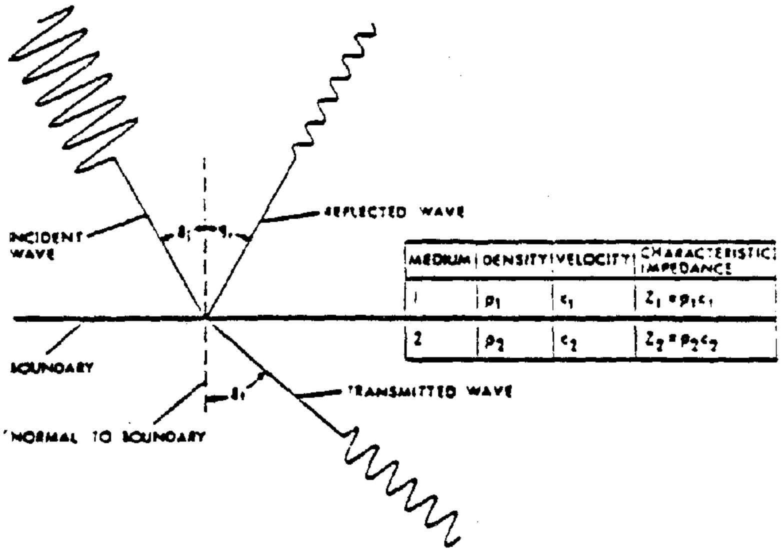
The propagation of sound energy is also dependent on the uniformity of the media. Regions of dissimilar density or interfaces between different materials, such as air and water or muscle and bone, will produce reflections of the wave at the boundaries (Figure VII-3). The ratios of the reflected and transmitted intensities to the incident intensity are expressed for normal incidence as follows:

$$T = 4 \frac{Z_a Z_b}{(Z_a + Z_b)^2}$$

$$R = \frac{(Z_b - Z_a)^2}{(Z_b + Z_a)^2}$$

$$T + R = 1$$

where T and R are the transmission and reflection coefficients, respectively, Z is the impedance, and a and b refer to the two regions a and b. These expressions imply that the more dissimilar the materials or media, the greater the amount of energy reflected at their boundary; for example, very little sound energy (less than 0.1%) will be transmitted to a solid body if the sound wave has been traveling through a gas such as air.



MEDIUM	DENSITY	VELOCITY	CHARACTERISTIC IMPEDANCE
1	ρ_1	c_1	$Z_1 = \rho_1 c_1$
2	ρ_2	c_2	$Z_2 = \rho_2 c_2$

FIGURE VII-3. DIAGRAM ILLUSTRATING THE BEHAVIOR OF A WAVE INCIDENT ON THE BOUNDARY BETWEEN TWO MEDIA

Taken from reference US0677

VIII. APPENDIX II

APPLICATIONS OF ULTRASOUND

TABLE VIII-1

APPLICATIONS OF SONICS AND ULTRASONICS

Measuring elastic and dissipative properties of solids
Engine (gas and steam) pressure indication and detonation
Detecting noise and vibration in engines and machinery
Measuring vibrational strains in structural members
Determination of pressure zones in pillars
Measuring elasticity of yarns
Detection of schools of fish
Geophysical prospecting
Measurement of fluid depth in wells
Hydrographic surveying
Sonar—sound navigation and ranging
Induction of molecular rearrangement
Determination of physical properties of liquids and gases
Detecting air bubbles in aircraft bearings
Killing staphylococci bacteria and bacteriophage
Breaking sulfathiazole crystals for faster reaction
Development of antibodies by jarring antigens loose from shattered germs
Mixing powdered metals in manufacture of cemented carbide tools
Detecting separations in bonded metal strips
Mercury delay line
Detecting icebergs
Homogenization of milk
Emulsification for giving smoother ice cream, mayonnaise, and other food products

Acceleration in ageing wines and spirits
Acceleration of chemical reactions
Transformation of chemical compounds
Stimulation or destruction of bacteria in food products
Underwater signaling
Echo depth sounding
Treating seeds to stimulate plant growth
Increasing plant yield
Flocculation of suspended particles or gas bubbles in liquids
Transformation of crystal structures
Killing of small fish and frogs
Heating of media that absorb supersonic waves
Movements of particles into nodes of standing wave systems
Mixing of metals to produce alloys
Detection of imperfections in castings
Emulsification of oil and water
Emulsification of mercury and water mixtures
Drilling glass with another piece of glass
Dispersion of metal from a cathode during electrolysis (manufacture of catalytic agents)
Increasing oxidation reactions
Changing starch into dextrine
Decomposing gums and gelatin
Speeding solidification of molten tin and aluminum
Producing finer-grain metals
Speeding uniform cooling and hardening of steel
Degassing of liquids

Freeing fused metals from gas inclusion
Coagulating aerosols
Precipitation of industrial smokes
Testing metals for hardness
Testing metals for defects
Increasing virulence of bacteria
Decreasing virulence of bacteria
Disintegration of cells to release endotoxins, enzymes, polysaccharides, and hemoglobin under aseptic conditions
Treatment of plastics for clothing
Treating paint for smoother, more durable finish and decreased drying time
Distribution of photographic emulsions for fine-grain film
Liquefaction of iron hydroxides
Measurement of metal thickness
Tinning aluminum sheet
Production inspection of metal sheet
Opening garage doors
Production of cavitation
Vibration testing of airplanes
Dispersion of fog
Determination of saline and silt levels in hydrography
Absolute altimeter
Bias for magnetic recording
Television light valve
Inaudible superimposed radio signaling
Compression and expansion of media through which the ultrasonic waves pass
Subsea geophysical prospecting
Radar and loran trainers
Examination of automobile tires for flaws

Taken from reference US0965

TABLE VIII-2

SONIC AND ULTRASONIC FREQUENCY PHENOMENA

MEGACYCLES	100	Killing Germ Life in Canned Foods	SUPERAUDIBLE
	20	Upper Range General Motors Sonigage	
	15	Radar Trainer — MIT Velocity and Absorption Studies in Liquids	
	14	Interferometer Studies with Televiso Ultrason	
	12	Upper Range Sperry Reflectoscope	
	10	German Aircraft Bearing Testing	
	7.5	Practical Upper Limit Televiso Ultrason	
	5	Upper Range Sperry Thruray	
	2.8	Upper Range Branson Audigage	
	2.25	Middle Frequency Sperry Thruray	
	2	Vacuum Tube Arc in Air By Palaiologos	
	1.6	Upper Radio-Frequency Limit of Standard Broadcast Band	
	1.5	Upper Range Crystalab Ultra-Sonerator	
	1.4	Lower Range Branson Audigage	
	1	G.E. Materials Tester — Lower Range Sperry Thruray — Upper Range Brush Hypersonic Analyzer — Penicillin Production	
1 MEGACYCLE			
1,000 KILOCYCLES			
KILOCYCLES	835	Biological Experiments with Focused Ultrasonic Waves	
	780	Poulsen Arc in Gas by Dieckmann	
	612	Tests on Susceptibility of Lower Animal Forms to Ultrasonic Waves	
	600	Highly Polymerized Molecules can be Split	
	540	Lower Radio-Frequency Limit of Standard Broadcast Band	
	500	Lower Range Sperry Reflectoscope — Hydrogen Whistle by Hartmann	
	450	Standard Frequency of Televiso Ultrason	
	400	Lower Range Crystalab Ultra-Sonerator — Upper Range for Forming Emulsions	
	300	Quartz Transducer — Oil Bath Experiments of Wood and Loomis — Lower Range of Emulsion, Hg, Sn, S, Cu, Pb, Bi, Ag, Paraffins — Spark Gap Generator by Altberg, 1907 — Lower Range General Motors Sonigage	
	120	Air Current Generator by Hartmann, 1922	
	100	Upper Range Galton Whistle by Edelmann, 1900	
	90	Tuning Forks by Koenig, 1899	
	70	Upper Limit Ranging Signal of Bats	
	65	Upper Limit Sonar JP	
	50	Lower Range Brush Hypersonic Analyzer	
	40	Upper Range Components of Grasshopper Noise	
	33	Friction-Excited Vibrating Tube by Holtzmann	
	30	Upper Limit Sonar QCS/T and QJA — Common Midrange of Bias for Magnetic Recording	
	28	Brown Cricket	
	25	Small Meadow Grasshopper — Ultrasonic Garage-Door Opener	
	21.5	Submarine Signal Co. Type 788A Magnetostriction Depth Sounder	
	20.8	Early Magnetostriction Projector for Submarine Signals	
	20	Upper Range Flocculating Aerosols — Common Meadow Grasshopper	
	17.4	Brown Cricket	
	17	Lower Limit Echo Ranging Sonar QCS/T	
	16	PRACTICAL UPPER LIMIT OF YOUNG ADULT HUMAN HEARING	
	15	Early Underwater Signal Experiments by Langevin — Black Pole Warbler — Newly Hatched Robins	AUDIBLE
	14.2	Common Meadow Grasshopper	
	12	Aluminum Sheets Tinned in Zinc Bath	
	10	Lower Range Tests of Flocculating Aerosols — Upper Range Ship's Propeller at 1,000 Yards — Lower Limit Sonar QJA	
	9.3	Staphlococci Bacteria Killed	
	9	Submarine Signal Co. Laboratory Oscillator	
	8.3	Brown Cricket	
	8	Lower Limit Sonar JP	
	7.1	Common Meadow Grasshopper	
	7	Tone of Bats (¼-Second Pulses)	
	5	Ammonium Chloride Smoke Flocculation Experiments	
	4.186	Upper Limit Standard Piano	
	4	Tone Broadcast by Radio Station WWV	
	3.5	Nandillon Sonic Altimeter, 1928	
	2.5	Upper Range Chesapeake Bay Croakers	
	2	Lower Range Snapping Shrimp in Coral Waters — Upper Range Sea Robins — Delsasso Sonic Altimeter	
	1.1747	Upper Range Soprano, D Two Octaves Above Middle C	
	1.5	Dubois-Laboureur Sonic Altimeter, 1932	
1 KILOCYCLE			
1,000 CYCLES			
CYCLES	540	Fessenden Oscillator in Underwater Navigating Device, 1907	
	440	Standard Musical Pitch A (Broadcast by National Bureau of Standards Station WWV)	
	360	Submarine Signal Co. Sonic Oscillator for Homogenizing Milk	
	261.63	Middle C — Bottom-Dwelling Toadfish	
	200	Echoscope Sonic Altimeter, 1936 — Lower Range Sea Robins	
	100	Lower Range Ship's Propeller at 1,000 Yards	
	87.31	Lower Range Bass, F Second Octave Below Middle C	
	80	Small Meadow Grasshopper	
	60	Common Meadow Grasshopper — Upper Range, Buzz of Bats	
	27.5	Lower Limit Standard Piano	
	16	LOWER LIMIT NORMAL HUMAN HEARING	
	12	Lower Range, Buzz of Bats	SUBAUDIBLE →
	0		

Taken from reference US0965

TABLE VIII-3

ULTRASONICS IN INDUSTRY

Use	Application	Description
Established	Cleaning and degreasing	Cavitated cleaning solution scrubs parts immersed in solution
"	Control and measurements: burglar alarm, counting, liquid level control	Interruption or deflection of beam Doppler effect, damping of transducer by liquid
"	Defoaming and degassing	Separation of foam and gas from liquid, reducing gas and foam content
"	Foaming of beverages	Displacing air by foam in bottles or containers prior to capping
"	Drilling and abrading	Abrasive slurry interposed between sonically vibrated tool and workpiece
"	Emulsification, dispersion, and homogenization	Mixing and homogenizing of liquids, slurries, and creams
"	Nondestructive testing	Pulse-echo exploration of objects for flaws and resonance thickness gauging
"	Soldering and brazing	Displacement of oxide film to accomplish bonding without flux
"	Welding metals and plastics	Welding similar and dissimilar metals, soft and rigid plastics
Promising (no large-scale commercial use)	Agglomeration and particle precipitation	Separating solids from gases or producing larger particles
"	Atomization and vaporization	Atomizing liquids to provide aerosol, vaporizing fuel oil
"	Electroplating: agitation of electrolyte	Distributing and agitating electrolyte for uniform plating

TABLE VIII-3 (CONTINUED)

ULTRASONICS IN INDUSTRY

Use	Application	Description
Promising (no large-scale commercial use)	Impregnation of porous materials (textile, metal)	Increased density, absence of gas inclusions
"	Degassing of melts (metal, glass)	Improvement in material density, refinement of grain structure
"	Mixing of slurry (pulp)	Improvement in consistency
"	Agitation of chemical solutions, eg, photographic developer	Maintaining uniform concentration, deaeration of liquid
"	Accelerating chemical reactions	Aging of liquors, tanning of hides, extractions
"	Food treatment	Destroying molds, bacteria, tenderization, removing loose starch
"	Drying (plastic, paper, textile webs)	Turbulence and pressure pattern causes drying
"	Metal insertion into solid plastic material	Application of ultrasonic vibrations to metal insert producing localized softening as insert is pressed into plastic
"	Measurement: fluid flow, particle size	Noncontacting measuring method
Recent development	Hardness determination	Frequency of resonating probe is a measure of hardness
"	Metal working	Vibrated die or roller reduces friction during drawing or rolling, greater reduction in fewer passes, reduces grain size

Adapted from reference US1177

TABLE VIII-4

ULTRASONIC EQUIPMENT

Type	Purpose	Example	Producer	Input			Output	
				Power (W)*	Voltage (V)	Frequency (Hz)	Power (W)	Frequency (kHz)*
Cleaning equipment	Cleaning "	Cleaning system	Gulton Industries	80-425	115 (ac)	60	--	--
"	"	Geoscience ultrasonic cleaner	Geoscience Instrument Corp.	250-450	--	--	50-150	--
"	"	Ultrasonic cleaning tanks	Crest Ultrasonic Corp.	2-15 A	115	50/60	100-1,000	20-90
"	Degreasing	Ultrasonic vapor degreaser	Delta Sonics, Inc.	5 A	120-220	--	300-4,000	25, 45
"	"	Ultrasonic cleaners	Branson Instruments, Inc.	750	115	50/60	500	--
"	"	Ultrasonic pipette washer	Lab Items Ass.	--	--	--	--	25-45
"	"	Cleaning glassware, cleaning system	Multisonic Corp.	3-15 A	115	60	50 (avg)	40
"	"	Degreaser	Multisonic Corp.	11 A	115 (ac)	--	90 (avg)	40
Industrial	Machining, cutting, and grinding of materials	Impact grinder	Raytheon	250 (1 kVA)	115 115	-- --	100 700	22-28 20-27
"	Scaling equipment	Vibra-Seal	Klor Uv, Ind., Inc.	500-1,200	115	50-60	250-600	20
"	Flaw detection	Ultra-Scan	James Electric, Inc.	400-700	117±10	50-60	100	0.9-15 MHz
"	Wire bonding	Ultrasonic wire	Hugle Industries	2 A	110 (ac)	50-60	--	--

TABLE VIII-4 (CONTINUED)

ULTRASONIC EQUIPMENT

Type	Purpose	Example	Producer	Input			Output	
				Power (W)*	Voltage (V)	Frequency (Hz)	Power (W)	Frequency (kHz)*
Industrial	Welding plastics	Sonifier plastics welding system	Branson Instruments, Inc.	750-1,200	115	50/60	500-1,000	--
"	Defoaming and deaerating	Sontrifuge	Teknika	--	550	60	--	--
"	Plastic welding	--	--	100	12 (dc)	--	--	22
"	Aerolization	Multisonic 180 VF	Macrosonics Corp.	450	--	--	100	800
Medical equipment	Visualize internal body structures	Diagnostic sounder	Hewlett-Packard	285	115/230	50-60	--	1-10 MHz
"	Diagnostic	Ultrasonoscope	Hoffrel	105	115	50/60	--	1-10 MHz
"	Therapy (massaging)	Dual diasonic	Mettler Electronics Corp.	2 A	110-120	50-60	2-10 15 (max)	--
Biologic equipment	Research; physico-chemical manufacturing	Sonic oscillator model DF 101	Raytheon	750	110	50-60	250	10
"	Cell disruption	Sonifier cell disrupter model W-185C	Branson Instruments, Inc.	2.8 A	115	60	150	20
"	Research	Hypersonic equipment	Brush Development Co.	400	105-120	60	100	200-1000
Testing equipment	Flaw detection	Modular ultrasonic reflectoscope	Automation Industries	--	115 (ac)	50-60	--	0.2-25 MHz
"	Measuring resonant frequency of materials	James E-systems	James Electronics, Inc.	60-85	117	50-60	--	20-500

TABLE VIII-4 (CONTINUED)

ULTRASONIC EQUIPMENT

Type	Purpose	Example	Producer	Input Power (W)*	Input Voltage (V)	Input Frequency (Hz)	Output Power (W)	Output Frequency (kHz)*
Testing equipment	Detection of velocity of sound through solid	James V-scope	James Electronics, Inc.	100	105-130	50-60	1,200 (peak)	15-300
Miscellaneous	Burglar alarm	Ultrasonic annunciator	Euphonica Corp.	3	115 (ac)	--	--	--
"	Bird spotting	Ultrason E	Bird-X Inc.	45	28-110 (ac)	50-60	--	17
"	Measuring	Ultrasonic bulk increasing equipment	Digitrol Systems, Inc.	0.1 A	120 (ac)	--	--	--
"	Measure and control liquid levels	Sensall	National Sonics Corp.	<10	115	60	--	--
"	Underwater sound system	Diver-held sonar	Burnett Electronics Laboratories, Inc.	--	--	--	--	9-45

*Except where indicated

Adapted from reference US0987

TABLE VIII-5

ULTRASONIC PRODUCTS AND MANUFACTURERS

Product Type	Manufacturer	No. of Models	Frequency Range	Power Range
Industrial	Branson	27	25-55 kHz	20-2,000 W
"	Blackstone	12	20-40 kHz	13-205 W
"	Branson	1	25 kHz	100 W
"	Westinghouse	9	16.8-21.5 kHz	200-1,000 W (55%)
"	Crest	3	40 kHz	75-450 W
"	Blackstone	1	31.5 kHz	—
"	American Sterilizer	3	40 kHz	1,000 W
"	Blackstone	2	31.5 kHz	—
"	Interlab	6	25-50 kHz	1,000 W
"	American Process	7	22 kHz	4,000 W
"	Union Ultrasonics	1	—	20 W
"	Vernitron	3	400 kHz	—
"	Mettler	4	23-75 kHz	4,000 W
"	Detrex	1	26 kHz	416 W
"	Consolidated	3	90 kHz	750 W
"	Southern Cross	2	—	—
"	Branson	8	25 kHz	85 W
"	Barun-Blakeslee	—	20 kHz	500 W
Nondestructive testing	Branson	17	18 kHz - 30 MHz	10^{-4}-10^{-2} W
"	Magnallux	6	15 MHz	100-300 W

TABLE VIII-5 (CONTINUED)

ULTRASONIC PRODUCTS AND MANUFACTURERS

Product Type	Manufacturer	No. of Models	Frequency Range	Power Range
Nondestructive testing	Branson	1	1-3.5 MHz	1 mW
"	Automation Industries	3	200 kHz - 25 MHz	100 mW
"	James Electronics	5	15 kHz - 300 MHz	—
"	Automation Industries	4	2.25-5 MHz	300 W (input)
"	Picker	—	—	—
Probe	Blackstone	4	20 kHz	500 W
Grinding	Raytheon	3	20-27 kHz	100-1,000 W
"	Branson	1	20 kHz	300 W
Welding	"	3	"	120 W (head)
Machine tools	"	3	"	150-300 W
"	Bendix	3	"	2,400 W (input)
"	Branson	1	"	300 W
Seam bonding	"	3	"	300-550 W
"	UTL Logo	—	25-70 kHz	—
"	Branson	1	20 kHz	300 W
Soldering iron	"	11	"	10-1,500 W
"	Blackstone	2	20-22 kHz	120-950 W
"	"	1	38 kHz	—
Object detector	Westinghouse	1	40 kHz	—
"	Pacific Technical	1	75 kHz	1.58 W

TABLE VIII-5 (CONTINUED)

ULTRASONIC PRODUCTS AND MANUFACTURERS

Product Type	Manufacturer	No. of Models	Frequency Range	Power Range
Object detector	Connac	16	40 kHz	0.25 W (input)
"	Alton	1	"	90 dB
Detection sonar	Raytheon	7	2-50 kHz	—
"	"	2	100 kHz - 1.5 MHz	1-3 W
"	"	25	20-200 kHz	0.5-600 W
"	Inter-Ocean Systems	—	1 MHz	—
"	General Electric	—	—	—
"	Raytheon	—	—	—
Depth sounder	Edo Western	10	12-15 kHz	80 W
"	Simonsen Radio	15	38 kHz	7 kW
Telemetry	Raytheon	—	24-26 kHz	40 W
Velocimeter	Underwater Systems	4	400 kHz	—
Medical diagnostic	Branson	1	2.25 MHz	3-10 W
"	LKB	1	2 MHz	50 mW (50 mW/cm^2)
"	Magnallux	2	1-5 MHz	500 mW
"	Smith-Kline	3	2-5 MHz	79-225 mW
"	Picker	5	1-10 MHz	—
"	Hewlett-Packard	1	"	2 mW/cm^2
"	Siemens	1	2.5 MHz	20 mW/cm^2 (3 mW/cm^2)
"	Tokyo Shibaura	6	2-5 MHz	—

TABLE VIII-5 (CONTINUED)

ULTRASONIC PRODUCTS AND MANUFACTURERS

Product Type	Manufacturer	No. of Models	Frequency Range	Power Range
Medical diagnostic	Hoffman-La Roche	1	2 MHz	60.5 mW
"	"	1	2.5 MHz	—
"	"	1	2-8 MHz	—
"	Hewlett-Packard	1	2.1 MHz	62 mW (input)
"	Hoffrel	2	1-15 MHz	600 mW
"	Metrix	4	2-5 MHz	80 mW/cm^2
"	New Nippon Electric Company	1	—	15 mW/cm^2
Therapy	Siemens	2	—	—
"	Lindquist	3	—	—
"	Mettler	2	1 MHz	10-15 W
"	Bendix	1	—	15 W
Nebulizer	LKB	1	3 MHz	20 mW (10 mW/cm^2)
"	B±F Oxygen	1	1.25 MHz	50 W
"	Monagha	3	1.67 MHz	20 W
"	De Vilbliss	14	1.3 MHz	—
"	B&F Oxygen	1	1.25 MHz	50 W (input)
Cell disrupter	Branson	2	20 kHz	100-150 W
Biomedical probe	Blackstone	4	"	42-238 W
Analysis of solutions	Chesapeake Instruments	1	—	—

TABLE VIII-5 (CONTINUED)

ULTRASONIC PRODUCTS AND MANUFACTURERS

Product Type	Manufacturer	No. of Models	Frequency Range	Power Range
Analysis of solutions	Raytheon	2	—	2-3 mW
Acoustic loudspeaker	Listening, Inc.	2	10-100 kHz	—
Intrusion alarm	Douglas Randall	7	19.2-40.1 kHz	0.157-01.802 W
"	Emelson Electric	1	40 kHz	0.05 W
"	Systems Donner	1	19.2 kHz	—
"	Normda	7	37-43 kHz	10 mW
"	Aerospace Research	1	26 kHz	1 mW
"	Systems Donner	1	19.2 kHz	—
"	Aerospace Research	—	—	—
Door opener	Pacific	—	—	—
"	Technical	1	75 kHz	263 mW (input)
Dental scaling	Litton	3	18-22 kHz	—
Degasser	Blackstone	3	22 kHz	67-118 W

Adapted from reference US1177

TABLE VIII-6

ESTIMATED SALES VOLUME FOR ULTRASONIC APPARATUS

Use	Sales Volume (millions of dollars) 1968	1973
Cleaning	18.0	30
Instrumentation	15.0	30
Medical ultrasonics	7.0	30
Miscellaneous processes	7.0	22
Assembly	5.0	20
Electronics	5.0	10
Consumer products	0.1	10
Packaging	0.2	5
Textiles	0.1	5
TOTAL	57.4	162

Adapted from reference US1177

Report 7
January 6, 1981

IX. APPENDIX III

MANUFACTURERS AND USERS OF ULTRASONIC EQUIPMENT

MANUFACTURERS OF ULTRASONIC EQUIPMENT

MEMBERS OF THE ULTRASONIC INDUSTRY COUNCIL
(271 North Ave., New Rochelle, NY 10801)

The Bendix Corp.
Instruments and Life Support Division
Hickory Grove Rd.
Davenport, IA 52808

Blackstone Corp.
1111 Allen St.
Jamestown, NY 14701

Branson Instruments, Inc.
76 Progress Dr.
Stamford, CT 06904

Cavitron Corp.
Cavitron Ultrasonics Division
11-40 Borden Ave.
Long Island City, NY 11101

Crest Ultrasonics Corp.
Mercer County Airport
Trenton, NJ 08628

Dukane Corp.
St. Charles, IL 60174

Fibra-Sonics, Inc.
4626 No. Lamon Ave.
Chicago, IL 60630

Lewis Corp.
Main St.
Woodbury, CT 06798

MANUFACTURERS OF ULTRASONIC EQUIPMENT (CONTINUED)

Litton Dental Products, Inc.
1928 Tigertail Blvd.
Dania, FL 33004

Phillips Manufacturing Co.
7334 N. Clark St.
Chicago, IL 60626

Raytheon Corp.
676 Island Pond Rd.
Manchester, NH 03103

Schick Electric, Inc.
216 Greenfield Rd.
Lancaster, PA 17604

Sonobond Corp.
310 E. Rosedale Ave.
West Chester, PA 19380

Ultra Sonic Seal
405 Smith St.
Farmingdale, NY 11735

Vernitron Piezoelectric
Division
232 Forbes Rd.
Bedford, OH 44146

Westinghouse Electric Corp.
P.O. Box 300
Sykesville, MD 21784

ALPHABETICAL LIST OF MANUFACTURERS

Acoustica Associates, Inc.
4060 Ince Blvd.
Culver City, CA 90203

Aerocean Instruments, Inc.
Southold
Long Island, NY 11971

Mr. Dennis Shapiro, President
Aerospace Research, Inc.
130 Lincoln St.
Boston, MA 02135

MANUFACTURERS OF ULTRASONIC EQUIPMENT (CONTINUED)

Mr. Martin H. Reiss, President
Alarmtronics Engineering, Inc.
154 California St.
Newton, MA 02195

Mr. Alton R. Higgins, President
Alton Electronics Co.
P.O. Box 398
Archer, FL 32618

Mr. Leopold Perlaky
Electronic Product Manager
American Instrument Co.
8030 Georgia Ave.
Silver Spring, MD 20910

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2424 West 23rd St.
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Baron-Blakeslee, Inc.
1620 South Laramie Ave.
Chicago, IL 60650

Mr. Lloyd Bostwick, Reliability
Engineering Specialist
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Dayton, OH 45401

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Bird-X, Inc.
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Birtcher Corp.
Medical Division
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B & F Oxygen and Equipment Co.
3912-16 Fuston St.
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Conrac Corp.
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991 Waimanu St.
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Smith Kline Instruments, Inc.
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Mr. K.A. Wheeldon, Director
Sonicaid Ltd.
Hood La., Nyetimber
Bognor Regis, Sussex, England

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4665 Joliett St.
Denver, CO 80239

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415 Clyde Ave., Suite 1
Mountainview, CA 94040

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Westerly, RI 02891

Hospital And Laboratory Division
The Southern Cross Manufacturing Corp.
Chambersburg, PA 17201

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Systron and Donner Corp.
6767 Dublin Blvd.
Dublin, CA 94566

Mr. J. Kreuter, Director
Medical Electronics
Vernitron Medical Products, Inc.
Empire Blvd. and Terminal La.
Carlstadt, NJ 07072

Ward Associates-Engineers
11330 Sorrento Valley Rd.
San Diego, CA 92121

Mr. William A. Wheatley
General Manager
Wave Energy Systems, Inc.
600 Madison Ave.
New York, NY 10022

MANUFACTURERS OF ULTRASONIC EQUIPMENT (CONTINUED)

LISTING OF MANUFACTURERS BY TYPE OF EQUIPMENT

COMPONENTS AND SUPPLIES

Generators

Acoustica Associates, Inc.
Aetna Electronics Corp.
Aerojet-General Corp.
Alcar Instruments, Inc.
Arenberg Ultrasonics Laboratory, Inc.
Bendix Corp., Pioneer Central Division
Birtcher Corp.
Blackstone Ultrasonics, Inc.
Branson Instruments, Inc.
Budd Co.
C & E Marshall Co.
Cavitron Ultrasonics, Inc.
Commander Laboratories, Inc.
Crest Ultrasonics Corp.
Delta Sonics, Inc.
Dynasonics Corp.
Edo Corp.
Electromation Components Corp.
Giannini Control Corp.
Heat Systems Co.
International Electronic Corp.
James Electronics, Inc.
L & R Manufacturing Co.
Lewis Corp.
Lindquist, R.J., Co.
McKenna Laboratories
Macrosonics Corp.
Matec, Inc.
Multisonic Corp.
Phillips Manufacturing Co.
Raytheon Co., Submarine Signal Division
Sonobond Corp.
Tronic Corp.
Ultra Sonic Seal Division, Kleer-Vu Industries, Inc.
Westinghouse Electric Corp.
Will Scientific, Inc.

MANUFACTURERS OF ULTRASONIC EQUIPMENT (CONTINUED)

Transducers

Acoustica Associates, Inc.
Aerojet-General Corp.
Aetna Electronics Corp.
Alcar Instruments, Inc.
Bendix Corp., Pioneer Central Division
Birtcher Corp.
Blackstone Ultrasonics, Inc.
Branson Instruments, Inc.
Budd Co., Industrial Division
C & E Marshall Co.
Cavitron Ultrasonics, Inc.
Channel Industries, Inc.
Chesapeake Instrument Corp.
Commander Laboratories, Inc.
Crest Ultrasonics Corp.
Delavan Manufacturing Co.
Delta Sonics, Inc.
Dynamics Corp. of America, Massa Division
Dynasonics Corp.
Eastern Co.
Edo Corp.
Electromation Components Corp.
Giannini Controls Corp.
Heat Systems Co.
International Electronics Corp.
James Electronics. Inc.
Krautkramer Ultrasonics, Inc.
L & R Manufacturing Co.
Linden Laboratories, Inc.
Linquist, R. J., Co.
McKenna Laboratories
Macrosonics Corp.
Multisonic Corp.
Phillips Manufacturing Co.
Raytheon Co., Submarine Signal Division
Ross Laboratories
Solidtronics, Inc.
Sonobond Corp.
Tronic Corp.
Ultra Sonic Seal Division, Kleer-Vu Industries, Inc.
Valpey Corp.
Westinghouse Electric Corp.
Will Scientific, Inc.

MANUFACTURERS OF ULTRASONIC EQUIPMENT (CONTINUED)

Transducer Materials - Piezoelectric

Acoustica Associates, Inc.
Alcar Instruments, Inc.
Blackstone Ultrasonics, Inc.
Budd Co., Industrial Division
Channel Industries, Inc.
Clevite Corp., Piezoelectric Division
Commander Laboratories, Inc.
Dynamics Corp. of America, Massa Division
Dynasonics Corp.
Edo Corp.
Electra Scientific Corp.
Heat Systems Co.
Honeywell, Inc.
James Electronics, Inc.
Linden Laboratories, Inc.
Penn Engineering and Manufacturing Corp.
Tronic Corp.
Ultra Sonic Seal Division, Kleer-Vu Industries, Inc.
Valpey Corp.

Transducer Materials - Magnetostrictive

Aetna Electronics Corp.
Alcar Instruments, Inc.
Blackstone Ultrasonics, Inc.
Commander Laboratories, Inc.
Dynamics Corp. of America, Massa Division
Lewis Corp.
Ultra Sonic Seal Division, Kleer-Vu Industries, Inc.

Transducer Materials - Ferroelectric

Aerojet-General Corp.
Channel Industries, Inc.
Commander Laboratories, Inc.
Edo Corp.
Electra Scientific Corp.
Linden Laboratories, Inc.

Electronic Components

Aerojet-General Corp.
Aetna Electronics Corp.
Cavitron Ultrasonics, Inc.
Chesapeake Instrument Corp.
Commander Laboratories, Inc.

MANUFACTURERS OF ULTRASONIC EQUIPMENT (CONTINUED)

Dynasonics Corp.
Eastern Co.
Edo Corp.
Freed Transformer Co., Inc.
Lewis Corp.
Phillips Manufacturing Co.
Raytheon Co., Submarine Signal Division
Will Scientific, Inc.

Chemical Supplies

Acoustica Associates, Inc.
Alcar Instruments, Inc.
Bendix Corp., Pioneer Central Division
C & E Marshall Co.
Commander Laboratories, Inc.
Dynasonics Corp.
Giannini Control Corp.
L & R Manufacturing Co.
Lewis Corp.
Multisonic Corp.
Phillips Manufacturing Co.
Tronic Corp.

INSTRUMENTATION

Test and Search Equipment

Alarm Systems

Acoustica Associates, Inc.
Budd Co., Industrial Division
Dynasonics Corp.
Edo Corp.
Giannini Controls Corp.

Gauging and Measuring Equipment

Acoustica Associates, Inc.
Branson Instruments, Inc.
Budd Co., Industrial Division
Commander Laboratories, Inc.
Dynamics Corp. of America, Massa Division
Dynasonics Corp.
Edo Corp.
Giannini Control Corp.
Ross Laboratories, Inc.

MANUFACTURERS OF ULTRASONIC EQUIPMENT (CONTINUED)

Medical and Dental

Acoustica Associates, Inc.
Aerojet-General Corp.
Alcar Instruments, Inc.
Bendix Corp., Pioneer Central Division
Birtcher Corp.
Blackstone Ultrasonics, Inc.
Branson Instruments, Inc.
Cavitron Ultrasonics, Inc.
Commander Laboratories, Inc.
Crest Ultrasonics Corp.
DeVilbiss Co., Atomizer Division
Dynamics Corp. of America, Massa Division
Fischer, R. A., and Co.
James Electronics, Inc.
Lewis Corp.
Lindquist, R. J., Co.
Mettler Electronics Corp.

Nondestructive (flaw detection) Test Equipment

Arenberg Ultrasonics Laboratory, Inc.
Branson Instruments, Inc.
Budd Co., Industrial Division
Commander Laboratories, Inc.
Delta Sonics, Inc.
James Electronics, Inc.
Krautkramer Ultrasonics, Inc.
Solar
TAC Technical Instrument Corp.

Control Equipment

Acoustica Associates, Inc.
Delavan Manufacturing Co.
Dynamics Corp. of America, Massa Division
Electromation Components Corp.
Raytheon Co., Submarine Signal Division

Sonar Equipment

Acoustica Associates, Inc.
Alcar Instruments, Inc.
Chesapeake Instrument Corp.
Channel Industries, Inc.
Clevite Corp., Piezoelectric Division
Commander Laboratories, Inc.

MANUFACTURERS OF ULTRASONIC EQUIPMENT (CONTINUED)

Dynamics Corp. of America, Massa Division
Eastern Co., Danforth White Division
Edo Corp.
Raytheon Co., Submarine Signal Division
Ross Laboratories, Inc.

POWER

Chemical and Food Processing Equipment

Acoustica Associates, Inc.
Aerojet-General Corp.
Blackstone Ultrasonics, Inc.
Branson Instruments, Inc.
Commander Laboratories, Inc.
Giannini Controls Corp., Powertron Division
Macrosonics Corp.
Sonic Engineering Corp.
Will Scientific, Inc.

Cleaning Equipment

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Aerojet-General Corp.
Alcar Instruments, Inc.
American Machine and Solvents Co., Inc.
Bendix Corp., Pioneer Central Division
Blackstone Ultrasonics, Inc.
Branson Instruments, Inc.
C & E Marshall Co.
Cavitron Ultrasonics, Inc.
Commander Laboratories, Inc.
Crest Ultrasonics Corp.
Delta Sonics, Inc.
DoAll Co.
Dynamics Corp. of America, Massa Division
Dynasonics Corp.
Electromation Components Corp.
Electronic Assistance Corp.
Giannini Control Corp.
Heat Systems Co.
International Electronics Corp.
L & R Manufacturing Co.
Lewis Corp.
McKenna Laboratories
Metalwash Machinery Corp.
Mettler Electronics Corp.
Multisonic Corp.

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Pall Corp., Aircraft Porous Media, Inc.
Phillips Manufacturing Co.
Raytheon Co., Submarine Signal Division
Redford Corp.
Richards Corp.
Solar
Sonicor Instrument Corp.
Tempress Research Co.
Tronic Corp.
Westinghouse Electric Corp.
Will Scientific, Inc.

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Cavitron Ultrasonics, Inc.
Dynamics Corp. of America, Massa Division
Edo Corp.
International Electronics Corp.
Raytheon Co., Submarine Signal Division

Machining Equipment

Cavitron Ultrasonics, Inc.
Delta Sonics, Inc.

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Aerojet-General Corp.
Blackstone Ultrasonics, Inc.
Cavitron Ultrasonics, Inc.
International Electronics Corp.
Sonobond Corp.
Solar

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Balckstone Ultrasonics, Inc.
Branson Instrument, Inc.
Cavitron Ultrasonics, Inc.
Commander Laboratories, Inc.
Delta Sonics, Inc.
Dynasonics Corp.
Electromation Components Corp.
Ultra Sonic Seal Division, Kleer-Vu Industries, Inc.

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Aerojet-General Corp.
Blackstone Ultrasonics, Inc.
Commander Laboratories, Inc.
Delta Sonics, Inc.
Electromation Components Corp.
International Electronics Corp.
Solar
Sonobond Corp.

RESEARCH AND DEVELOPMENT

Commercial

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Alcar Instruments, Inc.
Blackstone Ultrasonics, Inc.
Cavitron Ultrasonics, Inc.
Chesapeake Instrument Corp.
Commander Laboratories, Inc.
DoAll Science Center, Inc.
Dynamics Corp. of America, Massa Division
Dynasonics Corp.
Edo Corp.
Heat Systems Co.
Linden Laboratories, Inc.
Macrosonics Corp.
Raytheon Co.
Ross Laboratories, Inc.
Solidtronics, Inc.
Sonicor Instrument Corp.
Sonobond Corp.
TAC Technical Instrument Corp.
Westinghouse Electric Corp.

Government

Acoustica Associates, Inc.
Alcar Instruments, Inc.
Blackstone Ultrasonics, Inc.
Cavitron Ultrasonics, Inc.
Chesapeake Instrument Corp.
Dynamics Corp. of America, Massa Division
Edo Corp.
Heat Systems Co.
Linden Laboratories, Inc.

MANUFACTURERS OF ULTRASONIC EQUIPMENT (CONTINUED)

Macrosonics Corp.
Raytheon Co., Submarine Signal Division
Solidtronics, Inc.
Sonicor Instrument Corp.
Sonobond Corp.
Tronic Corp.
Westinghouse Electric Corp.

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Villa Nova & Florence Dr.
Woonsocket, RI 02895

A-F Industries, Inc.
11337-T Williamson Rd.
Cincinnati, OH 45241

AMF, Inc.
777 Westchester Ave.
White Plains, NY 10604

A-T-O, Inc.
4420 Sherwin Rd.
Willoughby, OH 44094

Abex Corp.
530 Fifth Ave.
New York, NY 10036

American Chain and Cable Co., Inc.
935 Connecticut Ave.
Bridgeport, CT 06602

Acheson Colloids Co.
1637 Washington Ave.
Port Huron, MI 48060

Advanced Alloys, Inc.
125 Adams Ave.
Hauppage, NY 11787

Air Products and Chemicals, Inc.
Box 538
Allentown, PA 18105

Alcan Aluminum Corp.
Alcan Metal Powders Division
P.O. Box 290
Elizabeth, NJ 07207

All Spec Metals, Inc.
P.O. Box 6036-T
Ft. Lauderdale, FL 33310

Allegheny Ludlum Industries, Inc.
Dept. TR
Oliver Bldg.
Pittsburgh, PA 15222

USERS OF ULTRASONIC EQUIPMENT (CONTINUED)

Allis-Chalmers Corp.
P.O. Box 512
Milwaukee, WI 53201

Aluminum Co. of America
1126 Alcoa Bldg.
Pittsburgh, PA 15219

American Can Co.
Packaging Operations
P.O. Box 1126, Wall Street Station
New York, NY 10005

American Chemical and Refining Co., Inc.
36 Sheffield St.
Waterbury, CT 06704

Ametek
Station Square Two
Paoli, PA 19301

Babcock & Wilcox Co.
161 E. 42nd St.
New York, NY 10017

Bearings, Inc.
3600 Euclid Ave.
Cleveland, OH 44115

Bendix Corp.
Bendix Center
Southfield, MI 48076

Bethlehem Steel Corp.
Bethlehem, PA 18016

Diamond Shamrock Corp.
1100 Superior Ave.
Clevelend, OH 44114

Carborundum Co.
Carborundum Center
Niagara Falls, NY 14302

Carpenter Technology Corp.
150 W. Bern St.
Reading, PA 19603

USERS OF ULTRASONIC EQUIPMENT (CONTINUED)

Century Brass Products, Inc.
60 Mill St.
Waterbury, CT 06720

Chase Brass and Copper Co.
20600 Chagrin Blvd.
Cleveland, OH 44122

Chemetron Corp.
111 E. Wacker Dr.
Chicago, IL 60601

Chemplast, Inc.
04-150 Dey Rd.
Wayne, NJ 07470

Chromalloy
Chromalloy Plaza
120 S. Central Ave.
St. Louis, MO 63105

Combustion Engineering, Inc.
900 Long Ridge Rd.
Stamford, CT 06902

The Continental Group, Inc.
633 Third Ave.
New York, NY 10017

Cyclops Corp.
650 Washington Rd.
Pittsburgh, PA 15228

Degussa, Inc.
Rte. 46 at Hollister Rd.
Teterboro, NJ 07608

Du Pont Company
Industrial Fabrics Division
Room 2500-2
Nemours Bldg.
Wilmington, DE 19898

Eaton Corp.
100 Erieview Plaza
Cleveland, OH 44114

USERS OF ULTRASONIC EQUIPMENT (CONTINUED)

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P.O. Box 2730
Hartford, CT 06101

FMC Corp.
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Chicago, IL 60601

Ferro Corp.
One Erieview Plaza
Cleveland, OH 44144

Firestone Tire & Rubber Co.
1200 Firestone Pkwy.
Akron, OH 44317

Flintkote Co.
Washington Plaza Bldg.
1351 Washington Blvd.
Stamford, CT 06904

Ford Motor Co.
Ford Glass Division
300 Renaissance Center, Suite 2300
Detroit, MI 48243

Franklin Research Alternatives, Inc.
4007-09 Linden St.
Oakland, CA 94608

GAF Corp.
140 W. 51st St.
New York, NY 10020

GTE Products Corp.
One Stamford Forum
Stamford, CT 06904

Gold Bond Building Products
Division of National Gypsum Co.
Gold Bond Bldg.
327 Delaware Ave.
Buffalo, NY 14202

B.F. Goodrich Co.
500 S. Main St.
Akron, OH 44318

USERS OF ULTRASONIC EQUIPMENT (CONTINUED)

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Akron, OH 44316

Gulf & Western Manufacturing Co.
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P.O. Box 999-A
Southfield, MI 48037

Houdaille Industries, Inc.
One Financial Plaza
Fort Lauderdale, FL 33394

Ingersoll-Rand
Woodcliff Lake, NJ 07675

Inland Steel Co.
30 West Monroe St.
Chicago, IL 60603

Johns-Manville Corp.
Ken-Caryl Ranch
Denver, CO 80217

Kaiser Aluminum & Chemicals Corp.
300 Lakeside Dr.
Oakland, CA 94643

Kawecki Berylco Industries, Inc.
220 E. 42nd St.
New York, NY 10017

Kennametal, Inc.
1 Lloyd Ave.
Latrobe, PA 15650

Koppers Co., Inc.
1420 Koppers Bldg.
Pittsburgh, PA 15219

Litton Industries, Inc.
360 N. Crescent Dr.
Beverly Hills, CA 90210

Mallory Metallurgical Co.
3029 E. Washington St.
Indianapolis, IN 46206

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970 New Durham Rd.
Edison, NJ 08817

Midland-Ross Corp.
55 Public Sq.
Cleveland, OH 44113

Modern Welding Co., Inc.
2880 New Hartford Rd.
Owensboro, KY 42301

Monsanto Co.
800 N. Lindbergh Blvd.
St. Louis, MO 63166

NFV Co.
P.O. Box 68-T
Yorklyn, DE 19736

Norton Co.
50 New Bond St.
Worcester, MA 01606

Ohio Rubber Co.
99 Ben Hur Ave.
Willoughby, OH 44094

PPG Industries
One Gateway Center
Pittsburgh, PA 15222

Park-Ohio Industries, Inc.
3802 Harvard Ave.
Cleveland, Oh 44105

Parker Hannifin Corp.
17325 Euclid Ave.
Cleveland, OH 44112

Peabody International Corp.
835 Hope St.
Stamford, CT 06907

Pennsylvania Engineering Corp.
32nd St.
Pittsburgh, PA 15201

USERS OF ULTRASONIC EQUIPMENT (CONTINUED)

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P.O. Box 1126
The Wall Street Station
New York, NY 10005

H.K. Porter Co., Inc.
Dept. TR78, Rm. 300
Porter Bldg.
Pittsburgh, PA 15219

Republic Steel Corp.
1441-T Republic Bldg.
Cleveland, OH 44101

Revere Copper and Brass, Inc.
605 Third Ave.
New York, NY 10016

Rexnord, Inc.
P.O. Box 2022
Milwaukee, WI 53201

Reynolds Aluminum Co.
P.O. Box 27003-ZA
Richmond, VA 23261

The Richardson Co.
2400 East Devon Ave.
Des Plaines, IL 60018

Rockwell International
600 Grant St.
Pittsburgh, PA 15219

St. Regis Paper Co.
150 E. 42nd St.
New York, NY 10017

Teledyne, Inc.
1901 Ave. of the Stars
Los Angeles, CA 90067

Teleflex, Inc.
155-T South Limerick Rd.
Limerick, PA 19468

3M Company
3M Center
St. Paul, MN 55101

USERS OF ULTRASONIC EQUIPMENT (CONTINUED)

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48-13 20th Ave.
Long Island City, NY 11105

Union Carbide Corp.
270 Park Ave.
New York, NY 10017

U.S.I. Chemicals Co.
National Distillers and Chemical Corp.
99 Park Ave.
New York, NY 10016

Van Dorn Co.
2700 E. 79th St.
Cleveland, OH 44104

Varian Assoc.
611 Hansen Way
Palo Alto, CA 94303

Vulcan, Inc.
Latrobe, PA 15650

Worthington Service Corp.
10 Industrial Rd.
Fairfield, NJ 07006

Walters Engineered Products
150 Industrial Park Rd.
Middletown, CT 06457

The Warner & Swasey Co.
Cedar & East Blvd.
Cleveland, OH 44016

Westlake Plastics Co.
P.O. Box 127
161 W. Lenni Rd.
Lenni, PA 19052

Westvaco Corp.
Westvaco Bldg.
299 Park Ave.
New York, NY 10017

Zircar Products, Inc.
1100 N. Main St.
Florida, NY 10921

X. APPENDIX IV

TRADE ASSOCIATIONS AND LABOR UNIONS

TRADE ASSOCIATIONS

Abrasive Engineering Society
1700 Painters Run Rd.
Pittsburgh, PA 15243

Acoustical and Insulating Materials Assoc.
205 W. Touhy Ave.
Park Ridge, IL 60068

Acoustical Door Institute
9820 South Dorchester Ave.
Chicago, IL 60628

Acoustical Society of America
335 East 45th St.
New York, NY 10017

Aerospace and Electronic Systems Society
345 East 47th St.
New York, NY 10017

Aerospace Industries Association of America
1725 DeSales St., N.W.
Washington, DC 20036

Aerospace Medical Association
Washington National Airport
Washington, DC 20001

American Academy of Physical Medicine
and Rehabilitation
Suite 922
30 North Michigan Ave.
Chicago, IL 60602

American College of Obstetricians and
Gynecologists
1 East Wacker Drive
Chicago, IL 60601

TRADE ASSOCIATIONS (CONTINUED)

American Association of Electromyography
and Electrodiagnosis
732 Marquette Bank Bldg.
Rochester, MN 55901

American Association of Ophthalmology
Suite 901
1100 17th St., N.W.
Washington, DC 20036

American Association of Pathologists, Inc.
9650 Rockville Pike
Bethesda, MD 20014

American Association of Physicists
in Medicine
Suite 620
111 East Wacker Drive
Chicago, IL 60601

American Association of Textile
Chemists and Colorists
Box 12215
Research Triangle Park, NC 27709

American Crystallographic
Association, Inc.
335 East 45th St.
New York, NY 10017

American Electroplaters'
Society, Inc.
1201 Louisiana Ave.
Winter Park, FL 32789

American Institute of Industrial
Engineers
25 Technology Park/Atlanta
Norcross, GA 30092

American Institute of Mining,
Metallurgical, and Petroleum Engineers, Inc.
345 East 47th St.
New York, NY 10017

American Institute of
Physics, Inc.
335 East 45th St.
New York, NY 10017

TRADE ASSOCIATIONS (CONTINUED)

American Institute of Ultrasound
in Medicine
6161 N. May Ave., Ste. 260
Oklahoma City, OK 73112

American Iron and Steel Institute
1000 16th St., N.W.
Washington, DC 20036

American Machine Tool Distribution
Association
4720 Montgomery Lane
Bethesda, MD 20014

The American Medical Association
535 North Dearborn St.
Chicago, IL 60610

American National Standards Institute, Inc.
1430 Broadway
New York, NY 10018

American Powder Metallurgy Institute
Box 2054
Princeton, NJ 08540

American Society for Medical Technology
Suite 200
5555 West Loop South
Bellaire, TX 77401

American Society for Metals
Metals Park, OH 44073

American Society for Microbiology
1913 Eye St., N.W.
Washington, DC 20006

The American Society for Nondestructive
Testing, Inc.
3200 Riverside Drive
Box 5642
Columbus, OH 43221

American Society for Quality Control, Inc.
161 West Wisconsin Ave.
Milwaukee, WI 53203

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American Society for Testing and Materials
1916 Race St.
Philadelphia, PA 19103

American Society of Brewing Chemists
3340 Pilot Knob Rd.
St. Paul, MN 55121

American Society of Mechanical Engineers, Inc.
345 East 47th St.
New York, NY 10017

American Speech and Hearing Association
10801 Rockville Pike
Rockville, MD 20852

American Textile Manufacturers
Institute, Inc.
Suite 300
1101 Connecticut Ave., N.W.
Washington, DC 20036

American Welding Society, Inc.
2501 N.W. 7 St.
Miami, FL 33125

Association of Canadian Distillers
Suite 506
350 Sparks St.
Ottawa, Ontario, CANADA K1R 7S8

Association of Industrial
Metallizers, Coaters, and
Laminators
61 Blue Ridge Rd.
Wilton, CT 06897

Audio Engineering Society, Inc.
60 East 42nd St., Rm. 2520
New York, NY 10017

Carbonated Beverage Institute
Room 1600
230 Park Ave.
New York, NY 10017

Chemical Coaters Association
Box 241
Wheaton, IL 60187

TRADE ASSOCIATIONS (CONTINUED)

Chemical Manufacturers Association
1825 Connecticut Ave., N.W.
Washington, DC 20009

Citizens Against Noise
P.O. Box 59170
Chicago, IL 60659

Construction Industry Manufacturers
Association
Marine Plaza - 1700
111 East Wisconsin Ave.
Milwaukee, WI 53202

Cutting Tool Manufacturers Association
Suite 120
6735 Telegraph Rd.
Birmingham, MI 48010

Diemakers and Diecutters Association
3255 South U.S. #1
Fort Pierce, FL 33450

Electrochemical Society, Inc.
Box 2071
Princeton, NJ 08540

Fluid Controls Institute, Inc.
Box 3854
Tequesta, FL 33458

Food Industries Suppliers' Association
Box 1242
Caldwell, ID 83605

Food Processing Machinery
and Supplies Association
Suite 700
1828 L St., N.W.
Washington. DC 20036

Foodservice Equipment Distributors Association
332 South Michigan Ave., Suite 1558
Chicago, IL 60604

Health Physics Society, Inc.
Suite 506
4720 Montgomery Lane
Bethesda, MD 20014

TRADE ASSOCIATIONS (CONTINUED)

The Institute of Electrical and
Electronics Engineers, Inc.
345 East 47th St.
New York, NY 10017

Iron and Steel Society of AIME
Box 411
Warrendale, PA 15086

Marine Technology Society
Suite 412
1730 M St., N.W.
Washington, DC 20036

Master Textile Printers Association
60 Glen Ave.
Glen Rock, NJ 07452

Metal Cutting Tool Institute
1230 Keith Bldg.
Cleveland, OH 44115

Metal Finishing Suppliers
Association, Inc.
1025 East Maple Rd.
Birmingham, MI 48011

Metal Powder Industries Federation
Box 2054
Princeton, NJ 08540

Metal Properties Council, Inc.
345 East 47th St.
New York, NY 10017

Metal Treating Institute, Inc.
1300 Executive Center Drive
Tallahassee, FL 32301

National Council of Acoustical
Consultants, Inc.
66 Morris Ave.
Springfield, NJ 07081

National Society for Cardiopulmonary
Technology, Inc.
Suite 307
1 Bank St.
Gaithersburg, MD 20760

TRADE ASSOCIATIONS (CONTINUED)

Noise Control Products and
Materials Association
410 North Michigan Ave.
Chicago, IL 60611

Packaging Machinery Manufacturers
Institute
2000 K St., N.W.
Washington, DC 20006

Process Equipment Manufacturers'
Association
P.O. Box 8745
Kansas City, MO 64114

Slurry Transport Association
Suite 3210
490 L'Enfant Plaza East, N.W.
Washington, DC 20024

Society for Experimental Stress Analysis
Box 277
Saugatuck Station
Westport, CT 06880

Society for Occupational
and Environmental Health
Suite 308
1341 G St., N.W.
Washington, DC 20005

Society of Rheology
335 East 45th St.
New York, NY 10017

Society for the Advancement of Material
and Process Engineering
Box 613
Azusa, CA 91702

Society of the Plastics Industry, Inc.
355 Lexington Ave.
New York, NY 10017

Sprayed Mineral Fiber Manufacture
Association, Inc.
1 Wall St., Ste. 2400
New York, NY 10005

TRADE ASSOCIATIONS (CONTINUED)

Steel Shipping Container Institute
2204 Morris Ave.
Union, NJ 07083

Steel Tank Institute
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111 East Wacker Drive
Chicago, IL 60601

Ultrasonic Industry Association, Inc.
481 Main St.
New Rochelle, NY 10801

Undersea Medical Society, Inc.
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New York, NY 10003

Distillery, Wine and Allied Workers'
International Union
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Englewood, NJ 07631

Industrial Union of Marine and Shipbuilding
Workers of America
1126 16th St., N.W.
Washington, DC 20036

International Association of Machinists
and Aerospace Workers
1300 Connecticut Ave., N.W.
Washington, DC 20036

International Association of Tool Craftsmen
3243 37th Ave.
Rock Island, IL 61201

International Brotherhood of Boilermakers,
Iron Shipbuilders, Blacksmiths, Forgers,
and Helpers
8th Ave. at State
Kansas City, KS 66101

International Chemical Workers Union
1655 West Market St.
Akron, OH 44313

International Leather Goods, Plastics
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265 West 14th St.
New York, NY 10011

International Masonry Institute
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823 15th St., N.W.
Washington, DC 20005

LABOR UNIONS (CONTINUED)

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1225 East McMillan St.
Cincinnati, OH 45206

International Union of Petroleum
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8131 East Rosecrans Blvd.
Paramount, CA 90723

Laundry, Dry Cleaning and
Dye House Workers International
Union
360 North Michigan Ave.
Chicago, IL 60601

Marine Workers Federation
6074 Lady Hammond Rd.
Halifax, Nova Scotia
CANADA B3K 2R7

Medical Technologists and
Technicians Association
Suite 310
1081 Carling Ave.
Ottawa, Ontario
CANADA K1Y 4G2

National Brotherhood of Packinghouse
and Industrial Workers
3855 Bellcrossing Drive
Kansas City, KS 66104

Oil, Chemical and Atomic Workers International Union
Box 2812
Denver, CO 80201

Sheet Metal Workers' International
Association
1750 New York Ave., N.W.
Washington, DC 20006

United Automobile, Aerospace,
and Agricultural Implement
Workers of America
8000 East Jefferson Ave.
Detroit, MI 48214

LABOR UNIONS (CONTINUED)

United Food and Commercial
Workers International Union
1775 K St., N.W.
Washington, DC 20006

United Garment Workers of America
200 Park Ave. South
New York, NY 10003

United Glass and Ceramic Workers of
North America
556 East Town St.
Columbus, OH 43215

United Mine Workers of America
900 15th St., N.W.
Washington, DC

United Steelworkers of America
Five Gateway Center
Pittsburgh, PA 15222

United Textile Workers of America
420 Common St.
Lawrence, MA 01840

XI. APPENDIX V

BIOPHYSICS OF ABSORPTION OF ULTRASOUND

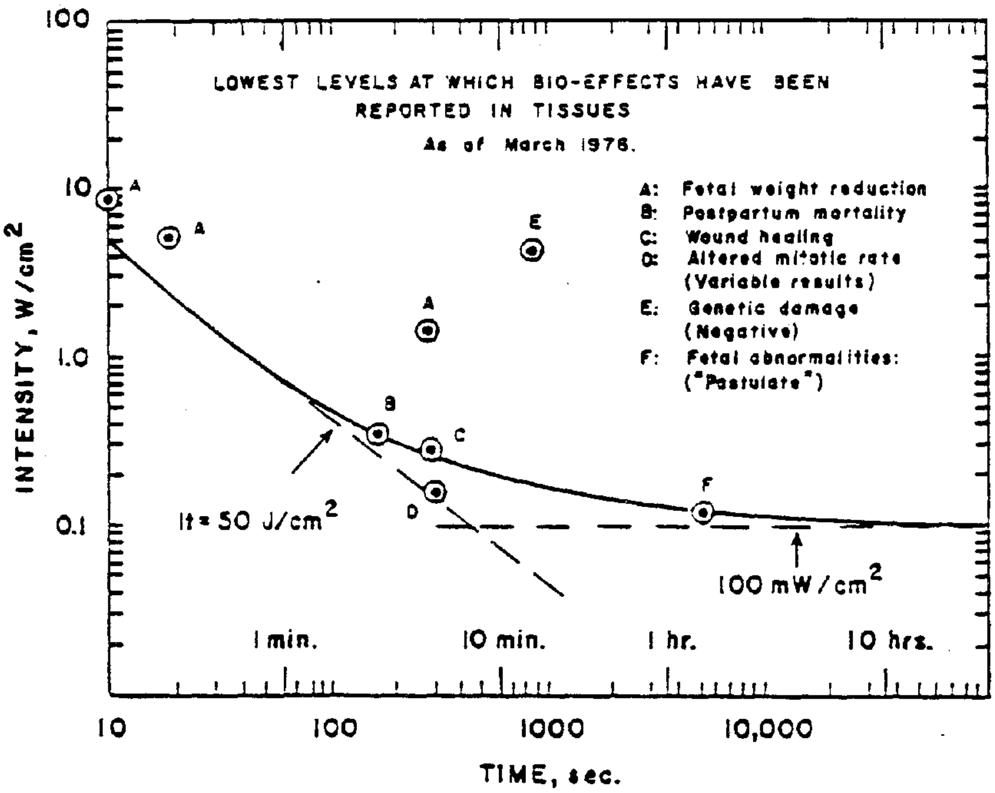

FIGURE XI-1. SUMMARY OF SELECTED DATA FOR BIOEFFECTS OF UNFOCUSED ULTRASOUND ON MAMMALIAN TISSUES

Taken from reference US0629

TABLE XI-1

ABSORPTION OF ULTRASOUND IN HUMAN TISSUE

Tissue	Intensity Absorption Coefficient at 1 MHz, (cm^{-1})	Frequency Dependence of Absorption Coefficient
Water	0.0002	ν^2
Blood	0.02	ν
Fat	0.07	ν
Liver	0.12	ν
Brain	0.12	ν
Muscle		
Across fiber	0.21	ν
Along fiber	0.06	ν
Skull bone	2.0	ν^2
Lung	9.4	ν^{-1}

Adapted from reference US0146

XII. APPENDIX VI

ULTRASONIC PROBES

A variety of devices for measuring ultrasonic energy have been developed since about 1940. These are described below.

Electromagnetic, Piezoelectric, and Thermoelectric Probes

Piezoelectric crystals have been described in Chapter I as the most common form of transducer for generating and radiating ultrasonic energy. They can operate in the reverse mode to respond to an ultrasonic field and by producing an electric current measure its pressure and intensity. Such probes are small and relatively sensitive, and they provide a virtually instantaneous measurement of ultrasonic intensity [US0714]. Although they are capable of measuring fields with intensities as low as 1 nW/cm^2 [US0714], they cannot be used for absolute measurements and need to be calibrated continually, are independent of frequency only below their resonant frequency, and are directionally sensitive, especially in the Fresnel region (near field) [US0714,US0732,US0765].

The dimensions and mass of the transducer are critical to its operation in ultrasonic fields, since they determine its resonance properties.

Below the resonant frequency, which is directly proportional to the dimensions and inversely proportional to the mass, piezoelectric transducers provide a flat response over a wide band of frequencies and are not subject to large misorientation errors in the far-Fresnel and Fraunhofer (far field) regions [US0765]. The difficulty in fabricating small accurate transducers, ie, with dimensions of less than five wavelengths [US0765], has limited their usefulness to ultrasonic fields with frequencies below 1 MHz [US0732].

Descriptions of the theory, design, operation, and application of piezoelectric probes for the detection and measurement of liquid-borne ultrasound have been published [US0144,US0639,US0649,US0800,US0847, US0885,US0945,US0946,US0947]. These probes, sometimes called hydrophones, are useful for measuring ultrasonic intensity where liquids are the coupling medium, such as cavitating cleaners or diagnostic and therapeutic devices. Juarez and Corral [US0835] designed a probe for airborne ultrasound that was more efficient than usual piezoelectric probes (efficiencies of 60% or less), and Frost and Szabo [US1026] obtained a patent in 1978 for a small, handheld probe intended for use with metals. Certain polymers exhibit a piezoelectric effect [US0806], and probes based on polymeric films could prove to be useful for measuring ultrasonic intensities. Cohen and Edelman [US0786,US0787] described the fabrication of films of poly(vinyl chloride) and poly(vinyl fluoride).

Thermoelectric probes using thermocouples embedded in acoustic absorbing material have been manufactured [US0765,US0825,US0943]. They respond to the heat generated in the absorber by ultrasonic energy and yield values of particle velocity and pressure directly. Since such probes are small and are accurate to within 2%, they are useful at frequencies in the megahertz range. However, such designs are sensitive to the ambient temperature [US0732]. Capacitance microphones [US0772,US0938,US0942] have been found useful for measuring liquid- or solidborne ultrasound.

Sound level meters can be adapted to measure ultrasound with frequencies up to 140 kHz [US1176]. Two recently designed modifications involve the use of special third-octave band pass filters and special condenser microphones and preamplifiers. With one design, impulse and peak sound pressure levels are expressed in A-scale-weighted decibels for frequencies up to 70 kHz. The second, which will be available in the fall of 1980, is a modified voltmeter-amplifier capable of providing readouts up to 140 kHz in decibels (A-scale weighted). Neither design is strictly portable: a source of alternating current is necessary, and the filter and amplifier are separate units suitable for laboratory bench use. In addition, their prices, which are 10 times that for audible sound level meters, are prohibitive for routine monitoring in occupational settings.

Optical Methods

As an acoustic field propagates through a medium, the local density is altered. Since the index of refraction of any medium is dependent upon its density, the passage of light through that medium will be altered by an acoustic field. Optical methods rely on measurements of either the refraction or diffraction of light by ultrasound [US0655,US0765] and can be used either to measure the absolute intensity or pressure of the ultrasonic field or to visualize the field [US0714]. The absolute measurements (no calibration or reference measurement is required) provide values for the intensity normal to the direction of propagation. Precise values can be obtained, since the field is not disturbed by the light nor are misorientation errors introduced.

With the diffraction method, the pressure and density variations induced in the medium by the propagating ultrasonic wave act as a grating that is capable of diffracting light with wavelengths much smaller than the distances between the periodic regions of rarefaction and condensation. The technique has been the subject of theoretical reviews and reports describing measuring systems [US0647,US0839,US0843,US0853,US0860,US0948]. Multiple reflections and high intensities distort the ultrasonic field [US0765]; thus, the method is basically useful for measuring low-intensity ultrasound at frequencies above 5 MHz [US0655]. Also, since the theory presupposes a plane wave front, the method is only useful in a free, ie, far, or a standing-wave field.

Refraction methods encompass a variety of techniques [US0893] for either visualizing, on film or by holographic methods, or measuring the ultrasonic field [US0655,US0714,US0765]. With the Schlieren systems [US0779,US0821,US0944], the light is refracted as it passes through the ultrasonic field. The light pattern can be photographed or the photodetector can measure the ultrasound-induced deviation in the light path. From this value the pressure and intensity can be calculated. Holographic methods operate on similar principles [US0679]. Interferometric methods were proposed in 1974 as measurement techniques especially suited for medical diagnostic devices [US0714]. The technique [US0648,US0733] was capable of directly measuring intensities as low as 1 nW/cm^2 at frequencies of 0.5-5 MHz. Visualization systems relying on light interference are useful for a wider frequency range. Other refraction techniques have been described [US0854,US0868], and Tsok [US0896] has developed a birefringence apparatus capable of measuring intensities from 10 $\mu W/cm^2$ to 3 W/cm^2.

Liquid Crystal Devices

The notion of visualizing ultrasonic fields was introduced above in the discussion of optical methods. Another technique developed for visualization relies on the use of liquid (also called nematic or cholesteric) crystals [US0692,US0717,US0814,US0824,US0831,US0836,US0837,US0859]. Here a color change occurs in the crystal display when light is scattered from the crystal face. An ultrasonic field will alter the optical properties of the crystal and, thus, alter its scattering. Crystal detectors have been claimed to be most useful for detecting frequencies in the upper megahertz range [US0824] and measuring intensities near 1 $\mu W/cm^2$ [US0814]. Their real value, as well as that of other thermoluminescent materials [US0635], is as dosimeters to measure the total dose of ultrasonic energy absorbed during an exposure period. Current developments are not sufficiently advanced to justify their use as ultrasonic energy probes.

Calorimetric Techniques

Measurement techniques in which ultrasonic energy is converted into thermal energy (heat) are direct and capable of high precision [US0765, US0958]. In such designs, a measurable rise in the temperature of an absorbing material with known and controlled mass and specific heat is correlated with the absorption of ultrasound. The calorimeter is usually immersed in a sound-absorbing medium, such as a water bath, to provide a constant-temperature environment; thus, the method is the least affected by the shape and mode of the ultrasonic field, the orientation of the detector, and the character of the region being sampled, ie, whether it is near or far field [US0714]. However, there are disadvantages to the technique: the need for enclosing the thermoprobe in some medium, liquid or solid, makes the designs bulky; since measurements of temperature increases require a long time in comparison with other techniques, the response is slow; and the probes must be precisely calibrated by obtaining heating curves of temperature rise with time for different ultrasonic power inputs. Since absorption of ultrasonic energy by most materials is frequency dependent, calibration may be a complex process and accurate operation over a wide band of frequencies may not be possible.

Three types of calorimeter designs, the constant or steady-flow, the transient, and the substitution systems, have been described [US0222, US0834,US0901,US0910,US0941] for use at frequencies up to 3 MHz and powers as low as 0.2 mW. The thermoprobes contain either thermocouples or thermistors. The latter have a faster response and do not require a reference as the former do. These thermal elements also serve as the basis for a second category of designs for making thermal measurements of ultrasonic energy [US0642,US0729,US0827,US0911]. For example, in one design parabolic cones are used to focus the ultrasonic radiation onto a thermistor embedded in an acoustic absorber [US0714]. The entire apparatus is immersed in a liquid-containing vessel. A variation on this design that does not require a water bath can measure powers as low as 1 mW at frequencies between 1 and 10 MHz [US0642].

Mechanical Methods

Mechanical detection of ultrasound represents the oldest and most widespread technique [US0775]. The method is based on the phenomenon of radiation pressure [US0871] and physically detects the difference in acoustic pressure at a boundary, ie, solid surface, between two acoustically dissimilar materials [US0655,US0765]. The force is independent of frequency and mode [US0714] and is directly proportional to the ultrasonic intensity [US0732]. Two types of radiometers are available: (1) those based on a small disc, known as a Rayleigh disc, the dimensions of which are smaller than the wavelength of the ultrasonic radiation, and (2) those using either acoustically reflecting or absorbing targets, the dimensions of which are much larger than the wavelength of the ultrasonic radiation. Various radiometers have been designed that use discs, spheres, or vanes for different frequency and intensity ranges [US0732].

Although Rayleigh disc radiometers, which are sensitive to the particle velocity, are better suited to air- or gasborne ultrasound than to liquidborne ultrasound [US0765], they are limited by size to use at longer ultrasonic wavelengths (lower frequencies). Radiation pressure devices accurate at intensities in the microwatt to milliwatt range have been designed [US0333,US0902,US0903]. These can be of three basic types: radiometers [US0902], float systems having plate- or cone-shaped reflectors suspended in water or some other liquid [US0657,US0752,US0846, US0939,US0940,US0950,US1143], or analytic balances having reflecting or absorbing targets immersed in water [US0333,US0653,US0771,US0845,US0903].

Portable units are available [US1143]; however, several commercial units tested by the Bureau of Radiological Health [US0646] are capable of resolving ultrasonic power to only 0.1 W and intensity to 10 mW/cm^2. According to their theory of operation, all radiation force methods assume plane-wave or well-defined, eg, standing-wave, ultrasonic fields; thus, they are not accurate in the near-field Fresnel region or in ultrasonic fields subject to multiple reflections. In addition, distilled and degassed water must be used for the float or balance methods to prevent the exertion of extraneous pressure on the target by cavitation.

Miscellaneous Methods

Several other methods have been suggested for measuring ultrasonic energy. The use of in-line power meters [US0656] allows the power at the transducer to be measured easily; however, the actual intensity transmitted to some point must be calculated and is subject to errors due to reflections and scattering. Furthermore, the formulas are not valid for the near-field region. Polaroid film has been suggested as a means to visualize an ultrasonic field [US0851]. The second is a chemical technique in which the extent of ionization of an ammonium nitrate solution is correlated with the ultrasonic energy absorbed [US1129]. A similar technique is used successfully for the dosimetry of ionizing radiation. The applicability of any of these methods to occupational exposure situations is limited.

XIII. APPENDIX VII

BIOLOGIC EFFECTS OF ULTRASOUND

This appendix compiles the reported effects of absorption of ultrasonic energy on humans and other animal species. Tables have been provided to summarize the exposure and effect data described in the text. Wherever the intensity and duration of exposure were given in a report, the dose incident on the animal was calculated.

Effects of Ultrasound on Humans

Although most of the information on the effects of ultrasound on humans has come from case studies and clinical observations, some information from experimental studies dealing with the potential hazards of therapeutic ultrasound is available. The majority of reports described below deal with applications of ultrasound either through direct or coupled contact of the body with the transducer.

(a) General Effects of Occupational Exposure

As stated in Chapter I, the first indications of possible hazard from exposure to ultrasound came from studies of workers exposed to jet aircraft engine noise. In 1949, Dickson and Watson [US0983] presented some preliminary results of a survey of 97 aircraft pilots and maintenance workers who had been exposed to such noise for an average of 15.5 months. The typical daily exposures were divided into four groups: less than 0.5 hours, 16 men; 0.5-1 hour, 23 men; 1-2 hours, 21 men; and more than 2 hours, 13 men. Ear protection was not generally used. Most of the subjective effects involved complaints of discomfort, deafness, and tinnitus. Clinical examinations revealed no detectable gross changes in the ear, nose, or throat, nervous system disorders, or changes in the electroencephalogram (EEG). Hearing losses were temporary. A second, more complete report by Dickson and Chadwick [US0984] in 1951 again noted the appearance of unsteadiness, dizziness, and lack of concentration in jet aircraft workers but pointed out that these subjective symptoms were produced erratically. Furthermore, the correlation between exposure and effect was too slight to warrant attributing the effects to ultrasound. In fact, after comparing data on bioeffects in the literature with a spectrum analysis of jet engine noise, Dickson and Chadwick concluded that high-intensity audible sound was responsible for so-called ultrasonic sickness.

Lisichkina [US0532] came to a similar conclusion for various industrial ultrasound sources in 1961. He surveyed 23 workers who used ultrasonic welders and compared their skin and body temperatures, pulse, blood pressure, reactions to auditory and visual stimuli, and blood cell counts with those of 15 fitters. Increases were observed in the first four of these variables for the workers using the welders; however, they could not be definitively attributed to exposure to ultrasound. By 1966, Parrack [US0116] had compiled more complete data on ultrasound exposure conditions (see Table XIII-1) and concluded that airborne ultrasonic fields are not significantly hazardous. He considered most of the subjective effects to be psychosomatic. Knight [US0284], in a 1968 study, also noted no effect of industrial ultrasound on hearing, balance, or psychologic profile. He tested 18 males working with cleaners operating at frequencies between 20 and 40 kHz and compared the results with those from a control group of 20 hospital staff members of similar age. Only a slight loss of hearing and increased nystagmus were observed. Reports on the subjective effects have been summarized in Table XIII-2.

After examining 28 females working with ultrasonic cleaners, Pazderova-Vejlupkova et al [US0203] concluded, in 1977, that long-term exposure to ultrasound was not detrimental to worker health. The female workers averaged 42.4 years in age and had been operating the cleaners, which operated at frequencies between 20 and 25 kHz, for an average of 38.6±5.4 months. In comparison with a control group of similar age, no statistically significant differences were found in urine and urine sediment, erythrocyte sedimentation, blood count (hematocrit value, hemoglobin, and erythrocyte, reticulocyte, thrombocyte, and leukocyte counts), differential count (neutrophil, lymphocyte, monocyte, and eosinophil counts), liver function, serum glutamic pyruvic transaminase (SGPT) and serum glutamic oxaloacetic transaminase (SGOT) activity, lipemia and cholesterol content, glycemia, electrocardiogram (ECG) and EEG. Gynecologic, endocrinologic, otorhinolaryngologic, dermatologic, and X-ray examinations also revealed no differences between the two groups.

TABLE XIII-1

ULTRASOUND EXPOSURE LEVELS

Equipment	Sound Pressure Levels (dB) in One-Third Octave Bands Centered on the Following Frequencies (kHz)					
	20	25	31.5	40	50	63
Dental drill						
Patient area	--	95	--	--	--	--
Operator's position	--	76	--	--	--	--
Ultrasonic cleaner						
Operator's position	101	86	91	89	86	85
Laboratory desk	80	63	71	69	64	62
Outer office	64	46	45	42	38	--
Jet aircraft engine						
Maintenance position	103	101	99	96	--	--
7.62 m forward	91	89	86	83	80	--
30.48 m behind	97	95	92	88	--	--
152.4 m behind	74	74	--	--	--	--

*dB = decibel
**kHz = kilohertz

TABLE XIII-2

SUBJECTIVE EFFECTS OF HUMAN EXPOSURE TO ULTRASOUND

Irradiated or Affected Tissue*	Effect**	Intensity (W/cm^2)***	Duration (min)***	Calculated Dose (kJ/cm^2)***	Method of Application	Frequency (MHz)***	Reference
Whole body	Subjective complaints	Jet aircraft	30-120	--	Airborne	--	US0983
"	"	"	--	--	"	--	US0984
"	Subjective complaints	Industrial exposures	--	--	"	--	US0374
"	Subjective complaints (-)	Industrial welders	--	--	"	--	US0532
"	"	Industrial equipment and jet aircraft: 30 nW/cm^2 - 2 $\mu W/cm^2$	--	--	"	14-88 kHz	US0116
"	"	Industrial cleaners	--	--	"	20-40 kHz	US0284
Ear	Perception	--	--	--	"	30-60 kHz	US0719
"	"	--	--	--	Contact	25-62 kHz	US0769
"	"	30 nW/cm^2 (20 kHz) - 30 mW/cm^2 (100 kHz)	--	--	"	0.02-0.1	US0789
"	"	0.1 mW/cm^2	--	--	"	20.1-108 kHz	US0820
"	"	2-4 mW/cm^2	--	--	"	0.032-0.2	US0555
"	"	15 $\mu W/cm^2$ (25 kHz) - 75 $\mu W/cm^2$ (225 kHz)	--	--	"	0.025-0.225	US0884
"	"	--	--	--	"	0.02-0.1	US0188

*Radiation was generally directed to the affected area. See text for complete details of ultrasound exposure
**Lack of effect denoted by (-)
***Except where noted

In contrast, in a series of studies published in 1978-79, Chemnyi and coworkers [US0556,US1041,US1156] reported that operators of handheld defectoscopes (ultrasonic inspection devices) exhibited a variety of minor effects. These included hyperhydrosis (sweating) and dyshydrosis of the palm of the hand, autonomic-vascular dystonia and autonomic polyneuritis, and microcirculatory disorders of the capillary bed of the nails, as well as microcirculatory disorders of the limbus and perilimbal conjunctiva and vascular changes in the anterior segment of the eye. No changes were observed in intraocular pressure, nor was there any microscopic evidence of pathologic changes in the various tissues of the eye. In general, the observed effects appeared to be limited to damage to the capillaries. Hemorrhagic rashes, blisters, and necrosis of the skin were also observed by Despotov and Khurkov [US0387] in the hands and arms of two women operating ultrasonic therapy devices. The effects disappeared within 2-3 weeks after the work was stopped.

Minor changes in the cardiovascular systems of workers using ultrasound have been reported. According to Ashbel [US0143], measurements of blood sugar levels in 40 workers who had operated cleaning baths, welders, and piercing devices for ceramics and alloys for 1-2 years indicated that blood sugar was decreased after each workshift; there was no change in the levels of controls. Sound pressures ranging from 90 to 117 decibels (dB) (0.1-50 $\mu W/cm^2$) were reportedly measured at distances of 5-10 m from the equipment in two frequency bands, 8-16 kHz and 16-31 kHz, although no data for the latter band were presented for the washers. Yazburskis [US0605] reported in 1975 that 21 men and 15 women who had operated ultrasonic

devices for 2-5 years had a reduced heart rate, blood pressure, and systolic:diastolic ratio and showed varied changes in the radioelectrocardiogram. The equipment operated at frequencies of only 8, 18, and 20 kHz; thus high-intensity audible sound was the probable cause of the effects.

This was also true for a report published by Gerasimova [US0215] in 1976, concerning presumed low-frequency ultrasound-induced changes in the excretion of catecholamines, and one by Bohanes and Kratochvil [US0034] in 1968, reporting such subjective effects as nausea, dizziness, and fatigue and changes in brain cortex function. In the first case, the operating frequencies were 8 and 16 kHz, whereas in the second, the equipment emitted 18.2-kHz sound. As with most of the Eastern European literature reporting presumed effects of exposure to ultrasound, the frequencies involved were below 20 kHz, ie, within the high-frequency audible sound range.

(b) Effects on the Ear

In a 1962 study describing the development of an ultrasonic guidance aid for the blind, Kay [US0719] reported that human subjects could perceive a frequency-modulated ultrasound signal varying between 30 and 60 kHz. That unmodulated ultrasound could be perceived by humans was reported by Bellucci and Schneider [US0769], also in 1962. Small ultrasonic probes emitting 25- and 62-kHz radiation were described by the subjects as producing a very high pitched squeaking that changed only in intensity as the probe was moved around the body and away from the body surface. Individuals with hearing loss showed two types of response. Those with no cochlear or vestibular function, such as several congenitally deaf children, deaf individuals also suffering from retinitis pigmentosum, and individuals lacking an eighth cranial nerve response, could not perceive ultrasound, whereas those with a weak cochlear response could. Therefore, the inner ear was suggested as the site of perception. Corso [US0789] suggested in a 1963 report that bone conduction is responsible for the perception of ultrasound. He tested 53 male and 50 female college students for their abilities to detect ultrasound at frequencies of 20-100 kHz. The thresholds for hearing were observed to rise at the rate of 15 dB per octave, such that a sound pressure of over 135 dB (20 mW/cm^2) was required at 100 kHz to elicit a response.

Sagalovich and Pokryvalova [US0555] reported results of a more extensive study of the perception of ultrasound in 1964. They tested 33 normal and 160 fully or partially deaf subjects with an audiometer producing ultrasonic frequencies between 32 and 200 kHz at intensities of 2-4 mW/cm^2. In all cases, the emitter was placed in contact with the individual's head, and, as in the study of Bellucci and Schneider [US0769], the perception of ultrasound improved when the probe was placed below the occipital region near the foramen magnum. Since deaf individuals suffering from primary neuritis of the auditory nerves could not perceive the ultrasound, whereas those with otosclerosis could, perception was attributed to bone conduction of mechanical waves. In a second study, published in 1966, Sagalovich and Melkumova [US0884] reported that the maximum frequency that could be perceived through bone conduction was 225 kHz. The threshold sensitivity was found to decrease from 15 to 75.26 $\mu W/cm^2$, corresponding to 81 to 115 dB, respectively, as the frequency increased from 25 to 225 kHz.

The threshold for perception (hearing) of ultrasound was reported by Haeff and Knox [US0820] in 1963 to be near the threshold for feeling, ie, 0.1 mW/cm^2. Their experiments with six men indicated that all so-called sound in the frequency range of 20-108 kHz was perceived to have a pitch of 8-9 kHz. Tissue resonances were suggested as responsible for the perceived effect. A more complete analysis of the phenomenon of ultrasonic hearing was published by Dieroff and Ertel [US0388] in 1975. In the first phase of the experiment, seven audiometric assistants with normal hearing were asked to match the sound perceived at frequencies of 20, 40, 60, 80, and 100 kHz with an audible sound signal. In all cases an ultrasound-induced crackling sensation was mimicked by high-frequency audible sound in the range of 13-16 kHz. In the second phase, ultrasonic hearing thresholds were determined for individuals with normal and impaired hearing. The thresholds for the latter, a group of 361 workers exposed to industrial impulse noise, were two to three times greater than those for 23 normal individuals over the frequency range of 20-100 kHz. A similar increase was noted for 108 of 348 workers from four other factories who had been found to suffer from some hearing (audible sound) loss. Results from the third phase of testing indicated that ultrasound was not perceived by 80 of 106 pupils tested in a school for the deaf but was perceived by all 63 pupils tested in a school for the hard-of-hearing. For 40 adults with damage to the inner ear, the ability to perceive ultrasound was inversely related to the extent of hearing loss. Dieroff and Ertel were hesitant to attribute the perception of ultrasound to any one area of the auditory system but suggested that the organ of Corti was probably responsible.

Damage to the human ear from exposure to ultrasound has not been mentioned so far, except for indications of threshold shifts for audible sound mentioned by Dieroff and Ertel [US0388]. In 1966, Grigoreva [US0990] reported that a 1-hour exposure to 20-kHz ultrasound at a sound pressure level of 110 or 115 dB (10 or 20 $\mu W/cm^2$) reduced the auditory sensitivities of five test subjects to sound at frequencies between 250 Hz and 10 kHz. Smith [US0998], on the other hand, reported in 1967 no significant effects on hearing thresholds. He used a 28-kHz ultrasound source and sound pressures of 85-100 dB (20 nW/cm^2 - 1 $\mu W/cm^2$) in testing 12 males and females.

Five-minute exposures to 25- to 42-kHz ultrasound produced by dental equipment did lead to temporary shifts in hearing threshold (TTS) and tinnitus, according to a 1976 report from Moller et al [US0424]. In tests of 9 female and 11 male subjects, they found that 10 experienced either TTS's of 10-20 dB for as long as 30 minutes or cochlear-type tinnitus or both. Consideration of such hearing threshold data, as well as reports of subjective effects, prompted Acton [US0101] to propose, in 1968, a limit of 110 dB (10 $\mu W/cm^2$) for exposure to ultrasound at frequencies of up to 40 kHz.

One case report, published by Newlands [US0317] in 1966, indicated that histologic changes in the human labyrinth occurred following clinical ultrasonic irradiation. Exposure was for 10 minutes at an intensity of 3 W/cm^2 and 15 minutes at 5.6 W/cm^2. When tissue was removed from the lateral semicircular canal 21 months later, new bone formation, disorganization of the membranous canal, and fibrous tissue replacement were observed. Similar alterations were reported by Arslan [US0476] to accompany ultrasound treatment of Meniere's disease. In his case studies, nystagmus was observed after contact exposure at intensities of 7-8 W/cm^2 and progressively more severe damage to the labyrinth occurred as the intensities were increased to 12-15 W/cm^2.

(c) Effects on the Eye

Ultrasound has been used clinically since 1967 to treat cataracts of the eye. In the process, known as phacoemulsification, a small ultrasonic probe is used at one point to fragment and then aspirate the lens nucleus. The procedure is not without complication, however, as Emery et al [US0164] pointed out in 1978. They surveyed 123 males and 77 females, ranging in age from 30 to 92 years, who had been treated for senile cataract with phacoemulsification an average of 22 months earlier. Examinations of the eyes revealed several cases each of corneal edema, wound leakage, flattening of the anterior chamber, glaucoma, hypotony, persistent iritis, posterior synechiae, cystoid macular edema, and retinal detachment. Opacification of the posterior capsule, which occurred in 32 of the individuals, was the major problem.

A 1977 review by Everett et al [US0214] indicated that retinal detachment occurred in 19 of 1,107 cases of cataract extraction by phacoemulsification. The average age of the 619 males and 488 females included in the study was 55.4 years, and most of the retinas became detached within 1 year after the treatment. Wilkinson et al [US0188] also reported, in 1978, a small incidence of retinal detachment following phacoemulsification. A total of 1,106 individuals were treated; of these, 394 were treated for cataracts in both eyes. Detachment occurred in 54 eyes, ie, 3.6% of the total.

Corneal changes have also been observed after phacoemulsification. In 1977, Polack and Sugar [US0218] presented case reports of five individuals who had suffered from corneal edema for 6 months following cataract extraction. Electron and optical microscopy revealed alterations in Descemet's membrane and endothelial cell disruption. Similar results were presented in 1977 by Arentsen et al [US0208] in a series of light and electron micrographs of corneal tissue obtained from four individuals. In a 1979 comparison of phacoemulsification with intracellular cataract extraction, Waltman and Cozean [US0575] observed that the corneas of individuals subjected to the former procedure showed 29% more endothelial cell loss than did those of individuals subjected to the latter procedure. Twenty-five individuals, averaging 62.15 years in age, were examined, and cell densities in the untreated eyes were compared with those in eyes of a normal population to ensure that the cataract extraction procedures were responsible for any cell loss.

(d) Effects on Tissues

Several reports have indicated some generalized effects of ultrasound on the tissues of the body. Wittenyellner [US0224] presented, in 1976, results from ultrasonic irradiation of his own thighs some 25 years earlier. Frequencies of 20-800 kHz were used at intensities of approximately 1.33 W/cm^2. Exposures over the 7.5 months of the experiments totaled 14 hours in some cases. An acute, cellular-serial inflammation, blistering of the stratified flat epithelium, loosening of the cutaneous and subcutaneous connective tissue, high-grade pigmentation of the basal layers, and accumulation of white blood cells in capillaries of the papillae were observed immediately after irradiation. The skeleton and muscle were normal, and edema did not occur. Microscopic examination of the skin 25 years after irradiation revealed no significant cellular effects. Increases in the permeability of the skin of men to NaI were reported by Dohnalek et al [US0141] in 1965. They exposed the forearms of seven volunteers to 800-kHz ultrasound for 10 minutes at intensities of 0.4-0.6 W/cm^2 after spreading a paste containing $Na^{131}I$ over the skin. Compared with controls, the thyroids of the irradiated men contained 3.6 times the amount of radioactive iodine.

That ultrasound has a direct heating effect has been observed. Based on results of a series of experiments with unanesthetized 17- to 25-year-old volunteers, Lehmann et al [US0294] reported in 1966 that the temperature increase and distribution in the thigh muscle depended on the temperature of the coupling medium used to transmit the ultrasound. A

1-MHz ultrasonic source producing an intensity of 1 W/cm^2 at the applicator face was used. At 18 and 21 C, the temperature within the muscle increased as the depth below the skin increased, to a maximum of approximately 42 C near the bone/muscle interface. The skin temperature increased to 26 C. At 24 C, on the other hand, the skin temperature rose to 46 C, more than 4 C greater than the temperature at the bone/muscle interface and 7.5 C greater than the temperature at the subcutaneous fat/muscle interface. This anomaly, observed with mineral oil as the coupling agent, did not occur when water was used.

Filipczynski [US0501] reported, in 1978, results of applying two ultrasonic blood flow meters to the arm of a male volunteer. The maximum temperature increases measured at the skin surface for 100-microsecond (µs) exposures were 2.3 C for the 8-MHz device, which produced an average intensity of 0.1 W/cm^2, and 12.5 C for the 9.5-MHz device. Swelling can follow ultrasonic therapy, according to a 1960 case report by Chieppo [US0784] and a 1961 case report by Block [US0773]. In both cases the patients were females, and edema was observed after the second or third treatment. A contact applicator was used, but no information on frequency or intensity was given.

(e) Effects on the Blood

Alterations in the human circulatory system, such as changes in blood flow accompanying changes in tissue temperature, have been observed after ultrasound irradiation. In 1953, Bickford and Duff [US0880] reported that contact exposure of the forearm to ultrasound led to intensity-dependent increases in blood flow and muscle temperature but a decrease in skin temperature. For each experiment, blood flow and temperature in one of the forearms of each of 20 men or 6 women were measured for 20 minutes before and after a 15-minute exposure to 800-kHz ultrasound. Average increases of 18 and 47% in blood flow after 2- and 3.5-W/cm^2 exposure, respectively, were measured, with the higher intensity exposure producing changes in tissue temperature of -1 C at the skin surface, -0.4 C in subcutaneous tissue, +1.8 C in the muscle at a depth of 1.5 cm, and +2.1 C at a depth of 3 cm. A series of experiments in which blood flow was measured in both forearms of each individual but only one forearm was exposed showed no increases in the untreated arm.

Abramson et al [US0368], in a 1960 report, extended Bickford and Duff's experiments [US0880] by using higher intensities and including oxygen uptake measurements. Their results indicated that combined 18- to 21-minute exposures to 1-MHz ultrasound at 0.3-1.2 W/cm^2 to the wrist and at 0.3-1.4 W/cm^2 to the forearm produced, relative to preexposure values, an average 100% increase in the peak blood flow during exposure, a 50% increase in total blood flow during the entire exposure period, but a 68% increase in total blood flow during the 20-minute period after exposure. In contrast to Bickford and Duff's results [US0880], increases in temperature were maximal in the subcutaneous tissue and minimal in the muscle tissue, 1.4 and 0.9 C, respectively. The peak response occurred in all cases during the final 5 minutes of exposure. Maximal increases in oxygen uptake occurred during the same period and averaged 93% higher than preexposure values. The total oxygen uptake during exposure and postexposure periods varied among the tested individuals (16 men); therefore, no correlation could be made with the pattern of increased blood flow.

Increased blood flow and tissue temperatures in the legs of 15 men exposed for 5 minutes to 1-MHz ultrasound were also reported by Lota [US0410] in 1965. A contact applicator was used for all experiments, which were performed in a room maintained at 23-24 C and 45-50% relative humidity. At an intensity of 1 W/cm^2, muscle temperature increased by a maximum of 1.3 C and skin temperature by 1.6 C at 5 minutes of exposure, whereas blood flow increased by a maximum of 21% 3 minutes after exposure. There was a gradual decrease in all three variables over the remainder of the 1-hour experimental period. Intensities of 0.5 and 0.75 W/cm^2 were found to produce no significant changes. Likewise, using airborne ultrasound at a frequency of 20 kHz and sound pressure of 110-115 dB (10-20 mW/cm^2), Grigoreva [US0990], in a 1966 study, found that a 1-hour exposure had no effect on the vascular system.

Hemolysis did not accompany exposure to ultrasound for up to 45 minutes, according to a 1968 report by Fishman [US0804]. Three volunteers immersed their hands in a bath-type ultrasonic cleaner operating at 80 kHz with an output power of 150 W. Blood samples taken before and after exposure revealed that no hemolysis had occurred. When samples of blood were exposed in test tubes, however, hemolysis was observed to take place within 5-15 seconds.

In a 1971 paper, Buchanan et al [US0782] described the use of a creatine phosphokinase (CPK) assay to determine the extent of ultrasound-induced muscle and nervous system damage. The direct contact applicator of a diagnostic ultrasound unit producing an intensity of 0.9 mW/cm^2 was used to irradiate 10 men for 20 minutes each. Ten nonirradiated men served as the control group. In blood samples taken three times before and 4, 8, 16, 24, and 48 hours after exposure, no significant differences in CPK levels were detected. Therefore, destruction of muscle or nervous tissue was assumed not to have occurred.

The effect on pituitary growth hormone secretion of using ultrasound as a means of inducing functional hypophysectomy was discussed in a 1975 report by Muggeo et al [US0425]. Sixteen individuals suffering from diabetic retinopathy and six with acromegaly were treated for 20-30 minutes with 3-MHz ultrasound at an intensity of 32 W/cm^2. Comparisons of human growth hormone levels in the blood before and 7 days after treatment indicated that no significant changes were induced by ultrasound, although Muggeo et al inferred a partial inhibition in the acromegalic individuals. Aniskova et al [US1014] noted in 1971 that treating females suffering from chronic inflammation of the uterine appendages with ultrasound affected secretion from the adrenal cortex and sympathetic-adrenal system and the concentration of histamine in the blood. Forty-three patients were irradiated 24-36 times with coupled ultrasound. Aniskova et al observed increases, relative to preexposure values, in the biologically active concentration of 11-hydroxycorticosteroids in the blood. The concentrations of the catecholamines epinephrine and norepinephrine and of histamine were also found to be increased. The significance of these changes was not discussed, however.

(f) Effects on the Nervous System

Indications of gross morphologic damage to the brain following therapeutic ultrasound were mentioned by Nelson et al [US0544] in a 1959 report. Ultrasound, at a frequency of 1 MHz and intensities of 5-10 W/cm^2, was applied by inserting a soundhead through the trephined skull, using Ringer's solution as the coupling medium. Exposures ranged from 2 to 14 minutes, but in those cases in which cell necrosis was evident (9 of 25) the extent of damage was not related to the duration of exposure. In 1960, Oka et al [US0083] also described the production of localized (denoted focal) brain lesions by focused ultrasonic radiation. In the two cases discussed, in which 1.46-MHz ultrasound had been used at an intensity of 170 W/cm^2, necrosis of cerebral tissue occurred within 3 seconds but was limited to the area on which the radiation had been focused. No changes in cerebrospinal fluid were detected.

Six other case reports involving the use of clinical ultrasound were presented by Garg and Taylor [US0704] in 1967. The intact skull of each individual was exposed to pulsed-wave (PW) 2-MHz ultrasonic radiation with a pulse rate of 430 pulses/second (pps) and a pulse width of 1 μs. Exposure was for 1 hour at an intensity of 1 mW/cm^2. Comparisons of EEG and of serum and cerebrospinal fluid levels of glutamic oxaloacetic transaminase, glutamic pyruvic transaminase, and lactic dehydrogenase before exposure and up to 24 hours after exposure indicated that irradiation did not produce any significant alterations. Tissue sections obtained by biopsy showed no evidence of edema, cellular infiltration, chromatolysis, myelin or glial cell changes, or hemorrhage.

The peripheral nervous system has also been the object of experimentation with ultrasound. In 1958, Lehmann et al [US0850] stated that 2 minutes of exposure in a water bath to 800-kHz radiation at an intensity of 1.5 W/cm^2 was sufficient to increase the pain threshold of the skin to heat by approximately 0.6 C. They attributed this analgesic effect to blocking of nerve function. That changes in nerve conduction velocity could be responsible for the loss of nerve function was discussed in 1961 by Madsen and Gersten [US0537]. A contact applicator was used to expose the area of the forearm above the ulnar nerve to ultrasound at intensities of 0.88, 1.28, and 1.92 W/cm^2. Eleven women and seventeen men, 19 to 43 years old, were tested. Decreases in conduction velocity of approximately 2% were measured at the two lower intensities, whereas only a slight decrease (0.8%) was measured at the highest intensity. The size of the decrease was directly proportional to the size of the area irradiated. Zankel [US0362] reported similar results in 1966. Irradiation for 10 minutes at an intensity of 1 W/cm^2 or for 5 minutes at 2 W/cm^2 produced significant reductions (14.9 and 12.2%, respectively) in the conduction velocity of the ulnar nerve. Nerve conduction velocity was reportedly increased by exposure to 800-kHz ultrasound, according to Edel and Bergmann [US1027]. Five minutes of irradiation at intensities of 0.5 and 1 W/cm^2 produced dose-dependent increases in velocity of up to 50% at 30 minutes postirradiation. Higher intensities, ie, 2 W/cm^2, or the use of water as a coupling medium instead of oil either did not affect or decreased the conduction velocity.

Esmat [US0165] also published contradictory findings in 1975. He irradiated 7 women and 13 men for 5 minutes with 800-kHz ultrasound at intensities of 0.5, 1, 1.5, and 2 W/cm^2. The contact applicator was placed on the right forearm of each test subject. When oil was used as the coupling medium, increases of up to 2% in conduction velocity were measured in the 30-minute period after exposure, with the size of the increase being inversely related to the intensity. A decrease in conduction velocity was noted when water was the coupling medium. A more complete study, yielding similar results, was published by Currier et al [US0161] in 1978. They measured the latency, amplitude, and duration of the action potential of the radial nerve of the irradiated forearm of each of five male subjects and compared the values with those obtained prior to exposure. A contact applicator emitting 1-MHz ultrasound at an intensity of 1.5 W/cm^2 was used. Increases in conduction velocity were indicated by the decreased latency. The amount of increase remained unchanged during the 15-minute period following exposure.

Contact exposure of the human forearm to 1-MHz ultrasound induced a complex polymodal sensation of burning, pricking, and pressure, according to a 1973 report by Makarov [US0305]. An intensity of 8.5 W/cm^2 and multiple exposures, each 0.1 second long, were used to produce the effect. In a series of experiments published between 1974 and 1977, Gavrilov et al [US0807,US1092,US1093] discussed the stimulation of human peripheral nerves by focused ultrasound. An ultrasonic generator capable of producing pulsed radiation at frequencies of 0.48, 0.887, 1.95, and 2.67 MHz, a radiating system able to focus the ultrasound to an area less than 2 mm in diameter, and an exposure chamber consisting of a temperature-controlled water bath were used throughout the experiments. The 1974 report [US0807] presented threshold intensities for the production of tactile, thermal, and pain sensations in the hands of five individuals. In all cases, the intensity required for a 1-millisecond (ms) pulse increased with the frequency of the radiation. For example, at 0.48 MHz, tactile sensations were noted in the palm at 16 W/cm^2 and pain was noted at 130 W/cm^2; at 2.67 MHz, the respective thresholds for thermal sensation were 120 and 4,500 W/cm^2.

More complete experiments were described in 1976 [US1092]. In these studies, pulse durations of 1, 10, and 100 ms were used, and more than 300 areas on one arm and one hand of each of seven test subjects were stimulated. The tactile and temperature sensations occurred at similar intensities for the three pulse durations; pain occurred at lower intensities for the longer durations. The final study [US1093], published in 1977, reported that tactile sensations were induced at intensities near 210 W/cm^2 for all three pulse durations but that the intensities required to induce sensations of warmth decreased from 12 to 1 kW/cm^2 as the pulse duration increased from 1 to 100 ms. The thresholds for the sensation of pain in the skin, soft tissue, and bone of the fingers and palm were observed to be independent of pulse duration but directly proportional to frequency. The threshold values for the forearm, however, were inconsistent. As could be expected, the temperature of the water bath affected the thresholds for temperature sensation; in some cases, a sensation of cold could be induced by ultrasound. Since the intensity, sound pressure, particle velocity, and local temperature change required to induce the various sensations depended on frequency, whereas the displacement amplitude did not, Gavrilov et al inferred that cavitation phenomena were not responsible for the effects.

(g) Effects on Reproduction

Ultrasound has been used diagnostically in obstetric and gynecologic examinations since the 1960's. In common practice, the applicator is placed directly over a coupling medium onto the abdominal surface. The attenuation of the ultrasound signal is small under such conditions, approximately 2.5 dB/cm, ie, 45%/cm [US0578]. The relative safety of diagnostic ultrasound has been assessed in several surveys. In 1970, Hellman et al [US0145] reported the results of a survey of 1,114 women in New York, Glasgow, and Lund who had been examined with ultrasound during their pregnancies. The equipment used for the diagnoses had operated at 2 MHz and produced maximum intensities at the skin of 3 or 10 mW/cm^2; more than 1,000 of the examinations had used pulsed ultrasound (400 pps). The frequency of fetal abnormality was found to be 1.4, 1.9, 3.25, 2.8, and 4.0% for women first examined with ultrasound during the first, second, third, fourth, and fifth 10-week periods of gestation, respectively. The average frequency, 2.7%, was 2.1% less than that found for the general population, taken from a large survey of fetal abnormalities involving 26 hospitals in the United States and more than 63,000 births. Koh et al [US1100] reported, in 1978, that in a survey of 6,788 women examined during the first trimester of pregnancy the incidences of fetal abnormality and abortion or premature delivery were 1 and 9.5%, respectively. These values were not significantly different from those for a control group. Berstine [US0242], in a 1969 study, described a similar lack of effect of ultrasound on fetal survival.

In 1972, Ziskin [US0951] published the results of a survey of clinical usage of diagnostic ultrasound. Representatives of 68 institutions reported that over a period of 25 years no adverse effects were observed from approximately 121,000 patient examinations. At 13 of the institutions the intensities ranged from 1 to 63 mW/cm^2; at the remaining 55 institutions the intensity of the ultrasound was not or could not be measured. Hill [US1134] compiled the then available (1975) information on typical exposure conditions (see Table XIII-3) and likewise noted that no evidence existed indicating ultrasound, at least under the conditions specified in that table, was hazardous. Fetal activity was not affected by exposure to diagnostic ultrasound, according to the results of a statistical analysis by Hertz et al [US0888] of movement during continuous ultrasonic monitoring.

Followup studies of infants exposed to diagnostic ultrasound in utero have also been done. The results of examinations of 171 children, ranging in age from 6 months to 3 years, were presented by Koranyi et al [US0842]

TABLE XIII-3

DIAGNOSTIC ULTRASOUND EXPOSURE VARIABLES

Technique	Range of Measured Values			
	Nominal Frequency (MHz)	Average Power (mW)	Peak Intensity (mW/cm^2)	Pulse Duration (µs)
Pulse-echo	1-15	0.3-21	1,400-95,000	1
Doppler	2-5	19-24	3-23	CW*
Therapy	1-3	To 25,000	To 25,000	CW

*CW = Continuous wave

and Falus et al [US0616] in 1972. Eighty-seven had been exposed between two and seven times to ultrasound at intensities of 1-4 mW/cm^2, but, of the 368 diagnostic examinations, only 34 occurred before the 20th week of gestation. Koranyi et al measured growth and tested social behavior and emotional development and stated that all were within the normal range. Chromosomal spreads obtained from 10 irradiated children were compared with those from 10 nonirradiated children and were found to show no significant differences in the number of disorders.

In 1977, Scheidt and Lundin [US0652] published the results of a comparative study of 303 women receiving amniocentesis and exposed to ultrasound, 679 receiving amniocentesis only, and 970 receiving neither. The average ultrasonic intensity ranged from 1 to 20 mW/cm^2, and 92% of the exposures occurred between the 14th and 20th weeks of gestation. The results of physical measurements, neurologic tests, and the Denver

Developmental Test, performed at approximately 1 year of age, showed no correlation between ultrasound exposure and neonatal abnormalities. A more complete report of the results was presented by Scheidt et al [US0205] in 1978.

Ultrasound therapy was found by Fedotova [US1032] to stimulate ovarian function in 147 women suffering from chronic salpyngitis, hypofunction of the ovaries, and climacteric hemorrhaging. The irradiation procedure consisted of 10, 20, or 30 exposures at intensities of 0.6-1 W/cm^2 for periods of 4-10 minutes each. No negative effects were reported. Suvorova [US1066] also observed normalization of menstrual function in 150 women treated at similar intensities and reported no harmful effects on reproduction.

Maternal, as well as fetal, chromosomal abnormalities have been the object of several other surveys of the effects of diagnostic ultrasound. A small-scale study of 35 women admitted to a hospital for termination of pregnancy was described by Abdulla et al [US0398] in 1971. Twelve were exposed for 1 hour to PW 1.5-MHz ultrasound at a peak intensity of 14 W/cm^2; 23 were exposed for 10 hours to continuous-wave (CW) 2-MHz ultrasound, from a fetal heart detector in the case of 12 of the women and from a fetal heart monitor in the case of the remaining 11. The average intensity was assumed to be no more than 5 mW/cm^2. Eleven nonirradiated pregnant women and their fetuses served as controls. Chromatid and isochromatid gaps and breaks were counted in chromosomal preparations from lymphocyte cultures of blood obtained within 48 hours after irradiation.

Approximately 1,000 cells were scored in each group, and no significant differences between irradiated and nonirradiated cells were detected.

According to a 1972 report by Lucas et al [US0301], fetal heart monitoring during labor did not produce an increase in fetal chromosome abnormalities. The monitor used produced CW 2-MHz ultrasound at an intensity of 5 mW/cm^2. No differences in the number of lymphocytes with chromosome aberrations or the type of aberrations were found between a group of 24 newborn infants who had been irradiated in utero and a group of 12 nonirradiated newborns. Results of a similar study using 10 pairs of irradiated and nonirradiated pregnant females were described by Watts and Stewart [US0900] in 1972. Exposures to CW 2-MHz ultrasound at an intensity of less than 12 mW/cm^2 ranged from 2 to 10 hours. Chromosomal preparations from lymphocytes revealed no increase in aberrations.

Mahoney and Hobbins [US0858] reported in 1973 that ultrasonic examination of pregnant women did not affect the subsequent growth of amniotic cell cultures. Each examination consisted of 3-5 minutes of exposure to PW ultrasound at a frequency of 1-2 MHz and peak intensity of 30 mW/cm^2. Comparisons were made between 83 cell cultures obtained from irradiated women and 33 cultures obtained from nonirradiated women.

(h) Summary

It appears that a variety of effects have been observed in humans following direct-contact or coupled exposure to ultrasound. As

Table XIII-4, which compiles the biologic effects data obtained for humans, indicates, the doses involved in the production of these effects have exceeded 100 J/cm^2.

Effects of Ultrasound on Animals

Except where noted, in all of the animal studies discussed in the following sections, ultrasonic energy was applied directly to the body either by contact with the ultrasound transducer or probe or through a coupling medium. The intensities were measured at the transducer face, and the use of the coupler or direct contact permitted the majority of ultrasonic energy to be transmitted to the body. The localized nature of the irradiation should be taken into account before comparisons with effects presumed to result from exposure to diffuse, airborne ultrasound are made.

(a) Lethality

The first experiments dealing with the effects of ultrasound on animals were discussed by Wood and Loomis [US0158] in 1927. They used a generator capable of exciting a quartz plate to vibrate, in an oil bath, at ultrasonic frequencies of 100-700 kHz. Lysis of cell suspensions of bacteria, protozoa, and red blood cells was observed immediately after immersion into the bath. Exposure to ultrasound was found to be lethal to fish and frogs within 1-2 minutes; however, a 20-minute exposure only induced a temporary paralysis of mice. As described in a 1953 report, Southam et al

TABLE XIII-4

BIOLOGIC EFFECTS OF HUMAN EXPOSURE TO ULTRASOUND

Irradiated or Affected Tissue*	Effect**	Intensity (W/cm^2)***	Duration (min)***	Calculated Dose (kJ/cm^2)***	Method of Application	Frequency (MHz)***	Reference
Ear	Hearing threshold shift	10-20 $\mu W/cm^2$	60	0.036	Airborne	0.02 kHz	US0990
"	Hearing threshold shift, tinnitus	--	--	--	Contact (teeth)	25-42 kHz	US0424
"	Hearing threshold (-)	0.02-1 $\mu W/cm^2$	--	--	Airborne	28 kHz	US0998
"	Degeneration of labyrinth	3 5.6	10 15	1.8 8.4	Contact	--	US0317
"	"	9-15	--	--	"	--	US0476
Eye	Corneal edema, iritis, hypotony, retinal detachment, capsular opacification, loss of endothelium	Phacoemulsification	--	--	"	--	US0164, US0188, US0208, US0218, US0214, US0575
"	Microcirculatory disorders in anterior segment	<1	--	--	Airborne	0.5-5	US1041
Skin and muscle tissues	Blistering and inflammation of skin	1.33	Up to 14 h	--	"	0.02-0.8	US0224
"	Temperature increases in skin and muscle	1	--	--	"	1	US0294
"	Temperature increase at skin	0.1	100 μs	10 $\mu J/cm^2$	"	8, 9.5	US0501
"	Swelling and edema	--	--	--	"	--	US0773, US0784

TABLE XIII-4 (CONTINUED)

BIOLOGIC EFFECTS OF HUMAN EXPOSURE TO ULTRASOUND

Irradiated or Affected Tissue*	Effect**	Intensity (W/cm^2)***	Duration (min)***	Calculated Dose (kJ/cm^2)***	Method of Application	Frequency (MHz)***	Reference
Skin and muscle tissues	Blisters and rashes on skin	--	--	--	Airborne	--	US0387
"	Sweating and polyneuritis of hands	--	--	--	Contact	--	US1156
Circulatory system	Increases in blood flow and tissue temperature	2-3.5	15	1.8-3.15	"	0.8	US0880
"	"	0.3-1.4	18-21	0.324-1.764	"	1	US0368
"	"	1	5	0.3	"	1	US0410
"	Microcirculatory disorders of hands	--	--	--	"	--	US0556
"	Reduced heart rate and blood pressure	--	--	--	"	--	US0605
"	Blood flow and temperature (-)	0.5, 0.75	5	0.15, 0.225	"	1	US0410
"	"	0.01-0.03	60	0.036-0.108	"	20 kHz	US0990
"	Destruction of muscle tissue (-)	0.9	20	1.08	"	--	US0782
"	Hemolysis (-)	--	45	--	Water coupled	80 kHz	US0804
Neuroendocrine system	Secretion of pituitary growth hormone (-)	32	20-30	38.4-57.6	Contact	3	US0425
"	Increase in concentration of glucocorticoids and histamine	--	--	--	"	--	US1014

TABLE XIII-4 (CONTINUED)

BIOLOGIC EFFECTS OF HUMAN EXPOSURE TO ULTRASOUND

Irradiated or Affected Tissue*	Effect**	Intensity (W/cm^2)***	Duration (min)***	Calculated Dose (kJ/cm^2)***	Method of Application	Frequency (MHz)***	Reference
Nervous system	Production of focal lesions in brain	5-10	2-14	0.6-8.4	Contact	1	US0544
"	"	170	3 s	0.51	"	1.46	US0083
"	Edema, chromatolysis, hemorrhage, nerve cell degeneration, enzyme levels in serum and cerebrospinal fluid, EEG (-)	1 mW/cm^2	60	3.6 J/cm^2	"	2	US0704
"	Decrease in nerve conduction	1.5	2	0.18	"	0.8	US0850
"	"	0.88, 1.28, 1.92	--	--	"	"	US0537
"	"	1 2	10 5	0.6	"	0.8	US0362
"	Increase in nerve conduction	0.5-2	5	0.15-0.6	"	"	US0165, US1027
"	"	1.5	5	0.45	"	1.5	US0161
"	Frequency-dependent induction of tactile, temperature, and pain sensations	130 (0.48 MHz) - 4,500 (2.67 MHz)	1 ms	0.13-4.5 J/cm^2	"	0.48-2.67	US0807
"	Pulse duration-dependent induction of tactile and temperature sensations	1,000 12,000	100 ms 1 ms	0.1 0.012	Water coupled	2.67 0.48	US1092 US1093
"	"	--	--	--	"	--	US0305

TABLE XIII-4 (CONTINUED)

BIOLOGIC EFFECTS OF HUMAN EXPOSURE TO ULTRASOUND

Irradiated or Affected Tissue*	Effect**	Intensity (W/cm^2)***	Duration (min)***	Calculated Dose (kJ/cm^2)***	Method of Application	Frequency (MHz)***	Reference
Reproductive system	Fetal abnormalities (-)	Diagnostic equipment: 3-10 mW/cm^2	--	--	Contact	--	US0100, US0145, US0242
"	"	Diagnostic equipment: 1-63 mW/cm^2	--	--	"	--	US0951, US1134
"	Fetal movement (-)	Diagnostic equipment	--	--	"	--	US0888
"	Neonatal development (-)	Diagnostic equipment: 1-4 mW/cm^2	--	--	"	--	US0842, US0616
"	"	Diagnostic equipment: 1-20 mW/cm^2	--	--	"	--	US0652
"	Ovarian function stimulated, menstrual function improved	0.6-1	4-10 min; 10,20, 30 times	0.144-0.6, up to 18	"	--	US1032, US1066
"	Chromosomal abnormalities (-)	Diagnostic equipment: 5 mW/cm^2	1-10 h	0.018-0.18	"	1.5, 2	US0398
"	"	"	--	--	"	2	US0301
"	"	Diagnostic equipment: 12 mW/cm^2	2-10 h	0.086-0.432	"	2	US0900
"	"	Diagnostic equipment: 30 mW/cm^2	3-5	0.324-0.54	"	1-2	US0858

*Radiation was generally directed to the affected area. See text for complete details of ultrasound exposure.
**Lack of effect denoted by (-)
***Except where noted

[US1009] used a water bath to irradiate the abdomens of mice. Ultrasound at an intensity of 1 W/cm^2 and frequencies of 0.5, 1, 1.5, 2, and 3.8 MHz was found to produce no significant effects after an exposure of 1, 5, or 25 minutes. At 10 W/cm^2, on the other hand, the time to death depended on the frequency of irradiation. For example, 3.8-MHz ultrasound was lethal within 6.8 minutes, whereas 0.5-MHz ultrasound was not lethal at exposures of up to 25 minutes. When exposure to 3.8-and 2-MHz ultrasound was fractionated, the total time necessary for death increased by approximately 150 and 50%, respectively. No gross morphologic abnormalities were noted.

The lethal effects of airborne ultrasound were described by Frings et al [US0261] in 1948. A siren emitting 18.5- to 19-kHz ultrasound at approximately 1 W/cm^2 was used for the irradiation. Such exposures were lethal to mice within 1-1.5 minutes, the time at which the body temperature reached 42-43 C.

Table XIII-5 summarizes the results of these studies on lethality.

(b) Effects on the Ear

Although ultrasound is considered to be imperceptible to most animals, the radiation may still interact mechanically with the structures that comprise the hearing apparatus, such as the middle or inner ear, the aural nerve, or the brain. Most reports of experimentally induced damage to the ears of various animals describe the use of a small ultrasonic probe either in direct contact with or coupled through some liquid medium to the

TABLE XIII-5

LETHAL EFFECTS OF ANIMAL EXPOSURE TO ULTRASOUND

Species	Effect*	Intensity (W/cm^2)**	Duration (min)**	Calculated Dose (kJ/cm^2)**	Method of Application	Frequency (MHz)**	Reference
Mouse	Lethality: frequency-dependent decrease in time to death	10	25 6.8	15 4.08	Water coupled (abdomen)	0.5 3.8	US1009
"	Lethality	178 (male) 268 (female)	20 s	0.356 0.536	Water coupled (gonads)	1	US0194, US0641
"	"	1	1-1.5	0.06-0.09	Airborne	19 kHz	US0261
Rat	"	1 2 3	10 5, 10 1	0.6 0.6, 1.2 0.18	Contact	1	US0048

*Lack of effect denoted by (-)
**Except where noted

tympanum. In 1956, Portmann et al [US1171] discussed the production of histologic and functional changes in the ears of 30 guinea pigs by a 10-minute exposure to 1-MHz ultrasound at intensities of 0.5-10 W/cm^2. At 0.5 W/cm^2, tranudates were observed under the epithelium of the tympanic membrane; these disappeared within 6 days. Hyperplasia and edema of the mucosa of the membrane were evident after exposure to 1.5 W/cm^2. The mucosa became thickened, the membrane filled with necrotic cells, and extensive polynuclear infiltration occurred after irradiation at 3.5 W/cm^2. Destruction of the organ of Corti and the myelin sheath of the auditory nerve began at intensities of 2-3 W/cm^2. Damage to the inner ear and nerve was observed to be immediate at 8 W/cm^2. Loss of hearing was also noted, with the threshold for lower frequencies being affected before that for higher frequencies. On the other hand, 30 minutes of exposure to 1.35-kHz ultrasound at only 0.9 W/cm^2 was sufficient to produce extensive damage to the inner ear of the guinea pig, according to McLay et al [US0536] in 1961. The effects, which included collapse of the membranous labyrinth and destruction of the vertical and lateral canals, organ of Corti, and stria vascularis, were not observed immediately following irradiation.

Degeneration of the labyrinth of the guinea pig caused by ultrasonic irradiation was also reported by Lundquist et al [US0412] in 1971. They surgically uncovered the labyrinths of 12 guinea pigs and exposed the membranous structure to 3-MHz ultrasound at an intensity of 22 W/cm^2. Electron micrographs revealed intracellular vacuolization and degeneration of the mitochondria and nucleus. Edema and rupture of the sensory

epithelium and destruction of the hairs were also observed. The extent of these effects was dependent on the time of exposure, which ranged from 2.5 to 15 minutes. No cochlear damage was observed. This was in contrast to the results presented in 1973 by Stahle and Sugar [US0221]. They exposed 51 guinea pigs to 1.25-MHz ultrasound at 20 W/cm^2 for only 3 minutes. Directcontact with the cochlea was maintained during irradiation. Microscopic examination of the inner ear at times varying from 10 minutes to 64 days following exposure indicated that the vascular damage observed in the stria vascularis, which included constriction, thrombus formation, and damage to the arterioles, venules, and capillary network, was progressive.

Ultrasonic irradiation of the labyrinth of rabbits was described by Arslan [US0475] in 1963 and Arslan and Sala [US1106] in 1965. Contact exposures varying from 40 to 120 minutes to 1-MHz ultrasound at an intensity of 13 W/cm^2 were found to affect the neuroepithelium of the cristae ampullaris. This effect was considered to be responsible for the nystagmus observed.

In a 1960 study, Brain et al [US0489] reported that direct application of 1-MHz ultrasound to the vestibular labyrinth of the cat led to morphologic changes. Eight cats were individually exposed over a 15-minute period to a progressively increasing intensity of radiation, estimated to be no more than 10 W/cm^2. Optical and electron microscopic examinations of the labyrinth were performed at 0.5 hours, 48 hours, 10 days, and 20 days. Vasodilation, increased capillary permeability, petechial hemorrhages, and the presence of protein exudates in the endolymph and perilymph represented the initial stages of damage. Degeneration of the neuroepithelium became evident at 48 hours, followed by vacuolization and nuclear disruption of the neural and supporting elements of the crista. Changes were also observed in the cochlea. Temperature measurements made during exposure indicated that no heating occurred. McGee et al [US0535] presented, in 1963, micrographs showing destruction of the organ of Corti of five cats that had had their cochleas irradiated with ultrasound for 4 minutes. In 1965, Giancarlo et al [US0508] described the use of a special surgical and irradiation procedure for exposing the vestibular labyrinth of the cat to ultrasound without affecting the cochlea. In the 20 cats exposed, degenerative changes in the sensory epithelium of the crista and macula included disruption of the basal nuclei; vacuolization, nuclear disintegration, and fusion of cells; and reduction in cell number in the vestibular ganglion. Localized damage to the sulcus cells of the organ of Corti and loosening of the stria vascularis were also observed.

Dalton, James, and coworkers have described the effects of ultrasound on the labyrinth of sheep, which is similar in size to that of the human, in a series of papers [US0491,US0522,US0718]. The 1963 report by Dalton [US0491] noted the presence of dilated blood vessels and disorganization of the neuroepithelium in the cristae of the semicircular canals and the maculae, as well as gross damage to the cochlea, in nine irradiated animals. The exposure conditions were presented in the 1964 report by James et al [US0522]. Irradiation consisted of direct exposure of the lateral semicircular canal to 1-, 3-, or 5-MHz ultrasound. The intensity was increased from 10 to 22 W/cm^2 and then maintained at the latter level for three successive periods, separated by 15 seconds of nonirradiation, of 2, 2, and 5 minutes. That nonthermal absorption of ultrasonic energy was responsible for some of the effects was suggested by James and Halliwell [US0718] in 1970. They measured temperature increases produced in the vestibule, lateral canal, and cochlea by CW and PW 3-MHz ultrasound and a heat probe. The average intensity of the CW radiation was equal to the peak intensity of the PW radiation, which had a pulse width of 10 ms and repetition frequency of 40 pps. Temperature increases were greatest with CW and least with PW irradiation. James and Halliwell inferred from the slower rate of temperature increase with thermal irradiation (heating) than with CW ultrasound that, with the latter, mechanical effects contributed to the generation of heat. A 20-minute exposure of the semicircular canal of a calf to 5-W/cm^2 ultrasound led to collapse of the endolymph, damage to the utricular macule and to the hair cells of the crista, and degeneration of the organ of Corti, according to a 1963 report by Formby [US0503].

A 1978 analysis of the response of the round window of the cat to 5-MHz ultrasound by Foster and Wiederhold [US0166] suggested that radiation pressure transients induced in the brain tissue, cochlear microphonics, and neural responses comprised the electrical response. For each experiment, a probe radiating ultrasonic energy with a frequency of 5 MHz, peak intensity of 30 W/cm^2, and pulse width of 68 μs was placed in contact with the dura mater. The auditory nerve responses obtained with this procedure were then compared with ones obtained using auditory stimuli, ie, clicks and pops. Such sounds induced microphonics and neural potentials only.

Table XIII-6 summarizes the available data on the effects of ultrasound on the animal ear.

(c) Effects on the Eye

Direct coupling of ultrasonic energy to the eye has been found to lead to a wide variety of effects. In 1956, Baum [US0240] reported that 5-minute exposures to 1-MHz ultrasound produced intensity-dependent changes in the eyes of 17 rabbits. Multiple exposures were also used. Intensities between 0.25 and 1 W/cm^2 produced slight warming of the orbital tissues. Reversible effects were noted after irradiation between 1.5 and 2 W/cm^2. These included variable conjunctiva, transient opacity of the cornea, paralimbal vascular congestion, increased ocular pressure, and flare. Finally, intensities of 2.5-3 W/cm^2 were observed to cause irreversible gross and microscopic changes; epilation and burning of the skin; subconjunctival hemorrhage; proptosis of the eyeball; congestion of the limbus and dilation of paralimbal vessels; opacities in the cornea; flare; edema and stromal hemorrhage of the iris, ciliary body, and cornea; infiltration of the limbus by lymphocytes, eosinophils, and polymorphonuclear lymphocytes; protein exudates in the anterior chamber; and posterior synechiae in the iris.

TABLE XIII-6

EFFECTS OF EXPOSURE TO ULTRASOUND ON EARS OF ANIMALS

Species	Effect*	Intensity (W/cm^2)**	Duration (min)**	Calculated Dose (kJ/cm^2)**	Method of Application	Frequency (MHz)**	Reference
Guinea pig	Epithelial changes in tympanic membrane	0.5	10	0.3	Contact	1	US1171
	Hyperplasia and edema of membrane mucosa	1.5	"	0.9			
	Necrosis of membrane, organ of Corti, and nerve myelin	3	"	1.8			
	Destruction of inner ear and auditory nerve	8	"	4.8			
"	Destruction of inner ear	0.9	30	1.62	"	1.35	US0536
"	Dose-dependent damage to labyrinth	22	2.5-15	3.3-19.8	"	3	US0412
"	Vascular damage to inner ear and cochlea	20	3	3.6	"	1.25	US0221
Rabbit	Damage to labyrinth	13	40-120	31.2-93.6	"	1	US0475, US1106
Cat	Degeneration of labyrinth and cochlea	10	15	9	"	1	US0489
Sheep	Vascular damage to labyrinth, destruction of cochlea	10-22	9	5.4-11.88	"	1, 3, 5	US0491, US0522, US0718
Cow	Damage to labyrinth, degeneration of organ of Corti	5	20	6	"	--	US0503

*Lack of effect denoted by (-)
**Except where noted

Exposures at commonly used diagnostic intensities did not damage the eye, according to a 1974 report by Ziskin et al [US0912]. Twenty male rabbits were irradiated with 9.5-MHz ultrasound at an intensity of 33.7 mW/cm^2. Gross and microscopic examinations made immediately and 4-15 days after both 1- and 4-hour exposures revealed no abnormalities.

Superficial corneal defects were described in rabbits in 1965 by Jankowiak et al [US0379]. Ten exposures on alternate days were performed under one of three exposure conditions: 0.05 W/cm^2 for 1.5 minutes, 0.1 W/cm^2 for 1 minute, and 0.2 W/cm^2 for 0.5 minutes. For each dose, the right eyes of four rabbits were irradiated, through a coupling medium, with 1-MHz ultrasound. Electron micrographs were prepared 23 days after exposure and compared with micrographs obtained from the nonirradiated eyes as well as from three controls. Erosion of the cornea, slow pupillary reaction, erythrocytic extravasion of the ocular fundi, and degeneration of the nerve cells of the retina were observed for all three exposures. Preisova et al [US0551], in 1965, attributed such changes to temperature increases at the surface of the eye. These ranged from 1.05 to 1.6°C after exposures at intensities of between 0.05 and 2 W/cm^2.

A 1967 report by Rosenberg and Purnell [US0334] described the production, in 109 rabbits, of lesions in the ciliary body and temporary reduction in intraocular pressure by focused PW ultrasound. Average intensities of 12 W/cm^2 for 3-MHz radiation and 28 W/cm^2 for 7-MHz radiation, corresponding to peak values of 58 and 135 W/cm^2, respectively,

were used. The exposures were short, 2-45 seconds, and 2-10 irradiations were performed on each eye.

In 1978, Olson et al [US0180,US0179] discussed the production of lesions of the corneal endothelium of the rabbit. The damage was associated with the ultrasonic phacoemulsification procedure and was found to heal within 24 hours after exposure. Cats treated similarly showed a loss of endothelial cells and edema of the cornea, according to a 1976 report by Binder et al [US0383]. They, however, attributed the damage to the non-irradiation procedures of the phacoemulsification technique. Polack [US0183] reported that phacoemulsification and phacofragmentation produced dose-dependent degeneration of the corneal endothelium as well as corneal edema in rabbits and cats. Exposure to focused 2.07-MHz ultrasound was reported by Moiseyeva and Gavrilov [US0201] in 1977 to cause reversible turbidity of the lens of the rabbit; ie, the effects disappeared within 4-5 weeks in the former case but persisted for 1 year in the latter. Exposure conditions were not reported specifically for these experiments but appear to have involved intensities of no more than 350 W/cm^2 and exposure durations of 1-2 minutes.

The production of cataracts has also been studied. In 1966, Bernat et al [US0582] described the effects of 800-kHz ultrasound at an intensity of 1.5 W/cm^2 on the rabbit eye. A 10-minute direct contact exposure of one eye of each animal produced an immediate rise in intraocular pressure, swelling of the cornea, and exudation of protein into the anterior chamber. When three exposures were performed on successive days, cataracts were observed to form beginning 8-9 days after exposure. The dose required to produce a cataract in the rabbit was discussed by Torchia et al [US0351] in 1967. Experiments performed on 200 rabbits using a CW 3-MHz ultrasound generator indicated that the logarithm of the intensity necessary for cataract production varied inversely with the time of exposure, such that at 90 W/cm^2 1-second exposures were sufficient but at 30 W/cm^2 7 seconds were required. Cataracts did not form with exposures of 0.5 seconds or less. Pulsed ultrasound was less efficient for inducing cataracts.

In a 1978 report, Lizzi et al [US0174] disagreed with Torchia et al. The former group used 9.8-MHz ultrasound to irradiate the eyes of 60 rabbits. They found that for exposures shorter than approximately 0.1 second, a constant amount of energy was required for cataract formation; ie, the logarithm of intensity was inversely proportional to the logarithm of exposure duration. Progressively increasing intensities were necessary for longer exposures. For example, cataracts were produced by a 0.05-second exposure at 1,100 W/cm^2, a 0.1-second exposure at 600 W/cm^2, and a 5-second exposure at 250 W/cm^2. Based on the results of experiments with PW ultrasound, Lizzi and Driller [US1103] suggested in a 1978 abstract that thermal mechanisms were responsible for producing permanent chorioretinal lesions in rabbits. Two exposure regimes, using focused 9.8-MHz ultrasound at intensities up to 1.5 kW/cm^2, were compared: long pulses (50-200 ms) with low repetition frequencies (<10 pps) and short pulses (10-50 μs) with high repetition frequencies (>10 pps). The time-averaged PW intensities required to produce lesions were found to be equal to the intensities required for CW ultrasound.

Damage to the retina and optic nerve has been observed following ultrasonic irradiation. In 1964, Purnell et al [US0434] noted that chorioretinal lesions could be produced in the eyes of 40 rabbits by exposures of 2-3.5 seconds to 1-MHz ultrasound at an intensity of 1 MW/cm^2. Cataract formation was also observed. Low-frequency ultrasound was found to produce similar lesions, according to a 1969 study by Karlin [US0376]. Focal chorioretinal lesions and scleral damage were observed in 91 of 100 rabbits exposed to the 25-kHz ultrasonic radiation.

The effects of ultrasonic irradiation on the retina and optic nerve were discussed by Jankowiak and Majewski [US0071] in 1965. Exposures similar to those described above [US0379] led to atrophy of the horizontal nerve fibers of the retina, which lack a myelin sheath, and focal demyelination of the nerve fibers of the optic nerve and in the visual center of the cerebral hemisphere. On the contrary, Moiseyeva and Gavrilov [US0201] observed no changes in the retinas of rabbits irradiated with focused 2.07-MHz ultrasound at maximum intensities of 250-350 W/cm^2 and exposure durations of 1-2 minutes. Other effects on the optic nerve were described by Goodwin [US0584] in 1968. He irradiated the exposed optic nerves of rabbits with 3.75-MHz ultrasound and noted that, above a threshold intensity of 107 W/cm^2, there was an intensity-dependent decrease in latency, increase in conduction velocity, and increase in amplitude of the electrical response. Biochemical changes in the ganglious cells of the retina have also been reported. A 1978 study by Marmur and Plevinskis [US0198] stated that the concentration of proteins and carboxyl groups was increased in the retinas of 254 rabbits irradiated with focused 880-kHz ultrasound at intensities of 0.2, 0.4, and 0.6 W/cm^2. The exposures consisted of 10 daily irradiation sessions of 5 minutes each. The fact that irradiation at 1 W/cm^2 produced decreases in protein and carboxyl group concentrations was not explained.

The permeability of the eye has been found to be affected by ultrasound. Zaiko and Mints [US0468] reported, in 1962, that exposure to 800-kHz ultrasound at intensities of 0.4-4 W/cm^2 for 1 minute increased the permeability of the cat eye to radioactive phosphorus (^{32}P). The average increase in permeability induced in the cornea, chamber fluid, iris and ciliary body, vitreous body, and crystalline lens was approximately 30%. These changes were correlated with an intensity-dependent increase in intraocular pressure, which attained a maximum 5 minutes after irradiation and then decreased to preexposure values by 30 minutes. Thirty-two cats and rabbits were tested in the experiments. Similar results using ultrasound at the same frequency but at the lowest intensity mentioned above were presented by Marmur [US0419] in 1964. Exposure of 55 rabbits for 5 minutes each was observed to increase the permeability to Na_2SO_4 (^{35}S served as radioactive tracer) of the aqueous and vitreous humors, cornea, and crystalline lens of the eye. Increased amounts of ^{35}S, relative to nonirradiated eyes, were present in all of these tissues for as long as 72 hours after exposure.

The effects of ultrasound on the eye are summarized in Table XIII-7.

TABLE XIII-7

EFFECTS OF EXPOSURE TO ULTRASOUND ON EYES OF ANIMALS

Species	Effect*	Intensity (W/cm^2)**	Duration (min)**	Calculated Dose (kJ/cm^2)**	Method of Application	Frequency (MHz)**	Reference
Rabbit	Variable conjunctiva, corneal opacities, hypertony	1.5-2	5	0.45-0.6	Contact	1	US0240
	Burning and epilation of skin, hemorrhage, congestion of limbus, corneal opacities, edema of iris, inflammation, protein exudation	2.5-3	"	0.75-0.9			
"	Superficial corneal defects	0.05 0.1 0.2	1.5 min/d for 10 d 1 min/d for 10 d 0.5 min/d for 10 d	0.045 0.06 0.06	Coupled	1	US0379, US0551
"	Lesions in ciliary body, reduction in intraocular pressure	12 28	2-45 s for 2-10 irradiations	0.048-12.6	Contact	3 7	US0334
"	Lesions in retina, choroid, and sclera	<1500	0.01-20 s	0.015-30	"	9.8 (PW)	US1103
"	Lesions in retina	600	40-50 s	24-30	"	2.07	US0201
"	Microscopic damage (-)	33.7 mW/cm^2	60, 240	121-484	"	9.5	US0912
"	Cataracts	1.5	10 min/d for 3 d	2.7	"	0.8	US0582
"	"	90 30	1 s 7 s	0.09 0.21	"	3	US0351
"	"	1,100 600 250	0.05 s 0.1 s 5 s	0.055 0.06 0.75	"	9.8	US0174
"	Damage to retina, demyelinization of optic nerve	1 MW/cm^2	2-3.5 s	2-3.5 J/cm^2	"	1	US0434
"	"	0.05 0.1 0.2	1.5 min/d for 10 d 1 min/d for 10 d 0.5 min/d for 10 d	0.045 0.06 0.06	"	1	US0071

TABLE XIII-7 (CONTINUED)

EFFECTS OF EXPOSURE TO ULTRASOUND ON EYES OF ANIMALS

Species	Effect*	Intensity (W/cm^2)**	Duration (min)**	Calculated Dose (kJ/cm^2)**	Method of Application	Frequency (MHz)	Reference
Rabbit	Damage to optic nerve evidenced by changes in electrical response	107	--	--	Contact (nerve)	3.75	US0584
"	Increase in permeability to ^{32}P	0.4-4	1	0.024-0.24	Contact	0.8	US0468
"	Increase in permeability to $Na_2{}^{35}SO_4$	0.4	5	0.12	"	0.8	US0419
"	Biochemical changes, damage to retina	0.2-1	5 min/d for 10 d	0.6-3	"	0.88	US0198
Rabbit, cat	Destruction of corneal endothelium	--	5	--	"	--	US0183

*Lack of effect denoted by (-)
**Except where noted

(d) Effects on Tissues

Heating of body tissues by ultrasound was mentioned by Southam et al [US1009] in their 1953 report. Exposures of mice at intensities of 10 W/cm^2 were observed to cause increased body temperature, hindquarter paralysis, and hemorrhaging in the lung, liver, and spinal cord without visible rupture of the capillaries. These effects were more evident after irradiation with 2- and 3.5-MHz than with 1- and 0.5-MHz ultrasound. In 1959, Gersten [US0808] described ultrasound-induced increases in tissue temperature. He irradiated anesthetized dogs for 1 minute with directly coupled 0.49-, 1-, and 3-MHz ultrasound at intensities of 1 and 1.5 W/cm^2. Temperature increases in the thigh, knee, spinal column, and sciatic nerve were greatest in the subcutaneous tissue of each area and least in the muscle tissue, intra-articular area, spinal canal, and periosteum, respectively. The temperature increase below the skin surface was inversely dependent on frequency, with 0.49-MHz ultrasound producing the greatest increases.

The skin has been shown to be damaged by ultrasonic irradiation. Bell and Argyris [US0756] compared the effects of 1-MHz ultrasound on the skin of 86 mice in the growing and resting phases of the growth cycle and reported, in 1957, that growing skin was more susceptible to ulceration. By determining that the temperature changes induced on the skin by ultrasound and focused visible light were similar and that both produced similar effects, they inferred that heat was the causative factor. Similar results for 52 mice irradiated for 30 seconds with 1-MHz ultrasound at an intensity of 360 W/cm^2 were reported by Argyris and Bell [US0474] in 1969. Both studies revealed loss of the epidermal layer, pycnotic nuclei, inflammation, edema, and muscle separation. Superficial heating of the skin of pigs was reported in 1963 by Godfrey et al [US0614] after exposure to ultrasound at an intensity of 3 W/cm^2 for 3 min/d for 2, 3, and 4 weeks. According to a 1973 report, Chirkina [US0247] was able to observe inflammation and necrosis of the skin of shaved rats following daily 5-minute contact exposures to 830-kHz ultrasound at an intensity of 0.6 W/cm^2 for 5 days and at 1.8 W/cm^2 for 1 day. The observed effects included vascular stasis, hemorrhaging, edema, mast cell degranulation, and leukocytic infiltration. Exposures at 0.2 W/cm^2 were found to stimulate skin regeneration.

The ultrasound-induced transmission of drugs through the skin, called phonophoresis, has been discussed in several reports. Novak [US0872], in a 1964 report, stated that an exposure of 5 minutes to 2 W/cm^2 increased the absorption of the anesthetic lidocaine into rabbit muscle by approximately 15%. The technique has been attempted with anesthetized pigs in a series of studies by Griffin and Touchstone [US0622,US0815,US0816]. In 1962, they showed [US0622] that a combined treatment of ultrasound (3 W/cm^2 for 5 minutes) and cortisol increased the content of cortisol in the skeletal muscles of eight boars by approximately 1.65 times that found after ultrasound treatment alone. A comparison [US0816], published in 1968, between exposures of six swine to 1-MHz ultrasound at 0.3 W/cm^2 for 17 minutes and of four swine at 0.1 W/cm^2 for 51 minutes indicated that the latter was approximately 20 times more effective in increasing the content of cortisol in the muscles of the back. That altering the depth of penetration of ultrasonic energy into the body by using differing frequencies had no effect on the amount of cortisol penetrating the tissues was shown in the 1972 report [US0815]. Frequencies of 90, 250, 500, 1,000, and 3,600 kHz were compared in exposures of 1 W/cm^2 for 17 minutes. Cortisol extracted from the muscles and peripheral nerves of the fourth swine used at each frequency indicated that 250 kHz and 3.6 MHz were most effective and 500 kHz and 1 MHz were least effective for phonophoresis. Griffin stated that he chose the pig for his studies because of the similarity of its soft tissue proportions to those of humans. By measuring the increase in the concentration of ^{131}I in the thyroid, Dohnalek et al [US0141] stated, in 1965, that ultrasound irradiation increased the permeation of NaI through the skin. The abdomens and hind legs of rabbits and dogs were shaved, a paste containing the radioactive iodide was applied, and then an ultrasonic applicator was placed over the paste. Ten minutes of exposure to 800-kHz ultrasound at an intensity of 0.8-1 W/cm^2 was sufficient to increase iodine penetration in dogs and rabbits to 2.4 and 3.85 times greater, respectively, than in nonirradiated controls.

Ultrasound has been found to alter the function of the gastrointestinal tract. A 1965 study from Faitel'berg-Blank [US0375] showed that 5 minutes of exposure to 800-kHz ultrasound at an intensity of 0.5 W/cm^2 increased absorption of glucose in the gastric mucosa of 19 dogs by an average of 2.7% while changing absorption by the intestinal mucosa insignificantly. Increases in absorption were not observed after anesthetization of the skin of the abdomen or the mucous membranes of the stomach and intestine nor after blockage with novocaine of the vagosympathetic nerve trunk and the intervertebral ganglia. Denervation of the intestinal loop, bilateral division of the splanchnic nerves, or extirpation of the solar plexus also lowered or abolished the ultrasound-induced increase in absorption. Similar effects on the control of absorption by the nervous system were noted with irradiation at an intensity of 1.5 W/cm^2. Acid secretion by the gastric mucosa of six dogs was reduced temporarily (1-2 weeks) by irradiation with unfocused ultrasound at an intensity of 2.5 W/cm^2 for 5 minutes, according to a 1966 report by Smith et al [US0340]. Lesions resembling peptic ulcers were also observed to form approximately 1 week after irradiation with 5 W/cm^2 and to persist for 1-2 months.

A dose-dependent disruption of the mast cells of the rat mesentery was reported by Valtonen [US0352] in 1968. The abdomens of adult males were irradiated with 1-MHz ultrasound at 1 W/cm^2 for 1 minute, 2 W/cm^2 for 2 minutes, and 3 W/cm^2 for 1, 2, and 3 minutes. The percentage of intact mast cells in the intestine was reduced by 24.5% by a dose of 60 J/cm^2 and by 52.3% by 900 J/cm^2.

Additional ultrasound-induced effects have been reported in other tissues. Ter Haar et al [US1147] reported, in 1978, that 4 minutes of exposure at 2 W/cm^2 to 3-MHz ultrasound induced contractions of the smooth muscle of the mouse uterus. Their frequency was observed to increase by 60% during the irradiation. Retardation in the growth rate of the rabbit larynx, accompanied by alterations in the pattern of growth, were reported by Karduck and Richter [US0397] in 1975. They irradiated the thyroid cartilage of twelve 4-week-old rabbits for 10 minutes, using an intensity of 5 W/cm^2. Scanning electron and reflecting light micrographs taken 1, 6, and 12 weeks after exposure revealed increasingly smaller areas of cartilaginous necrosis. Chondroneogenesis was observed to begin at 6 weeks, but growth of the endolaryngeal perichondrium was asymmetric.

The variety of effects produced in the soft tissues of animals by ultrasound are given in Table XIII-8.

(e) Effects on the Skeletal System

As pointed out in Chapter I, bone has the largest ultrasonic absorption coefficient of any of the tissues of the body; thus, high temperatures can be expected to be produced in and near the skeleton by ultrasound. Nelson et al [US0115] presented, in 1950, the results of measurements made in the hindlegs of three anesthetized dogs following exposures of 1.5 minutes to 800-kHz ultrasound. Increases in the temperatures of the muscle, bone cortex, and bone marrow averaged 1.1, 5.9, and 5.4 C, respectively. At twice the power output, the increases were 2.2, 10.5, and 10.3 C, respectively. Experiments with longer exposures at lower intensities showed that the temperature increase was dependent on dose and not intensity. Similar large temperature increases in bone were reported by Herrick [US0763] in 1953; however, the temperature increase in the cortex of the dog femur was found to be nearly twice as large as that produced in the

TABLE XIII-8

EFFECTS OF EXPOSURE TO ULTRASOUND ON SOFT TISSUES OF ANIMALS

Species	Effect*	Intensity (W/cm^2)**	Duration (min)**	Calculated Dose (kJ/cm^2)**	Method of Application	Frequency (MHz)**	Reference
Dog	Heating of subcutaneous layer	1, 1.5	1	0.06, 0.09	Contact	0.49, 1, 3	US0808
Pig	Superficial heating of skin	3	3 min/d for 2, 3, 4 wk	1.08, 1.62, 2.16	"	--	US0614
Mouse	Ulceration of skin	360	0.5	10.8	"	1	US0474, US0756
Rat	Inflammation and degeneration of skin	0.6, 1.8	5	0.24, 0.72	"	0.83	US0247
Rabbit	Phonophoresis	2	5	0.6	"	--	US0872
Rabbit, dog	"	0.8-1	10	0.48-0.6	"	0.8	US0141
Pig	"	3	5	0.9	"	--	US0622
"	Phonophoresis (longer exposure more effective)	0.3 0.1	17 51	0.306	"	--	US0816
"	Phonophoresis (middle frequencies more effective)	1	17	1.02	"	0.09, 0.25, 0.5, 1, 3.6	US0815
Mouse	Frequency-dependent increases in body temperature, hemorrhaging of lung, liver, and spinal cord, paralysis	10	--	--	"	0.5, 1, 2, 3.5	US1009
"	Induction of uterine contractions	2	4	0.48	"	3	US1147
"	Biochemical changes in skin, lungs, and peritoneal cells (-)	1	100-200 s	0.1-0.2	"	2	US0792
Rat	Dose-dependent disruption of mast cells in mesentery	1 2 3	1 2 1, 2, 3	0.06 0.24 0.18, 0.36, 0.54	"	1	US0352
Rabbit	Retardation in growth of larynx	5	10	3	"	--	US0397

TABLE XIII-8 (CONTINUED)

EFFECTS OF EXPOSURE TO ULTRASOUND ON SOFT TISSUES OF ANIMALS

Species	Effect*	Intensity (W/cm^2)**	Duration (min)**	Calculated Dose (kJ/cm^2)**	Method of Application	Frequency (MHz)**	Reference
Dog	Increase in absorption by gastric mucosa	0.5, 1.5	5	0.15, 0.45	Contact (intestinal loop)	0.8	US0375
"	Decreased acid secretion by mucosa	2.5	5	0.75	"	—	US0340
	Ulceration of mucosa	5	5	1.5			

*Lack of effect denoted by (-)
**Except where noted

marrow. Pulsed ultrasound at a frequency of 1 MHz and an intensity of 1 W/cm^2 was used. Exposures of 2 minutes produced duty cycle-dependent increases in the cortex of 0.98 C at a duty cycle of 0.1, 1.98 C at 0.2, 4.19 C at 0.4, and 12.28 C at 1 (CW). According to a 1967 report by Lehmann et al [US0293], the same distribution of temperature increases was produced in the femur of a hog exposed to ultrasound for 5 minutes at an intensity of 1.5 W/cm^2. The respective increases for the marrow, spongy bone, cortical bone surface, and muscle were 0.93, 4.56, 3.57, and 2.15 C. Temperature increases in the knee joint of the hog were described in a 1968 report by the same group [US0849]. The largest increases occurred in the meniscus and the smallest in the intercondylar fossa and muscle tissue surrounding the joint. The hogs were anesthetized in both of the aforementioned experimental studies.

Changes in bone tissue have also been observed. Multiple exposures of the upper tibial epiphysis of 9 dogs and 27 rabbits to 800-kHz ultrasound produced variable changes in the growing bone, according to a 1953 study by DeForest et al [US0791]. X-ray examinations made 6-7 months after one to twenty-one 5- or 10-minute exposures revealed development of regions of rarefaction and fractures in the epiphysis, widening of the epiphyseal line, displacement of the epiphysis, erosion of femoral condyles, sclerotic changes, dislocation of the knee, and edema. Bone growth was not accelerated. Bender et al [US0241] reported contradictory results in 1954. Two- to five-minute ultrasound irradiations were given up to 25 times to the femurs of 26 dogs. Microscopic examinations made from 0.5 hours to 21 weeks after exposure showed no significant changes in the

cortical bone. However, hemorrhage, osteogenesis, and fibrosis were observed in the marrow, as was formation of new bone in the subperiosteal region.

Stimulation of bone healing or new bone growth was not found to occur in the 1957 study by Ardan et al [US0697]. They irradiated the femurs of 67 adult dogs with ultrasound at intensities of 0.5-2.5 W/cm^2. Three- to five-minute exposures were found to produce cortical and medullary fibrosis, fibrous tissue defects, delays in healing, discoloration and eburnation, and fractures. Their rates of occurrence were dependent on the applied dose. Osteogenesis was not observed in any of the femurs. In 1960, Janes et al [US0620] reported no changes, ie, neither growth nor destruction, in the femoral bones of seven dogs exposed for 10 minutes to 800-kHz ultrasound at intensities of 0.6, 1, 1.5, and 2 W/cm^2. Microradiographic, microangiographic, as well as normal and polarized light microscopic observations were made from 1 to 3.75 years after exposure. However, higher intensities and longer exposures were capable of inducing necrosis of cortical bone, according to a second study published by Janes et al [US0523] 2 years later. The femurs of 13 dogs were exposed at intensities of 2.2 and 5 W/cm^2 for 15 or 30 minutes. Rarefaction and periosteal reaction were evident in all of the dogs; within 2 weeks after exposure at the higher intensity, death and avascularization of the cortex in the diaphyseal region occurred. Thickening of the periosteum and new bone growth in the medullary cavity and periosteal regions were also observed at the same time. Janes et al considered this growth to represent healing of the ultrasound-induced damage and not stimulation of new bone growth.

Damage to the bone marrow was reported by Payton et al [US0324] in 1975. A series of ten 5-minute irradiations with 875-kHz ultrasound was performed on the femurs of six dogs over a period of 14 days, with three dogs exposed at an intensity of 1.5 W/cm^2 and three at 2.5 W/cm^2. Examinations of the blood and marrow made 39 and 50 days after exposure indicated no significant changes, relative to preexposure values, in hematocrit, hemoglobin content, red blood cell (RBC) count, white blood cell (WBC) count, reticulocyte fraction, sugar content, osmotic fragility of blood cells, and coagulation time. Peripheral blood smears provided no evidence of fragmentation, marrow regeneration, or aplasia. Changes were observed only when two of the dogs were exposed to a second series of 10-minute irradiations at 2.5 W/cm^2. Under these conditions, the clotting time of the peripheral blood and the pressure and fat content of the marrow were seen to increase, the periosteum became discolored (yellow) and the bone brittle, and a fibroblastic reaction occurred.

Two reports dealing with the effect of ultrasound on bone mineral metabolism were published by Kolar et al [US0526,US0527] in 1964 and 1965, respectively. With one group of 45 rats, one knee of each rat was irradiated with PW ultrasound for 5 minutes at an intensity of 4.75 W/cm^2; with a second group, the neck was similarly irradiated. Five irradiated rats from each group and five controls were injected with radioactive calcium (^{45}Ca) 4, 8, 16, 21, 28, 42, 62, 84, and 102 days after exposure. No bone deformities were noted, but slight reductions in calcium uptake in the tibia, scapula, and incisors were observed between days 42 and 102.

The responses of bone tissue to ultrasound are summarized in Table XIII-9.

(f) Effects on the Circulatory System

Ultrasound has been found to affect the structure and function of the heart. In 1961, Zimny and Head [US0469] described the results of experiments with 38 ground squirrels irradiated with CW 1-MHz ultrasound for 3 minutes at an intensity of 0.5 W/cm^2, 1 minute at 1 W/cm^2, 6 minutes at 1.25 W/cm^2, or 6 minutes at 3 W/cm^2. Biochemical examinations of the cardiac muscles of awake and hibernating animals exposed in the left thoracic area indicated significant reductions in adenosine triphosphate (ATP) and phosphocreatine levels of 37-46% and 68-82%, respectively. Glycogen and inorganic phosphate levels were found to increase but not significantly. Changes in heart mitochondria enzyme activity were reported by Maneva and Beleva-Staikova [US1119] in 1976. Ten to twelve rats were irradiated for 5 minutes at each of three intensities (0.2, 0.6, and 1 W/cm^2), and the activities of succinate dehydrogenase, cytochrome oxidase, and $NADH_2$-cytochrome C reductase were measured 1, 24, and 48 hours later. Decreases in activity were noted for all three enzymes.

Applying ultrasonic energy directly to the canine mitral valve produced mitral lesions, congestive heart failure, an inflammatory reaction,

TABLE XIII-9

EFFECTS OF EXPOSURE TO ULTRASOUND ON SKELETAL SYSTEM OF ANIMALS

Species	Effect*	Intensity (W/cm^2)**	Duration (min)**	Calculated Dose (kJ/cm^2)**	Method of Application	Frequency (MHz)**	Reference
Dog	Dose-dependent increases in bone temperature	--	1.5	--	Contact	0.8	US0115
"	Dose-dependent heating of cortex greater than that of marrow	1	2	0.12	"	1	US0763
Hog	Temperature increase in cortex greater than that in bone surface, muscle, and marrow	1.5	5	0.45	"	--	US0293, US0849
Rabbit, dog	Inhibition of bone growth, alteration in bone structure	--	5, 10	--	"	0.8	US0791
Dog	Hemorrhage, fibrosis, and osteogenesis of marrow	--	2-5 for 1-25 times	--	"	--	US0241
"	Dose-dependent inhibition of new growth and healing, fibrosis, eburnation, discoloration, fracturing of bone	0.5-2.5	3-5	0.09-0.75	"	--	US0697
"	Rarefaction and periosteal reaction of bone, necrosis and avascularization of cortex	2.2, 5	15, 30	1.98-9	"	0.8	US0523
"	Increase in pressure, fat content, and blood clotting time of marrow; bone became discolored and brittle	2.5	5 min/d for 20 d	15	"	0.875	US0324
"	Bone growth and structure (-)	--	2-5 for 1-25 times	--	"	--	US0241
"	Histologic changes in bone (-)	0.6, 1, 1.5, 2	10	0.36-1.2	"	0.8	US0620
"	Blood and tissue of bone marrow (-)	1.5, 2.5	5 min/d for 10 d	4.5, 7.5	"	0.875	US0324
Rat	Reduction in ^{45}Ca uptake	4.75	5	1.225	"	--	US0526, US0527

*Lack of effect denoted by (-)
**Except where noted

and systolic murmur, according to a 1969 report by Reeves et al [US0436]. The examinations were performed at various intervals from 3 to 690 days after 5-20 minutes of exposure to 1-MHz ultrasound at an intensity of 5 W/cm^2. Paul and Imig [US0874] discussed, in 1955, the production of variable changes in blood flow after ultrasonic irradiation of the femur of the dog. Anesthetized dogs exposed to 800-kHz ultrasound at an intensity of 1 W/cm^2 for 15 minutes also showed average increases of 6 C in the temperature of the muscle tissue.

Several studies have been performed on the rabbit. In 1957, Totani et al [US1010] reported that irradiation with 55-kHz ultrasound caused a reduction in blood pressure after an intensity-dependent delay. The production of lesions in the central artery of the rabbit ear by 1-MHz ultrasound was described by Fallon et al [US0798] in 1972. Exposures at intensities of 25, 100, 400, and 1,500 W/cm^2 for maximum periods of 720, 40, 1.5, and 0.1 seconds, respectively, were found to cause vacuolization, degeneration, and necrosis of cells, endothelial loss, and inflammation in the arteries of 12 rabbits. Electron micrographs of the ultrasound-induced damage to the artery were presented by Fallon et al [US1087] in 1973. As in the previous study, examinations were made 1, 8, 30, and 72 hours after exposure. These revealed separation of arterial cell membrane and basement membrane of the smooth muscle cells, vacuolization of cells, and the formation of dense granules and $CaPO_4$ precipitates in and swelling of the mitochondria.

A series of three papers by Dyson and coworkers discussed the induction of RBC stasis in chick embryos by 3-MHz ultrasound. In the 1971 and 1972 reports, Dyson et al [US0054,US0936] attributed this effect to the temporary formation of RBC aggregates during irradiation. The threshold was lower for veins than for arteries, at slower heart beat rates, and with larger bore vessels. Stasis was observed only when the irradiated vessel was aligned parallel to the ultrasonic field. Aggregates appeared at half-wavelength intervals along the vessel, according to the 1973 report by Dyson and Pond [US0255]. The lowest threshold intensity reported was 0.79 ± 0.02 W/cm^2.

Changes in the amounts of various biochemicals in the blood have also been studied following ultrasonic irradiation. A 1965 report by Straburzynski et al [US0580] presented measurements of glutathione levels in 30 male guinea pigs exposed to 800-kHz ultrasound at 4 W/cm^2 for 10 minutes. Irradiation of the thorax and the lumbar region was found to reduce the glutathione content by 15 and 23.7%, respectively. Reduced levels were also found in the muscles, lungs, liver, and adrenals. The concentration of ascorbic acid, on the other hand, increased in the blood, muscles, and liver. A second study from the same laboratory, published by Bernat et al [US0583] in 1966, dealt with the content of protein and nitrogenous compounds in the blood as well as its osmolarity. The conditions of irradiation were the same as before [US0580] except that intensities of 0.5-4 W/cm^2 were used. Statistically significant increases in nitrogen content were noted 1 hour after irradiation at 2.5 and 4 W/cm^2 and in alpha-globulin at 4 W/cm^2. In addition, variable changes in protein and nitrogen content were observed in the lungs, liver, and intestine.

Multiple irradiation of guinea pigs with sonic and ultrasonic energy in the spectral range of 250 Hz to 32 kHz lowered the phosphorus levels of the blood, according to a 1967 study by Krzoska [US1045]. Exposures of 30 min/d at a sound intensity of 117 dB (8.45×10^{-4} W/cm^2) were given for 15 or 30 days. Decreases in total and acid-soluble phosphorus (predominantly ATP, fructose-1,6-diphosphate, and 2,3-diglyceric acid) were measured immediately and 14 days after exposure. The inorganic phosphorus and phospholipid contents were not affected by irradiation.

Results of a comparative study of lactate dehydrogenase (LDH) levels in the blood of 10 nonirradiated rats and 15 rats exposed to 60-kHz ultrasound for 15 minutes were presented by Fishman [US1034] in 1971. No significant differences in LDH, which is assumed to be released by disrupted cells, were found. Beleva-Staikova et al [US0190] discussed the effect of 880-kHz ultrasound on the synthesis of porphyrin compounds by rats in a 1978 report. Five-minute exposures at intensities of 0.2, 0.6, and 1 W/cm^2 were followed by determination 1, 24, and 48 hours after exposure of proto-, copro-, and uroporphyrins in erythrocytes, feces, and urine. Variable changes were detected, with no clear pattern of response.

Table XIII-10 summarizes the various effects of ultrasound on the blood.

TABLE XIII-10

EFFECTS OF EXPOSURE TO ULTRASOUND ON CARDIOVASCULAR SYSTEM OF ANIMALS

Species	Effect*	Intensity (W/cm^2)**	Duration (min)**	Calculated Dose (kJ/cm^2)**	Method of Application	Frequency (MHz)**	Reference
Rat	Decrease in enzyme activities in heart mitochondria	0.2, 0.6, 1 0.2	5 10 d	0.06, 0.18, 0.3	Contact	--	US1119
Squirrel	Reduction in levels of ATP and and phosphocreatine in heart	0.5 1 1.25 3	3 1 6 6	0.09 0.06 0.45 1.08	"	1	US0469
Dog	Mitral valve lesions, congestive heart failure, heart murmur, inflammation	5	5-20	1.5-6	Contact (mitral valve)	1	US0436
Rabbit	Arterial vacuolization, degeneration, necrosis, and inflammation; membrane separation	25 100 400 1,500	720 s 40 s 1.5 s 0.1 s	18 4 0.6 0.15	Contact	1	US0798, US1087
Guinea pig	Decreases in glutathione and ascorbic acid content and increases in nitrogen and protein content of blood	4	10	2.4	"	0.8	US0580, US0583
"	Reduced phosphorus levels in blood	0.845 mW/cm^2	15 d, 30 d	--	"	Spectrum from 0.25 to 32 kHz	US1045
Rat	LDH level in blood (-)	--	15	--	"	0.06	US1034
"	Porphyrin content of blood (-)	0.2, 0.6, 1	5	0.06, 0.18, 0.3	"	0.88	US0190

*Lack of effect denoted by (-)
**Except where noted

(g) Effects on Internal Organs

Several studies dealing with the general effects of ultrasound on the internal organs have been published. In 1970, Beleva-Staikova [US1017] reported that single, short exposures of rats to 880-kHz ultrasound at intensities of 0.04, 0.6, and 1 W/cm^2 and long-term exposure (5 days) at 0.04 and 0.2 W/cm^2 reduced the concentrations of ascorbic, dehydroascorbic, and diketogluconic acid in the liver, kidneys, and heart muscle. Fifty male rats were irradiated, and acid levels were determined 1, 24, and 48 hours after single exposures and immediately after the long-term exposure. The reductions observed in heart muscle were not significant. Changes in the nucleic acid content of several organs were reported by Chirkin et al [US1023] in 1971. Comparisons were made between one group of 150 rats exposed once to 830-kHz ultrasound at intensities of 0.2, 0.6, and 1.8 W/cm^2 and a second group of 150 rats exposed once a day for 5 days. Increases in the DNA and RNA content of the kidney were observed to remain stable between 10 minutes and 30 days after a single exposure: two maxima were observed, one at 10 minutes and a second between 1 and 7 days, after multiple exposure. Single exposures decreased the nucleic acid content in the liver and intestines slightly up to 90 days after exposure; nevertheless, two maxima were observed after multiple exposure. In a 1977 report, Keller and Tanka [US0197] stated that oxidative enzymes are more sensitive to ultrasonic irradiation than are hydrolytic enzymes. They measured the activities of 15 enzymes in the liver, kidney, and spleen of 90 rats irradiated with 800-kHz ultrasound for 2 minutes at intensities of 0.3 and 0.5 W/cm^2. Increased succinate dehydrogenase, decreased malate and lactate dehydrogenase, and decreased alkaline phosphatase and adenosine triphosphatase (ATPase) activities were seen to persist for 10 days after exposure. Measurements of organ weight 6 days after irradiation with 1-MHz ultrasound, presented by Longo et al [US0407] in 1976, indicated that spleen and adrenal weight are increased but liver and kidney weight remain unchanged in rats exposed for 3-5 minutes at an intensity of 1.5 W/cm^2.

No changes in the concentrations of cyclic adenosine monophosphate and guanosine monophosphate and histamine in the skin, lungs, and peritoneal cells of mice were reported by Glick et al [US0792], in 1979, to follow whole- and partial-body irradiation of mice with CW 2-MHz ultrasound. The mice were immersed in a water bath and exposed either to wide-beam (whole-body) radiation at an intensity of 1 W/cm^2 for 100 or 200 seconds or to radiation focused on the chest or abdomen at 8.4 W/cm^2 for 200 seconds (two 100-second exposures) or at 10 W/cm^2 for 12 seconds. Small lesions were observed in the organs or intercostal muscles following the double irradiations, whereas the 10-W/cm^2 irradiation was found to produce dilation of mesenteric blood vessels. The lack of effect on cyclic nucleotide or histamine concentration was considered by Glick et al to indicate that no cell disruption had occurred.

In rabbits, ultrasound has been shown to alter the content of amino acids, as well as produce lesions, in the internal organs. A 1970 report by Vibe et al [US0464] stated that ultrasonic irradiation at 3 W/cm^2 for 5 minutes increased the amino acid content of the liver, kidneys, spleen, stomach, intestines, and lungs of rabbits. The production of focal lesions in the rabbit kidney, liver, and testicle was found to be independent of frequency, according to a 1977 paper by Frizzell et al [US1145]. The threshold doses for lesion formation were determined for 2- and 6-MHz ultrasound using single pulses ranging from 1 to 60 seconds in length. Similar values were obtained for all three organs. The logarithm of intensity was inversely proportional to the logarithm of pulse duration, such that intensities of 10 kW/cm^2 and 100 W/cm^2 required durations of 1 ms and 100 seconds, respectively, to produce a lesion.

Many of the studies of ultrasound effects on organs have concerned the liver. In 1957, Bell [US0768] presented microscopic evidence of tissue necrosis following 15 seconds of irradiation of 52 mice with 1-MHz ultrasound and 24 mice with 27-MHz ultrasound at an intensity of 35 W/cm^2. Examinations made 1-15 days after exposure revealed blanching of tissue resulting from vascular occlusion, the presence of glycogen granules in the blood, vacuolization of parenchymal cells, and an influx of erythrocytes into the sinusoids. Direct irradiation or exposure of mice in a water bath was stated, by Cowden and Abell [US0048] in 1963, to lead to degeneration of the liver and testes. Congestion, fragmentation, and necrosis were found to occur following irradiation with 1-MHz ultrasound at intensities of 1-3 W/cm^2 for durations of 1-10 minutes. A dose of 1 W/cm^2 for 1 minute was observed to produce no alterations; the maximum sublethal dose was found to be 1 W/cm^2 for 5 minutes, 2 W/cm^2 for 3 minutes, or 3 W/cm^2 for 1 cm^2.

In an extensive study of lesion formation in mouse liver, published in 1965, Curtis [US1021] observed that the changes produced by focused ultrasound are, in general, localized to the surface of the irradiated lobe and depend on both the dose of ultrasonic energy and the rate of irradiation. He exposed over 400 mice to 1-MHz ultrasound in a water bath and microscopically examined liver tissue at various intervals from 1 minute to 30 days after exposure. The intensities were estimated to range from 10 to 70 W/cm^2, and single exposures lasted 2-40 seconds. Tissue damage included infarctive lesions, distension of sinusoids and their occlusion by swollen red blood cells, and distortion of the parenchymal cell plates. Cytoplasmic vacuolization, glycogen disruption, swollen mitochondria exhibiting a vesicular appearance, pycnotic nuclei, and disruption of nucleic acid structures comprised the cellular damage. At any one intensity for continuous ultrasound, the incidence of lesions was found to be linearly dependent on exposure duration, with intensities of 10 W/cm^2 and below considered as subthreshold; with pulsed ultrasound, the incidence depended on duty factor, where the logarithm of the reciprocal of the duty factor was linearly related to the intensity.

Majewski et al [US0857] stated, in 1966, that ultrasound-induced changes in parenchymal cells are temporary. He irradiated 35 rats with 1-MHz ultrasound for 5 min/d at an intensity of 3 W/cm^2. Electron micrographs taken after 5 and 10 exposures, as well as 15 days after the 10th exposure, indicated that cell vacuolization and a transient increase in the cell concentration of lysosomes and cytolysosomes had occurred. The effects of varying pulse conditions on ultrasound-induced damage to rat

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Report 7
January 6, 1981

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X. APPENDIX IV

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Birmingham, MI 48011

Metal Powder Industries Federation
Box 2054
Princeton, NJ 08540

Metal Properties Council, Inc.
345 East 47th St.
New York, NY 10017

Metal Treating Institute, Inc.
1300 Executive Center Drive
Tallahassee, FL 32301

National Council of Acoustical
Consultants, Inc.
66 Morris Ave.
Springfield, NJ 07081

National Society for Cardiopulmonary
Technology, Inc.
Suite 307
1 Bank St.
Gaithersburg, MD 20760

TRADE ASSOCIATIONS (CONTINUED)

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Materials Association
410 North Michigan Ave.
Chicago, IL 60611

Packaging Machinery Manufacturers
Institute
2000 K St., N.W.
Washington, DC 20006

Process Equipment Manufacturers'
Association
P.O. Box 8745
Kansas City, MO 64114

Slurry Transport Association
Suite 3210
490 L'Enfant Plaza East, N.W.
Washington, DC 20024

Society for Experimental Stress Analysis
Box 277
Saugatuck Station
Westport, CT 06880

Society for Occupational
and Environmental Health
Suite 308
1341 G St., N.W.
Washington, DC 20005

Society of Rheology
335 East 45th St.
New York, NY 10017

Society for the Advancement of Material
and Process Engineering
Box 613
Azusa, CA 91702

Society of the Plastics Industry, Inc.
355 Lexington Ave.
New York, NY 10017

Sprayed Mineral Fiber Manufacture
Association, Inc.
1 Wall St., Ste. 2400
New York, NY 10005

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Union, NJ 07083

Steel Tank Institute
Suite 600
111 East Wacker Drive
Chicago, IL 60601

Ultrasonic Industry Association, Inc.
481 Main St.
New Rochelle, NY 10801

Undersea Medical Society, Inc.
9650 Rockville Pike
Bethesda, MD 20014

LABOR UNIONS

Almagamated Clothing and Textile
Workers Union
770 Broadway
New York, NY 10003

Distillery, Wine and Allied Workers'
International Union
66 Grand Ave.
Englewood, NJ 07631

Industrial Union of Marine and Shipbuilding
Workers of America
1126 16th St., N.W.
Washington, DC 20036

International Association of Machinists
and Aerospace Workers
1300 Connecticut Ave., N.W.
Washington, DC 20036

International Association of Tool Craftsmen
3243 37th Ave.
Rock Island, IL 61201

International Brotherhood of Boilermakers,
Iron Shipbuilders, Blacksmiths, Forgers,
and Helpers
8th Ave. at State
Kansas City, KS 66101

International Chemical Workers Union
1655 West Market St.
Akron, OH 44313

International Leather Goods, Plastics
and Novelty Workers Union
265 West 14th St.
New York, NY 10011

International Masonry Institute
Suite 1001
823 15th St., N.W.
Washington, DC 20005

liver were described in 1969 by Taylor and Connolly [US0155]. The peak intensity of the 5.99-MHz ultrasound was 105 W/cm^2, and the duty factor was held constant at 0.1 during the 5-minute irradiation. Using a pulse width of 10 ms, lesions were observed to form within 1 day after exposure, followed by regeneration from 3 to 10 days after exposure. A small area of necrosis was produced by ultrasound with a 20-μs pulse width; no macroscopic damage was noted when a pulse width of 150 μs was used.

Taylor and Pond [US0894] also discussed, in 1970, the use of pulsed ultrasound to minimize thermogenesis in the liver. They exposed 40 anesthetized rats for 5 minutes to ultrasound with frequencies of 0.5, 1, 2, and 6 MHz. The pulse width was 10 ms and the pulse repetition frequency was 10 pps (duty cycle of 0.1), yielding an average intensity of 5.6 W/cm^2. Microscopic examinations made 6 hours to 7 days after exposure showed that centrolobular necrosis was more extensive at the lower frequencies.

In a 1974 report, Kremkau and Witcofski [US0288] stated that ultrasound was responsible for a reduction in mitotic activity in regenerating liver tissue. A partial hepatectomy (70%) was performed 2 hours after a 5-minute irradiation with 1.9-MHz ultrasound at 60 W/cm^2. Comparisons of mitotic activity, which was measured 30 hours after the hepatectomy, in 120 irradiated and nonirradiated rats indicated reductions of 18.9-79.7% at levels of significance of 0.05-0.0005.

Irradiation of the rat abdomen led to alterations in the enzyme activity of liver mitochondria, according to a 1977 report by Beleva-Staikova and Maneva [US1076]. Exposures of 5 minutes to 880-kHz ultrasound at intensities of 0.2, 0.6, and 1 W/cm^2 were followed by determinations of succinate dehydrogenase, cytochrome oxidase, and $NADH_2$-cytochrome C reductase activity 1, 24, and 48 hours later. Relative to preirradiation values, increases in the first two activities and decreases in the third were noted; however, a consistent pattern of response was not evident.

In a 1977 report, Chan and Frizzell [US1137] presented threshold doses for producing lesions in cat liver. For 3-MHz ultrasound, pulse durations of 0.03 to 1 second required intensities of 3 to 0.9 kW/cm^2, respectively. Destruction of cell nuclei occurred below and homogenization of tissue above 3 kW/cm^2.

Degeneration and disorientation of mitochondria, disturbance of pinocytosis, and dilatation of the endoplasmic reticulum were reported in rat kidney by Bernstine and Dickson [US0925] in 1972. These changes occurred after 0.25-5 hours of irradiation with CW 6-MHz ultrasound at intensities of 20-30 W/cm^2 but not with PW 2.25-MHz ultrasound with a pulse repetition frequency of 1,000 pps (duty cycle of 0.1) and peak intensity of 20 W/cm^2.

Ultrasound-induced changes in thyroid function have been investigated in rabbits and rats. Hrazdira and Konecny [US0273] reported, in 1966, that uptake of radioactive iodine (^{131}I) by the thyroid is reduced 10 and 50% by 5 minutes of irradiation with 800-kHz ultrasound at 1 and 2 W/cm^2, respectively. Autoradiographs of thyroid tissue also showed enlargement of follicles and epithelial thinning. Decreases of thyronins in the thyroid and increases in the blood were reported by Stereva and Beleva-Staikova [US1165] and Shchereva [US1166] in 1976 and 1977, respectively. As in previous reports from Beleva-Staikova and coworkers, ultrasound exposures were for 5 minutes at intensities of 0.2, 0.6, and 1 W/cm^2. Decreases of 40-70% were measured 24 hours after exposure in the concentrations of tetra-, tri-, and diiodothyronin in the livers of 46 rats [US1165]. At 1, 24, and 48 hours after exposure, increases of similar magnitude were measured in the amounts of total and protein-bound iodine in the blood of 240 rats [US1166]. In a 1964 report, Gorshkov et al [US0063] described a novel way to irradiate rats and rabbits with ultrasound. The animals were placed in a metal sphere that was then irradiated with sirens emitting 29- and 54-kHz ultrasound. No changes in the accumulation of ^{131}I in the thyroid were observed after irradiation at 80 and 95-100 dB (0.03 and 0.3-1 $\mu W/cm^2$) for up to 4-5 hours or for 1 h/d for 15 days.

Microscopic changes in the adrenal glands were reported by Jankowiak et al [US0258] in 1963. They irradiated 15 rabbits at an intensity of 4 W/cm^2 for 5 min/d and 15 others at 2 W/cm^2 for 10 min/d. Exposures (five in all) were performed every 2nd day. The only change observed was disappearance, by 12 days after exposure, of the fuchsinophilic granules in the cells of the glomerular layer of the adrenal cortex.

Krumins et al [US0988] reported, in 1965, on the production of lesions in the cat pituitary gland by 4-MHz ultrasound. Microscopic examinations made at various intervals up to 3 months after the 0.5-second irradiation indicated that ultrasound had produced vacuolization, degeneration of cell nuclei, depletion of secretion granules, and in some cases cell lysis. The presence of basophils 1-3 months after exposure suggested that regeneration was occurring.

The production of effects on the internal organs, including neuroendocrine glands, is summarized in Table XIII-11.

(h) Effects on the Nervous System

The use of ultrasound to produce focal lesions, ie, localized areas of cell destruction, in the brain of animals has been the subject of many investigations. In most cases, the ultrasonic radiation has been focused on the area to be destroyed and has been of high intensity. For example, Warwick and Pond [US0095] described, in 1968, the production of lesions approximately 1 mm in diameter in the brains of 800 mice exposed for 0.2-15 seconds to 3-MHz ultrasound at intensities of 25-0.2 kW/cm^2. Vascular occlusion was observed in the area of the lesion. Smyth [US0660], however, reported in 1965 no detectable changes in the brain tissue of 20 rats exposed for 20 min/d on 5 consecutive days. The intensity used, 10 mW/cm^2, was low.

Results of experiments with rabbits have been inconclusive. A 1951 report by French et al [US0669] noted that PW 15-MHz ultrasound was ineffective in altering the morphology of the rabbit brain. Although relatively long exposures (15-30 minutes) were used, the short pulse width (0.5 μs) and low repetition frequency (1,055 pps) were responsible for the

TABLE XIII-11

EFFECTS OF EXPOSURE TO ULTRASOUND ON NEUROENDOCRINE ORGANS OF ANIMALS

Species	Effect*	Intensity (W/cm^2)**	Duration (min)**	Calculated Dose (kJ/cm^2)**	Method of Application	Frequency (MHz)**	Reference
Mouse	Vascular occlusion, vacuolization of parenchymal cells, influx of erythrocytes into sinusoids of liver	35	15 s	0.525	Contact	1, 27	US0768
"	Infarctive lesions, distension and occlusion of sinusoids, distortion of parenchymal cells of liver (dose dependent)	10-70	2-40 s	0.02-2.8	Water coupled	1	US1021
Rat	Reduction of ascorbic acid content of liver and kidneys	0.04, 0.6, 1 0.04, 0.2	Once Once/d for 5 d	-- --	Contact	0.88	US1017
"	Increase in nucleic acid content of liver but decrease in content of kidney	0.2, 0.6, 1.8	Once, once/d for 5 d	--	"	0.83	US1023
"	Reduction in oxidative enzyme activity in liver, kidney, and spleen	0.3, 0.5	2	0.036, 0.06	"	0.8	US0197
"	Increase in spleen and adrenal weight; no change in liver or kidney weight	1.5	3-5	0.27-0.45	"	1	US0407
"	Temporary vacuolization and increase in lysosome concentration of parenchymal cells of liver	3	5 min/d for 5 and 10 d	4.5, 9	"	1	US0857
"	Variable changes in enzyme activities of liver mitochondria	0.2, 0.6, 1	5	0.06, 0.18, 0.3	"	0.88	US1076
"	Congestion, fragmentation, and necrosis of liver	1 2 3	5, 10 1, 5, 10 1, 3	0.3, 0.6 0.12, 0.6, 1.2 0.18, 0.54	"	1	US0048
"	Necrosis of liver (more extensive at lower frequencies)	5.6	5	1.68	"	0.5, 1, 2, 6 (PW)	US0894

TABLE XIII-11 (CONTINUED)

EFFECTS OF EXPOSURE TO ULTRASOUND ON NEUROENDOCRINE ORGANS OF ANIMALS

Species	Effect*	Intensity (W/cm^2)**	Duration (min)**	Calculated Dose (kJ/cm^2)**	Method of Application	Frequency (MHz)**	Reference
Rat	Focal necrosis of liver	10.5	5	3	Contact	5.99 (PW)	US0155
"	Reduction in mitotic activity in regenerating liver	60	5	18	"	1.9	US0288
"	Degeneration of mitochondria, disturbance of pinocytosis, dilatation of endoplasmic reticulum of kidney cells	20-30	0.25-5 h	18-540	"	6	US0925
	Lack of above effects	2	0.25-5 h	1.8-3.6	"	2.25 (PW)	
"	Decreases in thyronins in thyroid and increases in blood	0.2, 0.6, 1	5	0.06, 0.18, 0.3	"	0.88	US1166
"	Increase an ^{131}I uptake by thyroid	0.3	1-3 h	1.08-3.24	Airborne	28 kHz	US0063
Rat, rabbit	Reduction of ^{131}I uptake by thyroid	1, 2	5	0.3, 0.6	Contact	0.8	US0273
Rabbit	Increase in amino acid content of liver, kidneys, spleen, stomach, intestines, and lung	3	5	0.9	"	--	US0464
"	Microscopic changes in adrenals	2 4	10 min/d for 5 d 5 min/d for 5 d	6	"	--	US0258
"	Dose-dependent production of focal lesions in liver and kidney	100 10,000	100 s 1 ms	10	"	2, 6	US1145
Cat	Focal lesions in liver	0.9-3 kW/cm^2	1-0.03 s	0.9	"	3	US1137
"	Lesion formation, vacuolization, nuclear degeneration, depletion of secretory granules of pituitary	--	0.5 s	--	"	4	US0988

*Lack of effect denoted by (-)
**Except where noted

lack of effect. Cone-shaped lesions in the cortex and ellipsoidal lesions in the cortical region of the brain were described by Nakashima [US0543] in 1962. He irradiated various areas of the brains of 79 rabbits with 1-MHz ultrasound for 5-10 seconds at 150 W/cm^2. Hemorrhaging was not observed in the area of the lesion. Five exposures on alternate days were sufficient to produce passive hyperemia, demyelinization of the cortex, necrosis, and softening of the white matter, according to a 1963 report by Jankowiak et al [US0069]. These changes were observed in 30 rabbits 12-14 days after irradiation with 1-MHz ultrasound at intensities of 2 or 4 W/cm^2 for 10 or 5 min/d, respectively. The production of necrotic lesions devoid of hemorrhage was described by Young and Lele [US0077] in 1964. In this study, the rabbits were exposed for 0.5-5 seconds at an intensity of 630 W/cm^2.

That focused irradiation of the brain stem could produce localized lesions capable of inducing nystagmus in rabbits was shown by Sasaki [US0337] in 1965. Pulsed 1.1-MHz ultrasound, having peak and average intensities of 1,500 and 355 W/cm^2, respectively, was used, and exposures lasted for 3.5-4.5 seconds. In 1974, Gavrilov [US0706] discussed threshold doses for the production of two types of lesions in the rabbit brain. Intensities between 0.2 and 10 kW/cm^2 and exposure durations from 1 second down to 1 ms were tested. Cavitational lesions were stated to be produced by irradiation at the higher intensities and shorter times (1-10 ms), whereas thermal lesions were produced at lower intensities and longer times (0.1-1 second). The threshold intensities for 0.94-MHz ultrasound were found to be approximately 50% those for 1.72-MHz ultrasound.

The cat brain has received more attention than have the brains of other animals because its structure has been more completely determined. In 1944, Lynn and Putnam [US0855] described lesion formation by 5-15 minutes of exposure to 835-kHz ultrasound. They observed areas of torn tissue, cavities, edema, dilatation of capillaries, and necrosis of the skin adjacent to the irradiated area. Degeneration of neural ganglia and glial cells was extensive, whereas the blood vessels were largely intact. Damage limited to the white matter of the cat brain was described in 1955 by Barnard et al [US0042], who irradiated 104 cats with multiple short pulses of 980-kHz ultrasound. Examinations performed at various intervals between 2 hours and 30 days after exposure indicated swelling of the myelin, formation of varicosities, increases in interstitial fluid and perivascular space, but little or no damage to the blood vessels.

An analysis of lesion dimensions in the brains of cats exposed to ultrasound was presented by Ballantine et al [US0041] and Bakay et al [US0124] in 1956. Exposure to 2.5-MHz ultrasound at intensities between 330 and 870 W/cm^2 was found to produce lesions that were 1-6 mm^2 in size. Necrosis and histolysis were evident 10 minutes after irradiation. A second report, published by Ballantine et al [US0480] in 1960, stated that lesions with an average area of 1.7 or 2.6 mm^2 could be produced in the cat brain by irradiation with 2.7-MHz ultrasound at 1.7 kW/cm^2 after exposures of 0.25-0.3 or 0.35-0.4 seconds, respectively. The lesions were described by Astrom et al [US0477] in 1961. Necrotic areas contained fragmented and densely packed myelinated fibers, pycnotic nuclei, and severed blood vessels. Inflammation was evident 24 hours after irradiation with infiltration of the tissue by polymorphonuclear leukocytes, lymphocytes, monocytes, and macrophages. By 72 hours these cells had begun to be replaced by astrocytes and microglia. Between 1 and 12 months, the necrotic tissue was replaced by a dense gliotic scar.

Borison et al [US0484], also in a 1960 report, indicated that 30- to 90-second exposures to 1-MHz ultrasound at intensities of 4 or 5 W/cm^2 produced necrotic lesions in the midbrains of 55 cats. Gordon [US0509], however, reported in 1963 that contact irradiation of the cat cortex for 10 minutes at 8 W/cm^2 produced no more than a superficial vesicle, whereas a large area of necrosis was formed with a 10-minute exposure at 20 W/cm^2.

Cavitational lesions in the cat brain were described extensively by Barnard et al [US0125] in 1956 and later by Fry et al [US0009] in 1970. Exposures of 25-200 ms to 1-MHz ultrasound at a peak intensity of 5 kW/cm^2 produced areas devoid of blood vessels but densely packed with erythrocytes. Neurons were absent, the matrix was disrupted, and a large number of vacuoles were evident. Lele [US0633] discussed threshold doses for lesion formation in a 1977 report. Irradiation with PW 3.2-MHz ultrasound at a peak intensity of 1.5 kW/cm^2 produced lesions when the total time for which the brain tissue was exposed to ultrasonic energy, ie, the sum of the pulses, exceeded approximately 45 seconds. For example, with a pulse repetition frequency of 1,000 pps and an irradiation time of 30 minutes, pulse widths of 35 μs or more were required. Hemorrhage and tissue disintegration were observed to result from the so-called collapse cavitation in the brain tissue. Below intensities of 1.5 kW/cm^2, the lesions resembled those produced by heat.

Structural changes have also been observed in the spinal cord and the peripheral nerves. Fry and Dunn [US0010] reported, in 1956, that irradiation of the lumbar region of mice with 982-kHz ultrasound produced dose-dependent temperature increases. Continuous ultrasound at intensities of 54-154 W/cm^2 produced increases of 16.5-5.7 C after irradiation for 7.7-0.865 seconds. Irradiation with PW ultrasound with duty cycles of 0.1 and 0.4 led to smaller increases, 3.2-5.3% and 19-49% less, respectively, than those produced by CW ultrasound. The formation of detectable lesions in the spinal cord of mice 10-15 minutes after ultrasonic irradiation was described by Dunn [US0003] in 1958. Exposure to 982-kHz ultrasound at intensities between 48 and 160 W/cm^2 for periods of 25-0.8 seconds were also observed to induce immediate paralysis of the hind legs. These effects occurred without heating of the spinal cord.

Taylor [US0156] stated, in 1970, that gross hemorrhage, predominantly into the gray matter, was the major result of PW irradiation of the spinal cords of rats. For 3.2-MHz ultrasound at duty cycles of 0.1-0.025 and peak intensities of 25 and 50 W/cm^2, the total pulse time required for production of lesions was 30 seconds. For 1-MHz ultrasound the total effective irradiation time was 24 seconds. A second report, published by Taylor and Pond [US0025] in 1972, discussed results of similar experiments at frequencies between 0.5 and 6 MHz. Again, pulsed ultrasound, at a duty cycle of 0.1 and average intensity of 2.5 or 5 W/cm^2, was used to minimize thermal effects, and 72 irradiated rats were compared with 12 control rats for the extent of hemorrhage and paralysis induced by irradiation. Taylor and Pond found that at lower frequencies less total irradiation time was required to induce these effects: 12 seconds at 0.5 MHz but 120 seconds at 4.9 MHz.

An early report dealing with the peripheral nervous system was published by Anderson et al [US0103] in 1951. They reported that exposure of the spinal cords of rats and dogs to 800-kHz ultrasound at doses of 180 J/cm^2 and 1.8 kJ/cm^2, respectively, produced paralysis and necrosis of the cord, dura, and cauda equina. Chromatolysis of the nerve cells and pycnosis and fragmentation of the nuclei of the gray matter were evident, as was degeneration of the white matter. Exposure of the thighs of 20 dogs to ultrasound at 5 W/cm^2 for 10 minutes led to degeneration of the myelin of the sciatic nerve with consequent blockage of the action potentials. Edema, discoloration, and necrosis of the skin and subcutaneous tissue were also observed. Swelling, vacuolization, and fragmentation of the nerve fibers of the sciatic nerve were reported by Voskoboinikov [US0465] in 1960. He irradiated the thighs of 20 guinea pigs with PW 1.625-MHz ultrasound at an intensity of 0.5 W/cm^2. Microscopic examinations of tissue were made 2, 24, 48, and 72 hours after exposure and indicated that 3 minutes of irradiation did not produce detectable damage whereas 5 and 10 minutes of irradiation did. Exposure to continuous ultrasound at an intensity of 1 W/cm^2 for 3 minutes did, however, cause degeneration.

A variety of biochemical and functional changes have been described in the nervous system following ultrasonic irradiation. In 1964, Jankowiak et al [US0070] reported that irradiating the occiputs of 34 rabbits at an intensity of 3 W/cm^2 for 10-15 minutes induced secretion of 5-hydroxy-3-indoleacetic acid into the urine. Ballantine et al [US0041,US0480] and Bakay et al [US0124] mentioned the possible alteration of the blood-brain barrier of the cat by ultrasound in the three reports discussed above. Autoradiographs taken after injection with radioactive phosphorus (^{32}P) and micrographs taken after injection of trypan blue stain indicated that both substances had leaked into the parenchymal tissue surrounding the capillary network of the brain.

A 1959 report from Bakay et al [US0478] noted that focused 2.5-MHz ultrasound with intensities of 0.5-1.7 kW/cm^2 was capable of producing lesions in the cortex and subcortical tissue of cats. When radioactively labeled (^{32}P) sodium hypophosphate was injected into the cerebrospinal fluid or applied directly over the cortex, the lesions were not found to concentrate ^{32}P above those levels taken up by undamaged tissue. Thus, the blood-brain barrier was presumed to be intact. Shealy and Crafts [US0561] suggested in 1965, on the contrary, that irradiation of the cat brain under conditions described by Bakay et al [US0478] did damage the barrier.

The electrical activity of the nervous system has been found to be affected by ultrasound. Fry et al [US0008] reported in 1958 that cortical potentials evoked in the visual cortex of cats by light could be temporarily suppressed by ultrasonic irradiation of the lateral geniculate nucleus. Depression of spontaneous cortical activity was described by Battista and Quint [US0332] in 1962. The frontal, parietal, and occipital regions of the brains of 10 anesthetized cats were irradiated for 5-10 seconds with ultrasound at an intensity of 170 W/cm^2. Depressions in activity were observed to last for 100 seconds to several minutes. In a 1976 report, Hu and Ulrich [US0395] described the stimulation of the central nervous system by low-intensity ultrasound. The parietal areas of the skulls of three anesthetized squirrel monkeys were irradiated with PW 2.25- and 5-MHz ultrasound having a pulse width of 2 μs and repetition rate of 1,000 pps. Average intensities of 3-900 mW/cm^2 were found to evoke potentials at 0.2-5, 4-8, 17, and 35 Hz in the EEG.

Transmission of spinal reflexes was both stimulated and depressed by ultrasound, according to a 1962 report by Shealy and Henneman [US0092]. The spinal cords of anesthetized cats were exposed to 0.3-second pulses of 2.7-MHz ultrasound at 1-second intervals. Increases in the amplitude of the reflex were observed to be followed by decreases. As the period of irradiation increased, the time required for recovery of the reflexes to preirradiation patterns was found to lengthen. In 1963, Lele [US0073] reported that peripheral nerve conduction in cats and monkeys showed a similar pattern of initial stimulation followed by depression. The saphenous nerve of each animal was irradiated with 0.6-, 0.9-, and 2.7-MHz ultrasound. The conduction velocity and action potential were increased during the first phase of the response to irradiation. A reversible depression then occurred, followed by irreversible (permanent) depression.

Effects on behavior have been investigated. Irradiating rats and rabbits placed in a metallic sphere with 28- and 54-kHz ultrasound emitted from a siren produced increases in the latency of an unconditioned reflex, according to Gorshkov et al [US0063]. The thresholds for producing an effect were found to be one exposure of 4-5 hours or 15 daily 1-hour exposures at 95-100 dB (0.3-1 $\mu W/cm^2$) for 54-kHz ultrasound and at 125 dB (0.03 mW/cm^2) for 28-kHz ultrasound. In 1970, Shipacheva [US0441] reported that irradiation with 54-kHz ultrasound at an intensity of 1 $\mu W/cm^2$ for 1 h/d for 15 days increased the latent period for a defensive reflex in rats. Maze learning was reported to be unchanged by ultrasound in a 1950 study by Wilcox and Windle [US0978]. Eight guinea pigs were trained to run a maze; six were then exposed to jet aircraft engine noise for varying periods of up to 4 hours. Comparison of exposed and control guinea pigs indicated no significant differences in maze performance.

Exposures for 1.5 minutes to siren-produced 21.5-, 28-, and 33-kHz ultrasound with an intensity of 0.1 mW/cm^2 also was found to have no significant effects on maze learning or retention by rats, according to a 1953 report by Gilbert and Gawain [US1003]. Smyth [US0660], in a 1966 report, also noted no effect of ultrasound on the conditioned escape response of rats. Exposures of 52-120 minutes were tested, at an intensity of 10 mW/cm^2, and no differences from control values were found up to 7 days after exposure.

Table XIII-12 compiles the varied information on the response of the animal nervous system to ultrasound.

TABLE XIII-12

EFFECTS OF EXPOSURE TO ULTRASOUND ON NERVOUS SYSTEM OF ANIMALS

Species	Effect*	Intensity (W/cm^2)**	Duration (min)**	Calculated Dose (kJ/cm^2)**	Method of Application	Frequency (MHz)**	Reference
Mouse	Focal lesions and vascular occlusions in brain	0.2 kW/cm^2 25 kW/cm^2	15 s 0.2 s	3 5	Contact	3	US0095
"	Brain lesions (-)	0.01	20 min/d for 5 d	0.06	"	--	US0660
Rabbit	Brain lesions	150	5-10 s	0.75-1.5	"	1	US0543
"	Necrosis, demyelinization of cortex, hyperemia of brain	2 4	10 min/d for 5 d 5 min/d for 5 d	6	"	1	US0069
"	Focal lesions in brain stem	355	3.5-4.5 s	1.24-1.6	"	1.1	US0337
"	Necrotic lesions in brain	630	0.5-5 s	0.315-3.15	"	--	US0077
"	Frequency-dependent lesion production in brain	0.2-1 kW/cm^2 2-10 kW/cm^2	0.1-1 s 1-10 ms	0.2-20	"	0.94, 1.72	US0706
Cat	Lesion production, degeneration, necrosis of brain	--	5-15	--	"	0.835	US0855
"	"	--	1-2.5 s	--	"	0.98	US0125
"	Brain lesions	330-870	--	--	"	2.5	US0041
"	"	1.7 kW/cm^2	0.25-0.4 s	0.425-0.68	"	2.7	US0477, US0480
"	"	5 kW/cm^2	25-200 ms	0.125-1	"	1	US0009
"	"	1.5 kW/cm^2	45 s	67.5	"	3.2 (PW)	US0633
"	Lesions in midbrain	4, 5	30-90 s	0.12-0.45	"	1	US0484
"	Necrosis of brain	20	10	12	"	--	US0509
Mouse	Temperature increases in spinal cord	54-154	7.7-0.865 s	0.416-0.133	"	0.982	US0010

TABLE XIII-12 (CONTINUED)

EFFECTS OF EXPOSURE TO ULTRASOUND ON NERVOUS SYSTEM OF ANIMALS

Species	Effect*	Intensity (W/cm^2)**	Duration (min)**	Calculated Dose (kJ/cm^2)**	Method of Application	Frequency (MHz)**	Reference
Mouse	Lesions in spinal cord, hind-quarter paralysis	48-160	25-0.8 s	1.2-0.128	Contact	0.982	US0003
Rat	Hemorrhage of gray matter of spinal cord	0.63-5	30 s 24 s	0.019-0.15 0.015-0.12	"	3.2 (PW) 1 (PW)	US0156
"	"	2.5, 5	12 s 120 s	0.03-0.06 0.3-0.6	"	0.5 (PW) 4.9 (PW)	US0025
Rat, dog	Paralysis and necrosis of spinal cord, dura, and cauda equina	--	--	0.18 and 1.8	"	0.8	US0103
Guinea pig	Swelling, vacuolization, and fragmentation of sciatic nerve	0.5	5, 10	0.15, 0.3	"	1.625 (PW)	US0465
Dog	Degeneration of sciatic nerve myelin	5	10	3	"	0.8	US0103
Rabbit	Induction of HIAA secretion	3	10-15	1.8-2.7	"	--	US0070
Cat	Increase in permeability of blood-brain barrier	600	0.4 s, 30-50 pulses	7.2-12	"	2.5 (PW)	US0124
"	Damage to blood-brain barrier	0.5-1.7 kW/cm^2	--	--	"	2.5	US0478
"	Blood-brain barrier (-)	"	--	--	"	"	US0561
"	Depression of electrical activity in cortex	170	5-10 s	0.85-1.7	Contact (dura)	--	US0332
Monkey	Stimulation of electrical activity: cortical potentials evoked in EEG	0.003-0.9	--	--	Contact	2.25, 5 (PW)	US0395
Cat	Variable changes in transmission of spinal reflexes	--	0.3 s	--	"	2.7	US0092
Cat, monkey	"		--	--	"	0.6, 0.9, 2.7	US0073

TABLE XIII-12 (CONTINUED)

EFFECTS OF EXPOSURE TO ULTRASOUND ON NERVOUS SYSTEM OF ANIMALS

Species	Effect*	Intensity (W/cm^2)**	Duration (min)**	Calculated Dose (kJ/cm^2)**	Method of Application	Frequency (MHz)**	Reference
Rat	Increase in length of latency period of reflex	1 mW/cm^2	1-3 h	3.6-10.8 mJ/cm^2	Contact	28, 54 kHz	US0063
"	Increase in latency of a defensive reflex	1 $\mu W/cm^2$	1 h/d for 15 d	0.054 J/cm^2	"	54 kHz	US0441
"	Conditioned escape response (-)	10 mW/cm^2	52-120	0.031-0.072	"	---	US0660
"	Maze learning and retention (-)	100 $\mu W/cm^2$	1.5	0.009 J/cm^2	"	21.5, 28, 33 kHz	US1003
Guinea pig	Maze learning (-)	Jet aircraft	4 h	--	"	--	US0978

*Lack of effect denoted by (-)
**Except where noted

(i) Effects on Reproduction

As mentioned before, ultrasound has been and is used as a diagnostic tool in obstetrics and gynecology, reportedly without effect on maternal health or fetal development. Its effects on the reproductive system of animals as well as fetal development have been studied since 1970. The majority of animal reproduction experiments have used mice and rats because of their relatively short gestation times and large litter sizes. As with human surveys, most of the results of animal experiments have been negative.

In 1970, Woodward et al [US0097] published the results of a large-scale study with mice. Pulsed ultrasound at frequencies of 1, 2, and 3 MHz and peak intensities between 20 and 490 W/cm^2 (maximum average intensity of 27 W/cm^2) was used to irradiate 223 pregnant mice. Pulse widths ranging from 1 μs to 10 ms and repetition rates from 20 to 2,000 pps, which produced duty cycles ranging from 0.002 to 0.25, were compared. Exposures were kept constant at 5 minutes, yielding effective irradiation times ranging from 7 to 30 seconds. Irradiation was performed once during days 1 through 5, 8 through 12, or 12 through 16 of gestation. The resorption and abnormality rates for 2,060 irradiated fetuses were not found to be significantly different from those determined for 1,249 fetuses from 132 nonirradiated control mice. More complete details of the statistical analysis of the results were presented by Warwick et al [US0157] in 1970.

Mannor et al [US0307] discussed the results of a similar experiment in 1972. They irradiated 120 pregnant mice for 5 or 60 minutes with CW 2.28-MHz ultrasound at intensities of 164, 272, 490, and 1,050 mW/cm^2 and compared the incidence of fetal abnormalities with 40 nonirradiated controls. The mice were exposed once between days 8 and 20 of fetal gestation; examinations of fetuses were performed 1 or 2 days before birth and of neonates 21 to 28 days after birth. A total of 990 fetuses were irradiated. Examinations of the mothers, fetuses, and neonates for major defects as well as defects of internal organs indicated that no structural or teratogenic damage had occurred from irradiation at the three lower intensities. Twenty of the irradiated female fetuses were allowed to mature and to mate 8 weeks after birth; examinations of their offspring indicated no difference in the rate of malformations. Chromosomal spreads prepared from 28 mice at various times up to 72 hours after irradiation showed no difference in aberration rate or type. Abnormalities produced in the mice irradiated at 1.05 W/cm^2 were attributed to the production of temperature increases of 11-15 C in the uteruses of the pregnant mice.

Although no intensity values were provided for comparison with the above results, Martelli et al [US0420] also reported, in 1975, that ultrasound irradiation had no statistically significant effect on the production of fetal abnormalities in mice. The abdomens of 75 pregnant mice were exposed by direct conduct to either 10-MHz ultrasound at a power of 10 mW or 7-MHz ultrasound at 160 mW. In the first case one to six daily irradiations, each for 5-15 minutes, were performed, whereas the second involved only one 15-minute exposure. Comparisons with unirradiated controls, between the fetuses obtained from the irradiated and unirradiated horns of each mouse, and among fetuses irradiated on different days of gestation indicated no significant differences in incidence or type of abnormalities in the 389 irradiated fetuses examined.

In a series of studies described by Shoji and coworkers [US0887, US1120,US0442] between 1972 and 1975, limited teratogenic effects were ascribed to ultrasound. The abstracts of 1972 [US0887] and 1974 [US1120] stated that rib malformations and forefoot polydactyly occurred to a significantly greater extent in fetuses of mice irradiated with 2.25-MHz ultrasound at 40 and 100 mW/cm^2, respectively. Irradiation lasted for 5 hours on the 9th day of gestation in the first case and occurred between the 7th and 14th days of gestation in the second. In 1975, Shoji et al [US0442] reported that 17 types of malformations, including severe facial and cranial anomalies, reduced fetal weight, and late death, characterized a small but significant proportion of fetuses from mice irradiated for 5 hours on the 8th day of gestation. Abstracts of presentations by Muranaka et al [US1111,US1112] and Tachibana et al [US1127], published in 1973, 1974, and 1976, indicated that although fetal malformations in mice were associated with irradiation at intensities of 20-100 mW/cm^2, their incidence was not significantly different from that in controls. Pregnant mice were irradiated with 2.3-MHz ultrasound for 5, 10, and 30 min/d from day 8 through day 14 or from day 7 through day 13 of fetal gestation. Significant differences from control mice were noted in fetal weight at birth.

Fetal abnormalities in mice have been produced at higher intensities. Stratmeyer et al [US0643] reported, in 1977, that 2 minutes of irradiation of pregnant mice on the 10th day postcoitus (dpc) led to differences in organ and body weight between exposed and nonexposed fetuses. Continuous 1-MHz ultrasound at intensities of 0.25 and 0.8 W/cm^2 was used, and weights were measured 18, 21, 36, and 51 dpc (18 dpc is 1-2 days before birth). Significant increases were noted after irradiation at 0.25 W/cm^2 in body weight at 21, 36, and 51 dpc and in brain, liver, spleen, and heart weight at 36 and 51 dpc. Exposure to 1-MHz ultrasound at 2 or 2.5 W/cm^2 on the 8th day of gestation produced a high incidence of exencephaly in mice, according to a 1977 report by Rugh and McManaway [US0638]. Fetuses from 49 pregnant mice were examined on the 18th day of gestation: 343 of them had been irradiated for 3 minutes, and 107 were not irradiated and served as the control group. Visceral dysraphe, stunting, protruding tongue, and extra digits were observed in addition to exencephaly; the incidence of dead and resorbed fetuses did not differ from control values.

Another study using fetuses at the 8th day of gestation was described by Fry et al [US0641] in 1977. They irradiated pregnant mice with PW 1.364-MHz ultrasound having a pulse repetition rate of 1,000 pps. Peak intensities of 1,926, 567, and 250 W/cm^2, corresponding to average intensities of 59, 13.2, and 6.25 W/cm^2, were found to decrease average litter size by 50% after irradiation for 20, 100, and 300 seconds, respectively. In 1976, Curto [US0712] also reported that early postpartum mortality followed ultrasonic irradiation of fetuses in utero on the 13th day of gestation. Exposures of 3 minutes to 1-MHz ultrasound at intensities of

0.125, 0.25, and 0.5 W/cm^2 were found to increase the percentages of offspring dying before 21 days by 10.2, 8.8, and 22.5%, respectively, over the control value (4.2%). In 1979, Edmonds et al [US0530] published the results of an extensive study on postpartum survival of mice, which corrected several faults in Curto's [US0712] experimental design. Neonatal mortality was compared in 372 fetuses irradiated with CW 2-MHz ultrasound at an incident intensity of 0.5 W/cm^2 (in utero intensity of 0.44 W/cm^2) for 60-180 seconds, in 84 sham-irradiated controls, and in 84 unirradiated controls. The ventral, dorsal, and lateral areas of the mice were shaved and depilated, and each mouse was immersed in a 37 C water bath for near-field irradiation. There were no significant differences in mortality on the 25th day postpartum among fetuses irradiated on the 8th day of gestation and sham- and unirradiated controls.

Several effects of ultrasound irradiation on pregnant mice and their fetuses were described by Torbit et al [US1162] in 1977. Pregnant mice were shaved and immersed in a water tank for irradiation with 2-MHz ultrasound at an intensity of 1 W/cm^2 on day 1, 2, 4, 7, or 13 of pregnancy. On the 15th day of pregnancy, measurements of maternal and fetal weight and number of surviving offspring and electron microscopic examination of maternal ovaries revealed no statistically significant differences among irradiated, sham-irradiated, and unhandled control mice following exposure for 100 seconds. Decreases (values not reported) in maternal and fetal weight and number of offspring were said to have been observed following exposure for 400 seconds, as was disorganization of the corpea lutea. In a subsequent report from the same group, Stolzenberg et al [US1126] reported, based on dose-response curves obtained for mice irradiated on various days of pregnancy at 100, 200, and 400 J/cm^2, more limited effects. Maternal and fetal weights and postpartum survival were not affected significantly at any stage of gestation, except for possible decreases in fetal survival following irradiation at 400 J/cm^2 on days 1 and 13. Dose-dependent disruption of the cytoplasm and mitochondria of ovarian, corpus lutean, and placental cells was observed in light and electron microscopic studies.

Teratogenic studies with rats have also provided a threshold for the production of effects. In 1972, McClain et al [US0303] reported that exposure to CW ultrasound for either 0.5 or 2 h/d on days 8, 9, and 10 or days 11, 12, and 13 of gestation produced no significant differences, relative to controls, in viable fetuses, litter size, fetal weight, resorptions, implantations, skeletal and soft tissue abnormalities, and skeletal variations. Forty rats in total were irradiated. Pizzarello et al [US0181], in a 1978 report, noted a similar lack of effect following exposure to ultrasound at a power density estimated to be between 1.1 and 190 mW/cm^2. Pregnant rats were irradiated for 5 minutes on the 3rd, 5th, and 6th, or 15th day. A reduction in fetal size was the only ultrasound-induced change observed.

Exposing individual rat fetuses in the uterus to CW 3.2-MHz ultrasound did not lead to a significant incidence of malformations or death, according to a 1976 report by Sikov et al [US0219]. Individual 9-day-old embryos were exposed for 5 minutes at intensities of 2.8-32.4 W/cm^2 or for 15 minutes at 2.8-23.3 W/cm^2. Examinations were made at the 20th day of gestation. A properly selected control group was not available for comparison; nevertheless, fetal size and the incidence of mortality were within the accepted range of values. The LD_{50}'s for rat fetuses were determined to be 18.4 and 16.3 W/cm^2 for 5- and 15-minute exposures, respectively. Five of the eighty-nine survivors irradiated at 10.5 W/cm^2 had multiple malformations, such as cleft palate, anophthalmia, and exencephaly; however, the number of survivors was insufficient to establish a definite dose-effect relationship. In a second study, published by Sikov and Hildebrand [US1123] as an abstract in 1977, the apparent threshold for ultrasound-induced mortality and malformation was estimated to be 3 W/cm^2. The major effect of irradiation with continuous ultrasound with frequencies of 0.71 and 3.2 MHz and pulsed ultrasound of 2.5 MHz was stated to be gross and microscopic abnormalities of the heart.

Cephalic and cardiovascular changes have also been reported in chick embryos exposed to ultrasound. In 1963, Vasquez [US0898] described arrested development of the brain, anophthalmia, and absence of the ear and of the nasal and oral cavities after 1-30 minutes of exposure to 870-kHz ultrasound at 0.5-3 W/cm^2. Blood cell stasis, described before, and damage to the endothelial cells of the blood vessels were reported by Dyson et al [US0007] in 1974. Ultrasound with frequencies of 1, 3, and 5 MHz and intensities between 0.88 and 11.89 W/cm^2 was used. Yamaguchi and Vaupel [US1131] described, in a 1978 abstract, a variety of cardiovascular abnormalities in chick embryos irradiated with CW 2.1-MHz ultrasound for 1, 2, 4, 8, and 16 hours.

Irradiation of fetuses has not been found to affect the development of their behavioral repertoire. Murai et al, in a 1974 abstract [US1110] and a 1975 paper [US0312], reported that irradiation of pregnant rats on the 9th day of fetal gestation produced insignificant changes in emotional behavior, discrimination learning, orienting behavior, and neuromotor reflexes. The fetuses were exposed for 5 hours to 2.3-MHz ultrasound at an intensity of 20 mW/cm^2, and the behavior of 372 survivors, divided almost equally among irradiated, nonirradiated (sham exposure), and control groups, was analyzed at 21 days after birth. No significant differences were noted in onset of walking, urination and defecation responses, righting and grasp reflexes, negative geotaxis, cliff drop aversion, visual and vibrassa placing responses, and acceleration righting reflex. Open-field behavior, the aversive response, and discrimination were altered when offspring reached 150 days, but the alterations could not be definitely attributed to irradiation.

The possible genetic hazards of ultrasound have been studied in a variety of experiments. As with other tissues, the reproductive systems of animals may be assumed to be altered by ultrasonic irradiation. However, in 1963, Kirsten et al [US0720] reported that 1- to 7-day-old mice subjected to 5 minutes of irradiation with 1-MHz ultrasound subsequently produced litters of normal size. Continuous ultrasound at intensities of 1.7-4 W/cm^2 and pulsed ultrasound with an average intensity of 1-1.2 W/cm^2, pulse widths of 50 and 100 µs, and pulse repetition rate of 1,000 pps were used to irradiate 200 male and female mice, who were bred 7 weeks later. A similar lack of effect was reported at 10 mW/cm^2 by Smyth [US0660] in 1966.

Induction of dominant lethal mutations in male or female mice did not follow ultrasonic irradiation, according to a report published by Lyon and Simpson [US0302] in 1974. Male and female mice were placed in a water bath and their gonads were irradiated with 1.5-MHz ultrasound for 15 minutes under one of three exposure conditions: CW ultrasound at an intensity of 1.6 W/cm^2; PW ultrasound at the same average intensity, with a pulse width of 1 ms, duty cycle of 0.33, and peak intensity of 6.4 W/cm^2; PW ultrasound at an average intensity of 0.9 W/cm^2, with a pulse width of 30 μs, duty cycle of 0.02, and peak intensity of 45 W/cm^2. Measurements of pre- and postimplantation loss in matings of 11 irradiated male mice and 12 irradiated female mice with nonexposed mice indicated no significant differences from control values. Testis weight and spermatozoal counts were not found to be reduced, relative to controls, nor was the incidence of chromosomal translocations or aberrations found to be increased, at 3-56 days after irradiation.

Two reports by Fry et al [US0194,US0641], in 1977 and 1978, described ultrasound-induced effects on litter size after testicular and ovarian irradiation. Exposure to pulsed 1-MHz ultrasound with a pulse repetition rate of 1,000 pps, peak intensity of 1,525 W/cm^2, and average intensities of 30.5, 68.6, 105.9, 145.3, and 183 W/cm^2 reduced the size of the litters produced from matings performed 30 days after irradiation. Pup weight and the incidence of resorptions and runts were not significantly different from control values. The LD_{50}'s for male and female mice were 178 and 268 W/cm^2, respectively, for direct irradiation of the gonads.

Pourhadi et al [US0550] described the degenerative and mitotic lesions produced in the testicular tissue of mice by contact and water-coupled 1-MHz ultrasound in a comprehensive 1965 report. The intensities ranged from 1.8 to 4.5 W/cm^2, and the scrotum of each rat was irradiated once or twice for a total exposure time of 2, 5, or 10 minutes. Production of congestion, edema, or hypertrophy of the scrotum; necrosis, hemorrhages, and testicular atrophy; degeneration of the (in order of occurrence) spermatocytes, spermatids, and spermatogonia; and mitotic and chromosomal abnormalities was observed to be dose dependent. Testicular damage was reported by O'Brien et al [US0637] in 1977. The testes of mice were irradiated for 30 seconds with 1-MHz ultrasound at 10 and 25 W/cm^2. Microscopic examination of tissue at various periods up to 43 days after irradiation indicated disruption first of spermatocytes and then of spermatids and depletion of spermatogonia. A second report by O'Brien et al [US1153], in 1979, described similar results.

Ultrasonic irradiation of the testicles of 123 rats using water as the coupling agent also was observed to lead to degeneration of spermatocytes and then spermatogonia, according to a 1966 report by Andrianov [US0226]. The changes in the cell structure of the spermatogenic epithelium produced by irradiation with 800- to 810-kHz ultrasound for 5 minutes at 0.2, 0.6, and 0.8 W/cm^2 were temporary (preirradiation appearance regained within 30 days). They included the production of cytoplasmic granuoles and vesicles and disruption of the endoplasmic reticulum and mitochondria. Although the changes were more extensive at 2 W/cm^2 and were accompanied by disintegration of the nuclei, the appearance of the epithelium returned to normal within 30 days after exposure.

Fahim et al [US0256] reported, in 1975, that spermatogenesis in the rat was affected by ultrasonic irradiation. Sixty rats were exposed for 5 minutes to PW ultrasound at 1 and 2 W/cm^2. Reductions in sperm count, spermatids, and secondary spermatids were observed. Male rats irradiated once at 2 W/cm^2 or twice at 1 W/cm^2 did not produce offspring when mated every 5 days with nonexposed female rats for a period of 10 months after irradiation. A second report from the same laboratory, published by Dumontier et al [US0696] in 1977, suggested that the reduced sperm count was due to an alteration of the membrane permeability that precluded maturation of testicular cells. Male rats were irradiated with 1.1-MHz ultrasound at 1 W/cm^2. The testicular cells of those exposed for 5 minutes showed no microscopically detectable anomalies; however, the male rats were incapable of impregnating nonexposed female rats for 40 days after irradiation. Spermatocytes and spermatids of those male rats exposed for 10 minutes, on the contrary, exhibited irregular and leaky membranes between 4 and 48 hours after irradiation. The endoplasmic reticulum and mitochondria of the cells appeared swollen. Between 20 and 60 days after irradiation, the Sertoli cells were seen to contain large amounts of cell debris. Rats exposed for 10 minutes were incapable of impregnating female rats for 150 days. In 1978, Fahim et al [US0497] reported that water-coupled irradiation of rat testes with 3-MHz ultrasound led to variable changes in the concentrations of Na^+ and K^+ in the seminiferous tubules and testes. A dose of 0.9 kJ/cm^2 was applied in a 15-minute exposure at an intensity of 1 W/cm^2.

Rabbit testes exposed to 2.25-MHz ultrasound at 1 mW/cm^2 were not damaged, according to a 1969 report by Hahn and Foote [US0609]. One testis of each of 25 male rabbits was irradiated for five consecutive 2-minute periods, each at a different location on the testis. Sperm number, appearance, and motility were similar before and up to 3 weeks after irradiation. Testis size, the diameter of the seminiferous tubules, and spermatogenic activity were similar for both the treated and untreated testes of each animal 2 and 4 weeks after exposure. A temporary reduction in sperm count and motility in 14 monkeys (Macaca) was reported by Fahim et al [US0497], in 1978, following liquid-coupled irradiation with 3-MHz ultrasound. The 30-minute exposure, at an intensity of 0.5 W/cm^2, was found to be more effective with a 3% saline solution than with water.

Indications of ultrasound-induced alterations in the uterus have been obtained. A 1975 abstract from Hara et al [US1132] suggested that irradiation of the uterus of a pregnant rat with 2.4-MHz ultrasound irritated the uterus, suppressed uterine contractions, or irreversibly damaged the uterine wall, depending on the intensity (not given). Placental transfer of radioactively labeled strontium (^{85}Sr) was reported to be altered by ultrasound, according to a report by Engelhardt et al [US1084,US1085] in 1977. Fetal rats were irradiated with either CW or PW 2- or 2.5-MHz ultrasound for 3 minutes on the 16th day of gestation. Determination of ^{85}Sr uptake on the 18th day indicated that transfer of Sr had increased in both hypo- and euthyroid maternal rats, indicating that stress relaxation had occurred.

Chromosomal damage has not been found to result from ultrasonic irradiation, except for the production of aberrant mitotic figures and chromosomes in mice described by Pourhad et al [US0550] above. Galperin-Lemaitre et al [US0264] in 1973 and Levi et al [US0297] in 1974 reported that irradiation of golden hamsters had no effect on marrow cell chromosomes. The femoral and humoral areas were irradiated for 2 and 5 minutes with 0.87-MHz ultrasound at 1 and 1.5 W/cm^2. The bone marrow was then removed and chromosomal spreads were prepared from the medullary cells. Comparison of 1,176 irradiated cells with 327 nonirradiated cells indicated no significant increase in the number of chromosomal aberrations. A 1978 study by Harkanyi et al [US1133] also noted a lack of effect on mouse bone marrow chromosomes. Eighteen mice were exposed to 800-kHz ultrasound for 5 minutes at intensities of 0.1, 0.5, and 1 W/cm^2. The percentages of metacentrics, acentrics, rings, chromatid deletions, and chromosome deletions were determined for 250 marrow cells at each intensity. Comparison with percentages for 600 marrow cells from nonirradiated controls indicated no significant differences.

Effects on reproduction, both positive and negative, are summarized in Table XIII-13.

TABLE XIII-13

EFFECTS OF EXPOSURE TO ULTRASOUND ON REPRODUCTIVE SYSTEM OF ANIMALS

Species	Effect*	Intensity (W/cm^2)**	Duration (min)**	Calculated Dose (kJ/cm^2)**	Method of Application	Frequency (MHz)**	Reference
Mouse	Fetal abnormalities and resorption (-)	27	7-30 s	0.189-0.81	Contact	1, 2, 3 (PW)	US0097, US0157
"	Fetal abnormalities, subsequent capacity to mate, chromosome abnormalities (-)	0.164-0.49	5, 60	0.049-1.76	"	2.28	US0307
"	Specialized fetal abnormalities (-)	0.02-0.1	5, 10, 30 min/d for 7 d	0.042-1.26	"	2.3	US1111, US1112, US1127
"	"	10-160 mW	5-15 min/d, 1-6 d	--	"	7-10	US0420
"	Minor alterations in fetal development	1	100-400 s	0.1-0.4	"	2	US1162
"	Specialized fetal abnormalities	0.04, 0.1	5 h	0.72, 1.8	"	2.25	US0442, US0887, US1120
"	"	1.054	5, 60	0.32, 3.79	"	2.28	US0307
"	Exencephaly, extra digits, stunting, and other abnormalities	2, 2.5	3	0.36, 0.45	"	1	US0638
"	Increases in body and organ weight	0.25, 0.8	2	0.03, 0.096	"	1	US0643
"	Decrease of 50% in litter size	6.25 13.2 59	300 s 100 s 20 s	1.875 1.32 1.18	"	1.364	US0641
"	Dose-dependent increase in postpartum mortality	0.125, 0.25, 0.5	3	0.022, 0.045, 0.09	"	1	US0712
"	Neonatal mortality (-)	0.44	1-3	26.4-79.2 J/cm^2	Water coupled	2	US0530
"	"		--	0.2-0.4	Contact	2	US1126
Rat	Fetal resorption, abnormalities, weight, and survival; litter size (-)	--	0.5 or 2 h/d for 3 d	--	"	--	US0303

TABLE XIII-13 (CONTINUED)

EFFECTS OF EXPOSURE TO ULTRASOUND ON REPRODUCTIVE SYSTEM OF ANIMALS

Species	Effect*	Intensity (W/cm^2)**	Duration (min)**	Calculated Dose (kJ/cm^2)**	Method of Application	Frequency (MHz)**	Reference
Rat	Fetal resorption, abnormalities, weight, and survival; litter size (-)	1.1 and 190 mW/cm^2	5	0.33 and 0.057 J/cm^2	Contact	--	US0181
"	"	2.8-32.4 2.8-23.3	5 15	0.84-9.72 2.52-20.97	Contact (fetus)	--	US0219
"	LD_{50} for fetuses	18.4 16.3	5 15	5.52 14.67	"	--	US0219
"	Threshold for fetal death	3	--	--	Contact	0.71 and 3.2 (CW) 2.5 (PW)	US1123
"	Development of behavioral repertoire in neonates	0.02	5 h	0.36	"	2.3	US0312, US1110
Mouse	Microscopic changes in ovarian, corpora lutea, and placental tissues	--	--	0.2-0.4	Contact	2	US1126
"	"	1	100-400 s	0.1-0.4	"	2	US1162
"	Reproductive capacity of males and females: litter size (-)	1.7-4 1-1.2	5	0.51-1.2 0.3-0.36	"	1 (CW) 1 (PW)	US0720
"	Reproductive capacity of males and females: pre- and postimplantation loss (-)	1.6 0.9	15	1.44 0.81	Contact (gonads)	1.5 (CW and PW) 1.5 (PW)	US0302
"	Reproductive capacity: litter size	30.5-183	--	--	"	1 (PW)	US0194, US0641
"	Testicular damage: disruption of spermatocytes and spermatids, depletion of spermatogonia	10, 25	0.5	0.3, 0.75	Contact (testes)	1	US0637
"	Degeneration of testes	1 2 3	5, 10 1, 5, 10 1, 3	0.3, 0.6, 0.12, 0.6, 1.2 0.18, 0.54	Water coupled	1	US0048

TABLE XIII-13 (CONTINUED)

EFFECTS OF EXPOSURE TO ULTRASOUND ON REPRODUCTIVE SYSTEM OF ANIMALS

Species	Effect*	Intensity (W/cm^2)**	Duration (min)**	Calculated Dose (kJ/cm^2)**	Method of Application	Frequency (MHz)**	Reference
Mouse	Decreased spermatogenesis, inability to impregnate females for 10 months	1, 2	5	0.3, 0.6	Contact	-- (PW)	US0256
"	Inability to impregnate females for 1-5 months, microscopic changes in spermatocytes	1	5, 10	0.3, 0.6	"	1.1	US0696
"	Degenerative lesions and disruption of mitosis in testes	2.5-4	2-5	0.3-1.2	"	1	US0550
"	Degeneration of testes, disruption of spermatocytes	25	0.5	0.75	"	1	US1153
Rat	Disruption of spermatocytes and spermatids	0.2-2	5	0.06-0.6	"	0.8	US0226
"	Alterations in testicular electrolyte concentrations	1	15	0.9	Water coupled	3	US0497
Rabbit	Testes size, spermatogenic activity, sperm motility and appearance (-)	1 mW/cm^2	10	0.6 J/cm^2	Contact	2.25	US0609
Mouse	Chromosomal damage (-)	0.1, 0.5, 1	5	0.03, 0.15, 0.3	"	0.8	US1133
Hamster	"	1, 1.5	2, 5	0.12-0.45	"	--	US0264, US0297

*Lack of effect denoted by (-)
**Except where noted

(j) Summary

An analysis of the data presented above indicates that the majority of ultrasound-induced effects in animals concern exposures to doses in excess of 50 J/cm^2. Tables XIII-5 to XIII-13 present evidence for effects at lower doses; however, as the descriptions indicate, these are negligible.

XIV. APPENDIX VIII

SEARCH STRATEGY AND CRITERIA FOR EVALUATION OF LITERATURE

This appendix describes the strategy developed to meet the literature search requirements for a document on ultrasound. The process includes a literature search of worldwide primary, secondary, and tertiary sources to identify all relevant information, retrospective as well as current.

Search Strategy

First, the subject contents of over 110 online data bases available through the National Library of Medicine's MEDLARS, Lockheed Information System's DIALOG, and System Development Corporation's ORBIT were studied. Those data bases determined to be relevant to the subject of ultrasound were then searched. The computerized data bases contain a certain amount of overlap. However, since each one contains citations found exclusively in that data base, each relevant data base must be searched regardless of partial duplication elsewhere. Accordingly, a computerized literature search technique was used to eliminate duplication of effort as much as possible. This was accomplished by structuring the sets from a search profile into groups based on primary and subset file sources. For example, in a search of CA CONDENSATES (Chemical Abstract Service), which is partially contained in Chemical-Biological Activities (BAC) in NLM's TOXLINE, the subfile (CBAC) was separated from the new set.

The indexing characteristics of the sources and services consulted have distinct features. Some systems use controlled vocabularies, permuted term indices, free-text access, and combinations of the above. Both computerized and manual searches using specific terms were executed after taking into consideration the respective indexing characteristics. Manual searching was done by experienced literature specialists for any indexing or abstracting source not available on a computer system. Reference works, such as Ulrich's International Periodical Directory and Standard Periodical Directory, were consulted to identify periodicals relevant to the subjects being studied. Ulrich's also provides information on where these periodicals are indexed, and this information was also used to identify computerized and printed indexes for the search strategy.

The initial phase of information gathering focused on retrieving information on:

(1) Synonyms and trade names
(2) Physical properties
(3) Manufacturers and users
(4) Manufacturing processes
(5) Uses
(6) Production figures
(7) Estimates of numbers of workers exposed

(8) Toxicity

(9) Current standards

The following computer data bases were searched to locate some of the needed information:

Claims[TM]/US Patents (1971+)

The Claims/US Patents data base contains all patents listed in the general, chemical, electrical, and mechanical sections of the Official Gazette of the US Patent Office. Foreign equivalents from Belgium, France, Great Britian, West Germany, and the Netherlands are included for approximately 20% of the US patents in the file.

Compendex (1970+)

The Compendex data base is the machine-readable version of the Engineering Index that provides worldwide coverage of approximately 3,500 journals, publications of engineering societies and organizations, papers from proceedings of conferences, and selected Government reports and books.

GPO Monthly Catalog (1973+)

The Government Printing Office (GPO) Monthly Catalog contains records of reports, studies, fact sheets, maps, handbooks, conference proceedings, etc., issued by all US Federal Government agencies, including the US Congress. This data base provides access to legislative reports, standards and safety studies, production and distribution statistics, industry reports and projections, and labor standards requirements.

NTIS (1964+)

The National Technical Information Service (NTIS) data base consists of Government-sponsored research, development, and engineering information plus analyses prepared by Federal agencies, their contractors, or grantees. It is the means through which unclassified, unlimited distribution reports are made available from over 240 Federal agencies and departments such as NASA, DDC, AEC, HHS, HUD, DOT, and DOC.

PTS F&S Indexes (1972+)

The F&S Indexes cover both domestic and international companies, products, and industries. It also provides online access to a comprehensive bibliography of more than 5,000 publications cited in Predicast's publications.

PTS EIS Industrial Plants (current)

The EIS Plants data base includes current information on some 117,000 establishments operated by 67,000 firms. Data are generated from business magazines, trade journals, State and industrial directories, corporate financial reports, and Census Bureau statistics.

PTS Federal Index (1976+)

The Federal Index provides coverage of such Federal actions as proposed rules, regulations, bill introductions, speeches, hearings, roll calls, reports, vetoes, court decisions, executive orders, and con tract awards. The Washington Post and Federal documents such as the Congressional Record, Federal Register, Presidential documents, and Commerce Business Daily are indexed on a regular basis.

PTS US Statistical Abstracts (1971+)

PTS US Statistical Abstracts contains abstracts of published forecasts for the United States from trade journals, business and financial publications, key newspapers, Government reports, and special studies.

SPIN (1975+)

SPIN (Searchable Physics Information Notices) is designed to provide the most current indexing and abstracting of a selected set of the world's most significant physics journals. Coverage includes all of the journals published by the American Institute of Physics, including the Russian translations, as well as some additional American physics journals. Author-prepared abstracts enhance the relevancy of this data base, which is increasing by approximately 2,000 records monthly. SPIN covers all major areas of physics as well as mathematical and statistical physics, astronomy, astrophysics, and geophysics.

TOXLINE (TOXicology Information on-LINE)

TOXLINE, which is available from NLM, consists of computerized toxicology information with over 601,000 references to published human and animal toxicity studies, effects of environmental chemicals and pollutants, adverse drug reactions, and analytical methodology.

Searches were conducted on computer data bases that give information on research in progress; these data bases included:

Smithsonian Science Information Exchange (SSIE)

This data base contains reports of both Government and privately funded scientific research projects either currently in progress or initiated and completed during the most recent 2 years. Subject content encompasses all fields of basic and applied research in the life, physical, social, and engineering sciences.

Current Research Information System (CRIS)

The projects described in this data base cover research in agriculture and related sciences, sponsored or conducted by US Department of Agriculture research agencies, State agricultural experiment stations, State forestry schools, and other cooperating State institutions. Projects relevant to the subject of a document were identified, and the investigators were contacted to obtain information and status reports.

Customized literature searches were requested for noncommercial computer systems that could not be accessed by in-house systems. These systems included:

NIOSHTIC - Produced by the National Institute for Occupational Safety and Health

TIRC - Produced by Oak Ridge National Laboratory, Toxicology Information Response Center

Updating of literature was accomplished by searching the file updates according to the capabilities of each of the major data base distributors such as:

NLM's MEDLARS: A search strategy is formulated and run against SDILINE after monthly updates are entered.

SDC and LOCKHEED: Each of these systems has a search storage capability that allows a search formulation to be stored in the computer and called up when needed. These searches are run against appropriate files on a monthly or quarterly basis depending on the update schedule.

Current Contents publications in environmental sciences and other relevant categories were scanned on a regular basis to ensure complete identification of nonabstracted or nonindexed references. This also allowed for incorporation of any information published during and after the initial search.

Professional contacts with personnel and consultants in industry, Federal and State agencies, labor unions, trade associations, and other professional associations were used as sources of information on safety data sheets and process specifications as well as on handling, storage, and labeling. Research reports and exposure statistics were obtained and bibliographies from these reports were tree searched, providing additional information sources. Written and oral information exchanges afforded by professional society memberships, meetings, and conferences was also used.

Contract awards and grant listings were reviewed on a regular basis to identify sources of current research, unpublished data, and other pertinent information from scientific institutions and organizations.

A list of sources based on the professional experience in the disciplines of information science, physics, toxicology, industrial hygiene, and occupational medicine is included at the end of this appendix. Standard references included in the list consisted of sources that provide information on nomenclature, physical properties, uses, processes, production, producers, toxicologic data, and Federal and other occupational exposure standards. The standard sources include encyclopedias, handbooks, dictionaries, textbooks, and information profiles.

Evaluation of Literature

The search and retrieval process yielded 1177 articles. These were classified into five groups as follows:

(1) Human - studies describing observations or the results of experiments on humans exposed to ultrasound
(2) Animal - studies describing experimental results with various animal species
(3) Industrial Hygiene - reports discussing engineering controls, workplace practices, and monitoring methods concerned with ultrasound

(4) Analytics - theoretical and practical studies dealing with the determination of ultrasonic dose and the propagation of ultrasonic energy

(5) Miscellaneous - reports on the in vitro effects of ultrasound on tissues, organs, cells, and macromolecules; nonanimal species; and applications of ultrasound

The proportion that each group represented of the total is given below.

Human	14.5
Animal	33
Industrial hygiene	12.5
Analytics	7.5
Miscellaneous	32.5

Approximately 25% of the papers were considered to be of use for the development of the document. For determining the biologic effects of exposure to ultrasound, each paper was scanned for information on those exposure characteristics listed in Table I-2. Since none of the papers provided such complete information, acceptable information included:

(1) Species

(2) Intensity and duration of exposure

(3) Frequency of irradiation

(4) Effect or lack of effect

These do not represent minimal exposure data, however, because many human observations and some animal experiments did not mention all these factors. In such cases, if the paper was corroborative or the only paper discussing an effect or lack of effect, it was included. For the purpose of determining thresholds for effects or correlating exposure with effects, only those reports for which doses (see Chapters II and IV) could be calculated were used. This selection process applied to all papers in the human and animal categories and to some in the industrial hygiene and miscellaneous categories.

Papers in the analytic, industrial hygiene, and miscellaneous categories were used as needed for the preparation of those sections on ultrasound physics, uses of ultrasound and extent of exposure, occupational exposure levels, and potential for hazardous exposure. The miscellaneous category was purposely disregarded because the in vitro work concerned exposures of isolated cells, etc, in solution where strong cavitation occurs. Since this will not occur under occupational situations, the information was considered superfluous for the establishment of exposure limits and dose-response relationships.