Medical Ultrasound Exposure Measurements: Update on Devices, Methods, and Problems

Gerald R. Harris
FDA, Center for Devices and Radiological Health, Rockville, MD 20850

Abstract - Medical ultrasound fields span a wide range of exposure conditions, from the continuous, low-frequency vibrations of surgical fragmentation needles, to the intense, broadband pressure pulses produced by extracorporeal shock wave lithotripters. Each of these diverse conditions of use presents its own exposure measurement challenges. Furthermore, the sensors and techniques used to evaluate ultrasound exposures have had to evolve as new or expanded clinical applications have emerged. In this paper some of the more notable of these developments are presented and discussed. Topics covered include recent work on devices and techniques, methods of calibration, progress in standardization, and current problem areas, including the effects of nonlinear propagation. Emphasis is given to miniature hydrophones because of the prominent role they continue to play in ultrasound exposure measurements.

I. INTRODUCTION

As the medical uses of ultrasound have grown, so has the need for quantifying the acoustic field variables that define the extent of exposure. Added demands have been placed on the measurement devices as well. For example, increased bandwidths are necessary to faithfully reproduce the acoustic pressures associated with nonlinear wave propagation or high frequency applications; small detector size must be achieved to measure highly focused or high frequency fields, or to make measurements *in vivo*; robust devices or techniques are required to withstand the intense fields encountered in lithotripsy and focused surgery; and efficient means are needed to characterize the acoustic output in the complex scanning modes found in modern diagnostic imagers.

In this paper some of the more recent developments in medical ultrasound exposimetry are presented. For background on fundamental measurement techniques, instrumentation, and standards, as well as definitions of terms and concepts, the reader may consult [1], [2], [3], [4], [5]. The paper is organized by medical application category. Within each section, problems associated with the clinical device or with measurement of the relevant exposure quantities are identified, and the instruments and methods that have been developed to address these problems, or simply to improve current measurement practice, are described. Also, progress in measurement and labeling standardization is briefly discussed where applicable. A short description of *in vivo* measurements concludes the presentation.

II. DIAGNOSTIC IMAGING AND DOPPLER TO 15 MHZ

Diagnostic ultrasound exposimetry has received more attention that any other medical use category, paralleling the success of diagnostic ultrasound as a medical imaging modality. New and refined measurement approaches have appeared with some regularity, as have problems associated with characterizing the ultrasound fields. To emphasize where these developments seem to be most applicable, the discussion of diagnostic ultrasound has been separated into two frequency ranges, the higher range being covered in the next section. The choice of 15 MHz is somewhat arbitrary, although this frequency has been used to define the range of applicability for several International Electrotechnical Commission (IEC) standards discussed below.

A. Nonlinear propagation effects on p_r measurement

For hydrophone-based measurements, the presence of nonlinear propagation effects poses a serious impediment to the accurate assessment of ultrasonic exposure [6]. An obvious first consequence is that the harmonics generated necessitate an increased measurement bandwidth. A less apparent result is that for a distorted pulsed waveform, the bandwidth below the center frequency of the pulse must be extended as well, particularly for accurate measurement of the peak negative pressure, p_r [7], [8]. One reason is that the shorter the pulse, the broader the spectrum below as well as above the center frequency. Additionally for p_r, the waveform asymmetry resulting from the combined effects of source diffraction and nonlinear propagation cause the portion of the pulsed waveform where p_r occurs to be dominated by low-frequency components. The accuracy of the Mechanical Index (MI) decreases as well, because it is defined as the derated peak rarefactional pressure, measured under specified conditions, divided by the square root of the center frequency (f_c) [9], [10]. From [7] and [8], which contain both simulations and measurements of the effects of bandlimited response on p_r and MI, it is seen that to reduce errors to less than 5-10%, the hydrophone-amplifier bandwidth should extend at least an order of magnitude below the pulse center frequency. Current measurement standards require that the hydrophone-amplifier combination have a bandwidth with lower corner frequency of $f_c/2$ [11], [12], although in [11] it is recommended that this value be decreased to $f_c/20$.

Because of this result, at a minimum the combined frequency response of all components used to condition, amplify, or record diagnostic pulsed waveforms should extend down to approximately $f_c/20$. In addition, needle hydrophones should be used with caution, because of the roll-off in low-frequency response that has been observed in these devices [13], [14], [15], [16], [17]. This roll-off seems to be related to diffraction at the needle tip, and at least one modified design has been developed to ameliorate this problem [18]. A related issue is the need for low-frequency calibration standards, and in this regard several methods are being considered, including three-transducer reciprocity [13], interferometry [13], time delay spectrometry (TDS) [16], [17] and broadband pulse [15].

B. Nonlinear propagation effects on derated quantities

Medical ultrasound fields usually are measured in water, and one international standard specifies that outputs must be declared to the user in that form [19]. In the US, standards for diagnostic ultrasound equipment have been published that define acoustic output quantities in which a derating factor of 0.3 dB $cm^{-1}MHz^{-1}$ is applied to estimate *in situ* exposure values [9], [11], [20]. For computational simplicity this derating process assumes that ultrasound propagation is linear, but most diagnostic scanners can produce output levels in which nonlinear propagation effects are significant, not only in water but in tissue as well [6]. A problem arises because nonlinear propagation can lead to acoustic saturation, in which an increase in source voltage is not accompanied by an equivalent increase in field pressure. Attenuation in the propagation medium tends to counteract this effect, so saturation is relatively more pronounced in water than in tissue. Thus, a derated quantity calculated from a hydrophone-measured pressure at full output in water can lead to a significant underestimate of that quantity in tissue [21]. Several approaches are being studied to deal with this phenomenon.

Linear extrapolation of low-output levels: One proposal for making estimates of *in situ* exposures from water-based hydrophone measurements in the presence of nonlinear propagation is to perform a linear extrapolation of derated "small-signal" measurements; i.e., measurements at source output levels in the linear regime [22]. To define this small-signal, quasi-linear region, it has been suggested that a value of shock parameter $\sigma < 0.5$ be used [23]. One such parameter used for focused medical ultrasound beams and adopted in [11], [12] is the nonlinear propagation parameter, σ_m. Calculation of σ_m requires measurement of the focal distance and pressure, center frequency, and focal gain. Other, possibly more convenient nonlinearity parameters have been introduced [24], [25]. In [25] a frequency domain estimator of nonlinearity, the spectral index (SI), is defined (see Eq. (1)). Here P(f) is the power spectral value at frequency f, and f_6 is the frequency above f_c at which the spectrum first falls 6 dB below its value at f_c. As the measured hydrophone waveform becomes more nonlinear and generates more high-frequency harmonics, the value of the SI increases. The SI is a field quantity rather than a beam descriptor like σ_m, and as such may be calculated at any field location from a single hydrophone measurement. In practice the upper integration limit is chosen to reduce errors from high-frequency spectral noise (25 MHz was used in [25]). In [25] it was found that the SI tracked fairly linearly with σ_m, being numerically about a factor of 10 lower. Thus, a threshold value of 0.05-0.1 for the SI seemed to be appropriate for demarcating the quasi-linear region, but this concept needs further study.

$$SI = \int_{f_6}^{\infty} P(f)\,df \Big/ \int_{0}^{\infty} P(f)\,df \qquad (1)$$

Acoustic attenuators: It has been proposed that low-density polyethylene attenuators be placed in the ultrasound beam between the source and hydrophone to simulate an *in situ* exposure [26], [27]. The attenuation coefficient of this material has a frequency dependence similar to that of soft tissue, and the acoustic impedance is approximately 25% greater than that of water. The procedure recommended involves first measuring σ_m and f_c in water at the location where the *in situ* value is to be determined. Then the attenuator thickness is chosen so that its attenuation matches that of the desired tissue type. If $\sigma_m < 1$, the attenuator is placed in the beam next to the source transducer and the hydrophone measurement is made. If $\sigma_m \geq 1$, an additional measurement is made with the attenuator moved next to the hydrophone, and the two results are averaged. While this technique has advantages, it has not been widely evaluated.

Tissue mimicking materials: An obvious but to date difficult approach for obtaining accurate estimates of *in situ* exposure values when nonlinear conditions exist is to make measurements in a material that simulates all of the relevant properties of tissue, including attenuation. Recent work with a tissue mimicking liquid has been reported in which a roughly 60/40 mixture of deionized water and evaporated milk was used, along with a small amount of preservative [28]. At room temperature (22°C) the material had a speed of sound of 1526 m/s, a density of 1.03 g/cc, an attenuation coefficient of 0.27 dB $cm^{-1}MHz^{-1}$, and a nonlinearity parameter (B/A) of 5.7. The attenuation coefficient was designed to match the commonly used derating factor of 0.3 [9], [10], [11]. The other properties are a reasonable match to soft tissue. While this and other similar materials do not have the convenience, universal availability, and well-characterized properties of water, they are valuable for evaluating errors that may be introduced in making *in situ* exposure estimates using derated water-based measurements. Also, they provide a medium for experimental verification of various theoretical models that have been developed that include the effects of diffraction, attenuation, and nonlinear propagation on the radiated field.

C. Measurements in complex scanning modes

The ability of modern diagnostic scanners to operate not only with multiple focal zones, but in several modes at once, has made determining the peak values of acoustic quantities a challenging task, especially I_{SPTA} [29]. Many operator control settings alter the location of the maximum values, and generally not in an easily identifiable way. Several approach have been taken to alleviate this problem.

Establishing measurement protocols: As a start to determining the control settings that lead to a maximum state, a systematic approach for stepping through the process of measuring I_{SPTA} has been proposed for B-mode [30], [31]. The protocol involves, among other things, looping through changes in focal position, number of foci, and depth of field. The flow chart format is designed to reduce measurement time while increasing confidence that the maximum I_{SPTA} has been located. Others have used this procedure with some success, but in its implementation the importance of an inductive coil pick-up for reliable triggering of the acoustic pulse measurement system was noted, not only for providing a trigger, but also for providing information about pulse and frame timing [32]. It also was mentioned that a way to avoid triggering difficulties is to measure untriggered hydrophone output with an RF power meter to obtain the I_{SPTA}, as has been described previously (pp. 140-145 in [1]).

Measurement via hydrophone arrays: As an additional aid to facilitating measurements in scanning modes, both 1-D and 2-D hydrophone arrays are being used [33], [34]. The 1-D array system contains a PVDF membrane hydrophone with 21 elements of 0.4 mm diameter and 0.6 mm spacing. The -3 dB bandwidth is approximately 23 MHz. Scanning mechanics and processing and control electronics and software are included. Upgrades from a previous design include the ability to transfer acoustic output data in ASCII format, a reduction in noise equivalent pressure to 1 kPa, and a new 100 MHz A-D converter. A planned addition is the interfacing of an RF power meter as mentioned above to make easier the identification of system settings that result in maximum I_{SPTA}. The more recent 2-D array uses a vinylidene fluoride copolymer membrane with 64 (8x8) elements having 0.2 mm-diameter elements and a 1 mm spacing. A -3 dB bandwidth of > 30 MHz and a combined acoustic-electronic crosstalk of -30 dB are reported.

Measurement via acousto-optic diffraction: Another approach that has been used as an efficient means to obtain ultrasound field distribution measurements employs the phenomenon of acousto-optic diffraction (pp. 143-162 in [3]). When ultrasonic pressure waves propagate in transparent media, the density perturbations produce fluctuations in the optical refractive index, n. A beam of light passing through these local inhomogeneities will experience velocity (and phase) deviations. The total optical phase shift, ν, for a monochromatic light beam is given by $\nu=k\int \delta n\, dl$, where k is the optical wave number and δn is the change in n, which is integrated over the path of interaction of the light and sound. For small pressure variations, the local instantaneous change in refractive index is proportional to the pressure, the proportionality constant being the adiabatic piezo-optic coefficient, κ. Thus, with p as the acoustic pressure,

$$\nu = k\kappa \int p\, dl. \tag{2}$$

The light intensity in the scattered beam is a function of ν, and this relationship has been used for rapid 2-D mapping and visualization of the ultrasonic field pattern using a CCD camera [35], [36]. Pulsed fields can be measured by proper synchronizing of the light and ultrasound beams. The field distribution in the resultant optical image represents integrated pressure, so tomographic reconstruction has been used to obtain the pressure distribution by making multiple optical measurements at a series of angles through the ultrasound beam. The optical system in [35] uses schlieren imaging (with zeroth diffraction order suppressed), and reconstruction yields the 3-D pressure amplitude distribution, from which I_{SPTA} and ultrasonic power can be derived. In [36] the instantaneous perturbation of n (and pressure per Eq. (2)) is found via optical processing in which an iterative algorithm recovers the integrated phase change at instant t_i from measurements of optical intensity in two planes beyond the sound field and normal to the direction of optical wave propagation. After reconstruction the result is $p(x,y,z)$ at t_i, and the complete field $p(x,y,z,t)$ is obtained by varying t_i. (This result may be compared to a hydrophone scan, in which $p(t)$ is measured at points (x_i,y_j,z_k).)

In addition to its ability to provide rapid 2-D beam plots (albeit of an integrated field quantity), advantages of this technique are its inherently non-perturbing nature and good spatial resolution (< 0.1 mm). As the pressure amplitude increases, the validity of Eq. (2) diminishes, a consideration that applies to some of the higher output therapy and diagnostic applications. In these large amplitude cases useful optical images of the field have been made using the higher orders of diffracted light [37], but the relationship between light intensity and pressure needs further study.

D. Temperature rise phantoms

The thermal indices (TI) of the Output Display Standard [9], [10] have been in use since 1992. While they have proved useful as a predictor of thermal risk during diagnostic ultrasound procedures, they are based on theoretical models rather than actual measurements of temperature rise in tissue. Furthermore, to facilitate implementation of these indices on clinical systems, simplifying assumptions regarding tissue properties and beam geometries were made. Therefore, as a means to evaluate the theoretical models, as well as to estimate tissue heating from diagnostic ultrasound exposures experimentally, a thermal test object (TTO) has been proposed [38]. (Note that, strictly speaking, temperature rise is not an exposure quantity.) This TTO comprises a thin-film thermocouple (TFT) positioned between two layers of tissue mimicking material, each 4-8 mm thick and 50 mm in diameter. The top surface of the TTO is protected by a 6 μm-thick metallized mylar sheet. The bottom surface is coupled to an acoustic absorber by a mixture of 2% ethanol in water.

The TFT was chosen over bulkier thermal configurations to minimize viscous heating due to interaction between the thermocouple body and the ultrasound beam, and thermal conduction along the connecting wires, two artifacts that become significant as the beam dimensions decrease. The TTO is scanned in the ultrasound field much as a hydrophone would be. The sensitivity was found to be 10-16 μV/K, with a temperature resolution of 2 mK.

The advantage of a TTO approach is that no assumptions about the radiated field are made, only about the tissue model. Also, transducer self-heating is accounted for, a factor ignored in the TI models. The TTO in [38] contains no perfusion, although it has been shown that perfusion may be accounted for computationally [39]. Future work is proposed for comparing temperature rise in the TMM with that in tissue both *in vitro* and *in situ*.

E. Measurement of ultrasonic power

The radiation force balance (RFB) and planar scanning techniques remain the most common methods for measuring the temporal-average power in a medical ultrasound beam [11], [40], [41]. In the RFB measurement, error sources include forces due to target buoyancy, streaming, surface tension of target support structures, and external vibration. One RFB approach to minimize these confounding forces involves modulating the ultrasound and measuring the resultant radiation force at a frequency removed from their influence (20 Hz) [42]. Errors of less than a few percent are reported for powers from 0.1mW-30 W, and frequencies from 0.5-30 MHz.

Both the RFB and planar scanning methods require a somewhat complex set-up. A simpler technique that has been proposed, especially for routine calibration checks where the highest accuracy is not required, is based on measuring the temperature rise in an absorber placed in the ultrasound beam. This thermoacoustic sensing technique [43] comprises an ultrasound-absorbing plexiglass disk 1 cm thick x 3 cm in diameter. The water-borne ultrasound waves impinge upon the front face of the disk. The other disk surfaces must be thermally insulated, and an air layer has been used in the reported device. A temperature sensor at the back face (i.e., the planar plexiglass-air interface) measures the temperature rise, whose steady-state value is proportional to the power of the incident ultrasonic wave. Calibration of this thermoacoustic sensor requires knowledge of the sound absorption coefficient as a function of frequency, the thermal conductivity, and the acoustic impedance of the plexiglass absorber. The sensor has been tested for CW beams from 3-17 MHz [44]. The sensitivity over this range varied from 10-30 K/W, and the time to reach thermal equilibrium was ~13 minutes. This time could be reduced by decreasing the absorber thickness, but sensitivity would be decreased as well. Also, for measurement of pulsed waveforms, knowledge of the frequency spectrum is necessary.

F. Intercomparison measurements

In Europe two measurement studies on diagnostic fields, each coordinated by a national measurement institute, have been performed in accordance with IEC61157 [19]. In both, a diagnostic ultrasound device was circulated among participating laboratories and the results compared. In [45] 10 groups made measurements on a 5 MHz linear array scanner and a check source. It was concluded that the single most important factor contributing to the differences in results was the variety of hydrophone and amplifier systems used. In [46] a commercial diagnostic instrument was sent to 9 participants. Measurements were restricted to M-mode on the 3.5 MHz transducer used. While the majority of results were in good agreement with one another, significant deviations were found, indicating the importance of periodic checking of the measurement devices and procedures.

III. DIAGNOSTIC IMAGING AND DOPPLER ABOVE 15 MHZ

High frequency diagnostic applications include ophthalmology, dermatology, and intravascular ultrasound. The challenges here have been to improve the spatial and temporal measurement resolution, and to perform hydrophone calibrations at higher frequencies.

A. New hydrophone designs

Both needle and membrane hydrophones have been redesigned for measurements in higher-frequency focused fields. Thinner films to increase measurement bandwidth, and smaller active elements to reduce spatial averaging effects, have been used. To date, needle hydrophones with 9 μm PVDF film and diameters of 0.04, 0.75, 0.15, and 0.2 mm are obtainable commercially. In the modified needle mentioned in Sec. II.A [18], 4 μm copolymer film was used in an ellipsoidal configuration, and in one probe an effective diameter of 0.13 mm was measured, along with a <±0.3 dB response from 0.2-40 MHz. Bilaminar membrane hydrophones made from 9 μm PVDF sheets are available as well, one based on [47] with a 0.2 mm electrode diameter. In [48] a membrane hydrophone is described in which a 37 μm-diameter spot-poled electrode was formed on a single sheet of 4 μm P(VDF-TrFE) film. The measured effective diameter was <100 μm, and the -3 dB bandwidth was 150 MHz. In all of these needle and membrane designs reduced sensitivity is an important factor, and submersible integral amplifiers or short cable lengths are required. The 150 MHz bandwidth in this latter device was achieved at the expense of increased noise susceptibility, because only a single layer of polymer film was used. The noise canceling feature of a differential amplifier design has been proposed to offset this effect [49], and one such membrane device having a 0.2 mm spot size and 14 dB-gain differential amplifier is available, although no comparative test results have been reported.

B. Hydrophone calibration at high frequencies

No standards exist for hydrophone calibrations above 15 MHz, although the IEC has in process a draft document that addresses some aspects of this topic [50]. Calibration in this range is an active area of study, and some current work is described below.

The use of laser interferometry for calibrating hydrophones has become standard practice at some national measurement institutes, and recently extension of the calibration range to 60-70 MHz has been reported [51], [52], [53]. Both interferometer systems are of the Michelson type, but in one the optically reflective pellicle that is displaced by the ultrasonic wave is located at the water surface instead of being totally submerged. The stated advantage of this approach is that the optical phase shift to which the interferometer responds is not affected by changes in the refractive index of water caused by the propagating acoustic wave (see Eq. (2) and discussion). Thus, no correction for n is necessary.

In both systems, focused transducers driven to produce harmonically rich waveforms via nonlinear propagation are used to obtain a sufficient pressure SNR at the higher frequencies, the main problem being the inverse dependence of particle displacement on frequency for a given pressure. For one system the calibration uncertainty (at 95% C.L.) increased from ±4.6% at 20 MHz to ±25% at 60 MHz. This primary calibration method can provide reference hydrophones for use in secondary calibrations via substitution.

Two other less vetted but still useful methods for high frequency calibration have been reported of late. In one, the hydrophone response was compared to that predicted from theoretical nonlinear field calculations [54], [55]. In a more direct approach, TDS has been used to calibrate a membrane hydrophone from 1-40 MHz, and the maximum difference from an interferometric calibration of the same hydrophone was 1.3 dB [56].

C. Spatial averaging by hydrophone

At high frequencies the measurement of "point" field quantities is hampered by spatial averaging effects due to the finite size of the sensing element. Ideally, the receiver dimensions should be less than one wavelength, but at 15 MHz in water this value is 0.1 mm. One approach for overcoming the size limitations of available hydrophones has been to perform pulse-echo beam profile measurements using fine wire or spherical targets [57], [58]. Wire sizes down to 25 μm have been reported. An added advantage of this method is that the measurements characterize the transmit-receive response of the system. However, relating the measured waveforms and profiles to transmit-only quantities is difficult, so direct measurements of exposure fields are preferred [11], [12].

When hydrophone size guidelines cannot be met, an alternative approach is to perform a spatial averaging correction. The general procedure is first to choose a theoretical model to describe the acoustic pressure field at radial distance r and axial distance z from the source transducer (assumed circular). Next, taking the hydrophone output as proportional to the average pressure over its active surface, the spatial average of acoustic quantity $Q(r,z)$ (e.g., pressure) over that surface is calculated (denoted $\langle Q(r,z)\rangle$). Then correction factor C is computed as $C = Q(r,z)/\langle Q(r,z)\rangle = 1+\delta_Q$, δ_Q being the spatial-average deviation.

A simple approach recommend in an IEC Technical Report [59] assumes a jinc radial beam shape. The most comprehensive method proposed to date, however, incorporates the effects of nonlinear propagation into the analysis of the pressure distribution and δ_Q [60]. In this procedure δ_Q is expressed as a function of σ_m and new factor $\alpha_Q = b_{-6Q}/d_e$, where b_{-6Q} is the measured (i.e., spatial averaged) beamwidth for quantity Q, and d_e is the effective hydrophone diameter. In [60] δ_Q was computed for p_r as well as the peak compressional pressure (p_c) and pulse pressure-squared integral. As an example result, for p_r with $\sigma_m = 1$, δ_Q increased from <5% at $\alpha_Q = 5$ to >40% for $\alpha_Q = 1$. In general, δ_Q (or C) is a complex function of the hydrophone size and degree of distortion, and more simulation work is needed for both circular and rectangular fields, as well as experimental verification of results.

IV. Extracorporeal Pressure Pulse Lithotripsy

A. Hydrophone developments

The highly focused, large amplitude pressure fields produced by extracorporeally induced lithotripsy devices provide an efficient means for fragmenting urinary tract calculi. To address the characterization and safe use of these devices, two IEC standards are now available, one covering field measurements [61] and the other dealing with labeling and other safety aspects [62]. The field quantities called for include p_c and p_r, the energy per pulse, and the focal dimensions. As with diagnostic pulse measurements, the hydrophones used for determining these quantities must have a wide, uniform frequency response and a small active element, although the latter is not as critical, 0.5-1 mm being sufficient in most cases. Because of the potential for damage to the hydrophone, additional features also are important [63], [64]: robustness, to withstand the intense fields and possible cavitation effects; electrical shielding, to suppress RF interference and provide insulation from the conductive propagation media sometimes used; and a large dynamic range. In [61] a high-performance hydrophone, termed a "focus" hydrophone, is defined for measurements at the focus where the requirements are most demanding. It is stated that the focus hydrophone shall be equivalent to a single-film piezoelectric polymer spot-poled membrane type with film thickness not greater than 25 μm. While membrane hydrophones appear to provide generally faithful reproductions of lithotripsy pressure pulses, they are far from ideal. In addition to the damage issue, an artifact has been seen in the hydrophone waveform due to reflections at the hydrophone housing [65]. The presence of this artifact determines how far away from the lithotripsy beam axis measurements can be made, especially if that structure is highly reflective [66]. To overcome these problems, particularly with regard to hydrophone damage, several alternatives to the classical spot-poled membrane hydrophone design have been explored, as discussed below. While no single hydrophone design has yet emerged as the optimal choice, each of these variations has found use in lithotripsy field measurements.

Modified membrane hydrophone: In one modified membrane approach, unmetallized PVDF film was spot-poled and mounted in an enclosed chamber with an acoustic window. The chamber was filled with either dielectric fluid [67] or low-resistivity electrolyte [68], [69]. Electrodes were located in the chamber away from the film, close enough to collect the pressure-induced charge (via capacitive coupling in the former case), but far enough away to minimize damage from the shock waves. In a different approach, the goal has been to produce an inexpensive, disposable membrane [70], [71], [72]. In [72] a commercial shock gauge element was mounted on a housing containing degassed petroleum as a backing material for electrical isolation. In another design the resistance of the metal electrodes and leads is monitored to indicate when the film should be replaced [71].

Spot-poled ceramic hydrophone: In this variation on a spot-poled membrane, a lead titanate disk (15 or 30 MHz resonance frequency) having a diameter of less than ~1 cm was spot-poled and brass-backed, and this assembly was connected to a coaxial cable [73]. Lead titanate was chosen for its low radial mode coupling. Rise times <50 ns and effective diameters <0.5 mm have been achieved. A typical lifetime of between 200 and 1000 shots at the focus of a 100 MPa (p_c) lithotripter is reported, the major damage mechanism being pitting of the ceramic due to cavitation jets.

Capacitance hydrophone: To increase resistance to hydrophone damage, a hydrophone has been designed in which the incoming pressure wave modulates the air gap of a parallel plate capacitor formed by a steel front plate and a 2 mm diameter brass cylinder as the rear plate/electrode [74]. Assuming that the acoustic particle displacement is small compared to the air gap thickness d_o, the measured pressure, p(t), is proportional to $d_o e'/E_o C_o$, where C_o is the electrode capacitance, E_o is the capacitor DC bias voltage, and e' is the time derivative of the measured capacitor voltage. Measured pulse fidelity, especially the trailing edge, is degraded by attenuation in the front plate as well as its two-way travel time (about 3.3 μs for 10 mm-thick steel), plus the generation of slower velocity shear waves in this plate. However, the measured p_c seemed to be relatively unaffected by thicknesses of from 6-18 mm, and the durability of the hydrophone was good, with small pinholes being observed after 1000 pulses having peak amplitudes of 20-45 MPa. The effective diameter of the probe was calculated to be 2.1 mm due to the fringe electrical field at the capacitor boundary.

Electromagnetic hydrophone: Magnetic induction also has been used as a basis for constructing a robust hydrophone. In [75] a probe is described in which a 5 mm length (l) of 30 μm-thick copper wire was fused into the front face of a 5 mm-diameter plastic rod. The front of the rod then was placed in the field of a permanent magnet such that the fused section of wire was oriented normally to the acoustic and static magnetic (B=200 mT) fields. In this configuration the vibration of the wire due to the ultrasonic wave will induce a time varying voltage (e) at the wire terminals. Assuming that the wire thickness is negligible and the acoustic and magnetic fields are uniform over its 5-mm length, p(t) is proportional to e/Bl. This electrical signal was amplified by a preamp located close to the magnet. Input limiting of the preamp was necessary to clip the large signals arising from the lithotripter excitation pulse.

The high frequency response was limited by the wire thickness, 30 μm giving a theoretical -6 dB corner frequency of ~5 MHz. Also, errors will be caused by the transverse resolution of 5 mm and the assumption of uniform fields over this length. However, a prototype showed no signs of failure after exposure to 4000 pulses having a p_c of 30 MPa.

Another electromagnetic probe designed primarily for quality control measurements employed a 12.7 mm steel ball placed at the focus [76]. The ball was attached to a stainless steel rod containing the electromagnetic transducer located between the poles of a permanent magnet. Although the output of the probe does not follow the lithotripter pressure pulse, it has been related to both p_c and stone disintegration, and it was used to monitor the output of a lithotripter system over a 12-month period.

Fiber-optic hydrophone: The various deficiencies with hydrophones mentioned above (e.g., fragility in intense fields, susceptibility to RF interference, and, particularly for diagnostic fields, inadequate spatial resolution) have inspired the development of acoustic sensor designs based on fiber-optic (FO) detection techniques. In the most successful FO approaches, the fiber, cleaved to form a right circular cylinder, is aligned so that the endface is normal to the direction of acoustic propagation, just as a piezoelectric needle hydrophone would be. In this configuration the fiber behaves an extrinsic rather than intrinsic sensor, in that its basic function is simply to carry coherent light to the tip where the transduction process is initiated. The tip has been treated in several ways to create a reflected light signal that can be related to the acoustic field.

1) Bare fiber tip - In the simplest approach, light from a laser diode is coupled to a multimode fiber with a bare endface [77]. To a good approximation, the light is reflected according to the Fresnel intensity reflection coefficient, $R = [(n_c-n_w)/n_c+n_w)]^2$, where n_c and n_w are the indices of reflection of the fiber core and water, respectively. As discussed above in Sec. II.C, pressure variations in the acoustic wave cause a change in density, which in turn alters the refractive indices, and thus the reflected light intensity. Over most of the pressure range associated with lithotripsy pulses, the change in reflected light intensity has an approximately linear dependence on acoustic pressure, neglecting the acoustic scattering effects described below [77]. It should be noted that a change in n_c will occur as well, but due to the much lower compressibility of the fiber material, this effect is negligible [77].

The device in [77] had a bandwidth of 20 MHz, limited by the photodetector amplifier, an effective aperture of 0.1 mm, and good immunity to RF interference. Due to a relatively low sensitivity, the minimum detectable pressure was 0.5 MPa, a value acceptable for lithotripsy measurements, but one that could be reduced with a higher light source power or more sensitive photodetector. Also, in a comparison with a PVDF membrane hydrophone measurement, it was noted that the negative pressure tail or trough was shorter in the membrane-measured waveform. This has been attributed to the stronger water-fiber (silica) layer adhesion compared to that at the water-metal or water-polymer boundaries. This effect has been noted elsewhere, where p_r's of -25 MPa [78] and -59 MPa [79] have been measured with an FO hydrophone, and it has served as the basis for adjusting membrane hydrophone results [66]. The integrity of the tip can be checked by monitoring the quiescent reflected light intensity. The fiber tip has a high damage threshold, but should it be damaged by cavitation, the fiber can be recut without affecting sensitivity; however, to maintain the minimum noise level, a clean, smooth fiber endface must be achieved.

One problem reported in [77] is that diffraction at the needle tip distorts the measured pulse, just as in the case of piezoelectric needle hydrophones described in Sec. II.A. This problem is common to all FO hydrophones, and in [78] a simple extrapolation is shown to correct for overshoot in p_c. A more rigorous deconvolution method is mentioned below. Also, in the following FO hydrophone descriptions an improvement in sensitivity is achieved by treating the fiber tip, but at the cost of design simplicity and replacement ease.

2) Two-beam interferometer - To increase measurement sensitivity, the fiber tip has been mirrored and incorporated into the measuring arm of a two-beam interferometer [80], [81]. The optical phase change caused by the tip movement results in a signal proportional to the acoustic displacement or, when a heterodyne technique is used, particle velocity, both of which lead to a calculation of the pressure. To correct for the tip diffraction noted above, as well as other acoustic effects associated with the fiber, the magnitude of the displacement transfer function was measured experimentally using both TDS and interferometry [82]. Then, assuming minimum-phase behavior for the FO system so that the phase response could be uniquely determined, the measured lithotripsy pulse data were corrected via deconvolution.

3) Fabry-Perot interferometer - As an alternative to the optical complexity of two-beam interferometry, but still with improved sensitivity compared to the bare fiber design, a Fabry-Perot (FP) interferometer can formed by attaching an FP cavity to the end of the fiber [83], [84], [85], [86], [87]. When light is sent down the fiber, optical reflections occur at the interfaces between the fiber and cavity, and the cavity and load (water). The optical reflection coefficients are determined either by the Fresnel formula for uncoated cavity surfaces [83], [84], or by the type and thickness of metal coatings on these faces [85], [87]. In general an FP cavity is a multiple-beam interference device, but its operation can be explained by considering only the two initial reflections from the cavity surfaces. The intensity of the reflected light depends on the interference of these reflected beams, which in turn depends on the optical phase shift between them. Acoustically-induced changes in cavity thickness will vary this phase shift, and the acoustic pressure can be deduced from the optical, acoustic, and elastic properties of the cavity material, and the undisturbed cavity thickness (L).

Both polymer films and harder dielectric materials have been used for the cavity material, the former being more sensitive due to their greater compressibility. The latter, however, can be sputtered onto the endface [84], thus avoiding the degradation in frequency response that can arise due to the adhesive layer that bonds the polymer to the tip [85]. To avoid this adhesion problem, recently a polymer film has been vacuum-evaporated onto the fiber tip [87]. Also, to increase sensitivity, an FP stack of multiple dielectric layers has been deposited onto the fiber [88]. However, even without this last measure, sensitivities comparable to piezoelectric polymer hydrophones have been realized, and with significantly smaller sensitive areas. As with piezoelectric hydrophones, a trade-off is involved in the choice of L, in that sensitivity increases with increasing L, but for a broadband response, L should be smaller than the highest acoustic wavelength of interest. Also, both single- and multi-mode fibers have been used in these FP optical sensors. The former gives better spatial resolution (e.g., 6 μm in [87]), and is less susceptible to changes in sensitivity due to fiber bending [85], [87]. On the other hand, multi-mode FO hydrophones are easier to align with the laser before use [85]. Finally, as stated above, the tip diffraction problem needs further investigation in order to make the use of any type of FO hydrophone more practical.

B. Measurement of pulse energy

The energy impinging on the stone is the physical field quantity most closely associated with volume erosion [64]. This quantity usually is calculated from hydrophone scans in the focal plane, and for a circularly symmetric beam with radial dimension r, the energy E per pulse is, $E=2\pi Z^{-1}\int\int p^2(r,t)\,dt\,rdr$, where Z is the acoustic impedance of water. This quantity is not uniquely defined, however, until the temporal and spatial integration limits are specified [89]. In [61] the temporal integration time may be either over the initial positive pressure spike (T_P), or over the entire pulse (T_T) (both defined by the first and last 10%-of-peak pressure points). Also, in [61] the radial scan limit may be defined either by the -6 dB point ($E=E_f$), or by a specified distance R that corresponds to a particular stone dimension ($E=E_R$). A third scan limit has been described in which the integration is stopped at the point where $p_c = 5$ MPa [64]. In one study of these three spatially-defined pulse energies (using T_T and R=5 mm), it was found that E@5 MPa was highly correlated with fragmentation of model stones *in vitro,* whereas E_f was a poor indicator of stone destruction [90]. These and other results are summarized in [64], where it is emphasized that if lithotripters are to be compared based on pulse energy, then it must be established that the integration limits are the same.

C. Optical techniques

Acousto-optic methods also have been explored for characterizing lithotripsy fields. These include a schlieren system, in which a ruby laser pulse of 20 ns was synchronized to the acoustic pulse, giving a spatial resolution of 30 μm in water [91]. Also, a Michelson type interferometer has been adapted to measure the pellicle (i.e., particle) velocity, from which the acoustic pressure is calculated [92]. Movement of the acoustically thin but optically reflective pellicle causes a Doppler shift in the frequency of the reflected light. This frequency change results in a modulated light intensity, measurement of which allows the particle velocity can be calculated. The system bandwidth, limited mainly by the photodetectors, is 100 MHz, and the velocity range of 1-100 m/s corresponds to that produced in lithotripsy.

V. Therapeutic Ultrasound

Clinical uses of therapeutic ultrasound now encompass such areas as hyperthermia, enhanced drug delivery for thrombolysis, fracture healing, phacoemulsification, physiotherapy, and high intensity focused ultrasound (HIFU) for surgery and hemostasis. Lithotripsy, covered above in Sec. IV, would be included as well, and the requirements for hydrophones listed in Sec. IV.A also apply when measuring high-intensity surgical or therapeutic fields. Some important aspects of these measurements follow.

A. HIFU

There are no current standards for characterizing HIFU fields. Measurements typically have been made of the ultrasonic power, W_o, with an RFB, and the beam distribution in water around the focus. The beam plots have been obtained with both hydrophones (for derived I_{TA}) and the suspended ball radiometer (for I_{TA} directly) (see [3], p. 207). The ball is more robust, but the ball calibration factor is a complicated function of frequency, so its use is restricted to narrow bandwidth fields. Therefore, errors can be large when measuring high intensity fields in which nonlinear propagation effects lead to significant harmonic generation. Also, acoustic streaming can be an important source of measurement error at high intensities.

To address these measurement problems, and to provide a single exposure quantity with relevance to thermal lesion formation, a new intensity has been proposed [93]. Denoted I_{SAL}, it is the TA intensity spatially averaged over the -6 dB beam area, the latter measured under linear conditions. That is, $I_{SAL} = W_{-6}/A_{-6}$, where W_{-6} is the power within the contour defined by the half-maximum pressure, and A_{-6} is the area enclosed by that -6 dB contour. Measuring A_{-6} at low output as specified avoids the problems associated with hydrophone instability and damage, and the hydrophone need not be calibrated. In practice, *in situ* intensities are calculated using linear derating [93], [94].

Using the theoretical jinc-squared radial intensity distribution at the focus of a source with circular aperture, the spatial-peak pressure is $I_{SP} = 1.8 \cdot I_{SAL} = 1.56 \cdot W_o/(d_{-6})^2$, where $d_{-6} = (4A_{-6}/\pi)^{0.5}$. When these quantities were used in models of thermal lesioning threshold intensity and lesion size, the predictions agreed well with experimental results, and it was concluded that I_{SAL} was a useful exposure quantity for focused surgery in terms of both measurement ease and biophysical relevance.

Measurements of focal intensities at the highest levels used (several thousand W/cm^2) have been performed with spot-poled membrane hydrophones, either the disposable type [95], [96], (as in [71]), or with the pulse duration reduced dramatically (e.g., tens of μs or less) to minimize the risk of hydrophone damage, [97], [98]. In the latter case, the intensity for pulse durations used clinically is obtained by scaling the short-pulse measurements. All measurements should be made in clean, degassed water (1-2 ppm O_2) to reduce the potential for cavitation-generated damage or error (a statement applicable to all high-intensity measurement situations).

A more qualitative but very effective means that has been used to determine 2-D and 3-D beam distributions in water for HIFU transducers incorporates acousto-optic diffraction as in Sec. II.C [99]. As stated there, this approach is inherently non-perturbing, has good spatial resolution, and can provide a rapid means for observing beam characteristics. Once regions of high intensity are identified, they can be probed more critically using calibrated hydrophones.

Lastly, an electromagnetic pressure sensor has been developed for MRI-guided HIFU applications [100]. The transducer comprises 6 turns of 0.1 mm diameter copper wire wound on a plastic core measuring 40x3.2 mm. A voltage is induced in the coil by ultrasonically-mediated movement of the wire in the MRI device's static magnetic field. For 750 kHz ultrasound the sensitivity was 1.8 V/MPa, and the noise pressure level was 1 kPa for a 4.7 T magnet. The sensor is said to be useful for measuring pressure to calculate temperature rise, or in QC testing of the HIFU transducer.

B. Physiotherapy

Physical therapists adjust the level of exposure during a treatment using a quantity displayed on the equipment known as the effective intensity, defined as W_o divided by the effective radiating area, or ERA. The ERA is the area of the surface close to the transducer through which essentially all of the ultrasound power passes. The ERA is determined directly from field measurements, specifically via hydrophone scanning. A recent IEC standard for these devices [101] provides a more reproducible measurement method for the ERA, in that it is not based on a percentage of the maximum hydrophone output close to the transducer as in previous methods [102], and therefore it is not as sensitive to differences in hydrophone size or to hydrophone sampling that might miss the point of highest pressure. In the new approach, at several planes a 2-D array of hydrophone-measured data with step size Δs is sorted from lowest to highest, and a running summation is computed. An area proportional to the product $N \cdot \Delta s^2$ is then found, where N is the number of data points associated with 75% of the total summation. The ERA is found from an extrapolation of these areas back to the applicator surface. This method has been found to give reproducible results in a study among three measurement laboratories [102]. Also regarding the ERA, a non-scanning method has been proposed recently [103]. It involves RFB measurements of the power passing through a set of different-sized attenuating apertures. Acceptable agreement with the scanning-summation method was found, and this method is suggested as a fast, relatively simple procedure for measuring the ERA in a manufacturing or clinical setting.

C. Ultrasound-enhanced drug delivery

Ultrasound has been found to increase the rate of clot lysis when used in conjunction with various thrombolytic drugs. In one design, a small cylindrical piezoelectric transducer is mounted in the drug-delivery catheter and driven with both long-pulse and CW 1 MHz ultrasound [104]. The mechanisms of action are not completely understood, but both thermal and non-thermal contributions are likely, including stable cavitation. Accordingly, exposure measurements have included both power and pressure. Because the signals are narrowband, piezo-ceramic hydrophones are adequate for recording the pressure, with values close to the transducer being extrapolated from radial plots made normal to the cylinder axis. The power can be derived from hydrophone scan data, or via an RFB. In the latter case, a conical reflector has been used to direct the cylindrically diverging beam onto an absorbing RFB target.

The potentiation of chemotherapy by pulsed ultrasound has been demonstrated using unfocused, plane transducers. In one study of a 2 MHz, 3.8 cm-diameter source [105], a region of the field having a relatively smooth distribution was identified, and the pressure waveform was recorded over a central, transverse plane using a 2 mm sampling interval. Diagnostic pulse definitions for intensities and physiotherapy definitions for beam nonuniformity were calculated. This hybrid group of exposure quantities was then used to correlate exposure with biological response.

D. Low-frequency ultrasound surgery

In the 20-60 kHz range, ultrasound finds use in ophthalmic, neurological, dental, and plastic surgery, and also thrombolysis and angioplasty. Device operation involves the vibration of a small wire or hollow needle, resulting in destruction of tissue via mechanical means, including cavitation. Measured acoustic quantities include wire or needle tip displacement, frequency, pressure, and power. Measurement means are specified in a 1998 IEC standard [106], and are discussed in [107] and [108]. The power is derived from hydrophone measurements, using either a monopole or dipole source model depending on the assumed depth of the vibrating tip in water or tissue. One problem identified with this procedure is that as tip displacement increases, cavitation activity causes the calculated power to underestimate the true power. A correction has been described in which the high frequency components of the acoustic energy generated by cavitation implosions are measured with a hydrophone sensitive at megahertz frequencies [107]. Future revisions of the IEC standard may incorporate such a procedure.

VI. *IN VIVO* MEASUREMENTS

Piezoelectric needle hydrophones have been the traditional means for *in vivo* pressure measurements; however, other aproaches are being tried. For example, in [109] a seven-element linear array of PVDF elements was described that measures *in vivo* exposures intervaginally during an obstetric ultrasound examination. The 0.5-mm-diameter PVDF elements were spaced 1.5 mm apart along a stainless steel tube. For *in vivo* lithotripsy measurements, two modifications of the single-sheet, spot-poled membrane design have been used. In one, previously metallized and spot-poled PVDF film was formed into a hemispherical shell supported by a soft, low-impedance backing [110]. The resultant bulb was mounted on the end of a stainless steel tube, with electrical connection being made via a coaxial cable as in the needle hydrophone. In another lithotripsy hydrophone design for measurements in pigs, a piece of metallized, spot-poled film was stretched over a plastic ring having an outside diameter of 21.5 mm [111]. After connecting a coaxial cable, this miniature membrane hydrophone was then coated with silicone rubber before implantation to provide electrical insulation. More recently a fiber-optic hydrophone was used for measurements in patients undergoing clinical lithotripsy treatment [85]. In addition to small size, other advantages were: no electrical contacts to patient; performance unaffected by conductive body fluids; easily replaceable so cross-infection hazards minimized: and alignment errors reduced by wide angular response. Problems were experienced, as discussed in Sec. IV.A, but with further development these FO devices seem to hold promise for invasive *in vivo* exposimetry.

Regarding noninvasive measurements, quantitative mapping of ultrasound fields in tissue phantoms has been demonstrated via MR imaging [112]. Absolute measurements of acoustic displacement amplitudes were achieved, and the noise-equivalent pressure, calculated via a plane wave assumption at the 515 kHz frequency used, was 19 kPa. Advantages include the ability to make noninvasive measurements in opaque media, unlike the acousto-optic methods in Sec. II.C. However, the B-field gradient used was about ten times higher than that recommended for human imaging.

VII. Conclusion

This paper contains a review of the progress and problems associated with ultrasound exposure measurements. A wide array of topics was discussed, but coverage was by no means complete. For example, the measurement of transient stress waves induced purposefully or not by medical laser radiation was omitted. Also, non-invasive measurement of temperature rise in tissue via MRI or ultrasound was not discussed; nor were means to monitor cavitation activity. These latter two are not exposure measurements per se, but they should be mentioned when discussing means to assess the effectiveness and risk potential of medical procedures. A proper understanding of the capabilities as well as limitations of all these devices and methods is essential for accurate ultrasound field characterization, and it is hoped that the material presented here will contribute to that goal.

References

[1] G.R. Harris, P.A. Lewin, and R.C. Preston, Eds. Special Issue on Ultrasonic Exposimetry, IEEE Trans. *UFFC*, vol. 35, pp. 85-269, 1988.

[2] R.C Preston, Ed. Output Measurements for Medical Ultrasound. London: Springer-Verlag, 1991.

[3] M.C. Ziskin and P.A. Lewin, Eds. Ultrasonic Exposimetry. Boca Raton: CRC Press, 1992.

[4] M. Hodnett and B. Zeqiri, "A strategy for the development and standardization of measurement methods for high power/cavitating ultrasonic fields: Review of high power field measurement techniques," NPL Report CIRA-(EXT)015. Teddington, UK: 1997, ISSN 1361-5053.

[5] G.R. Harris and P.A. Lewin, "Ultrasonic exposimetry," Encyclopedia of Electrical and Electronics Engineering. New York: John Wiley, 1999, vol. 22, J.G. Webster, Ed., pp. 634-646.

[6] A.C. Baker, "Nonlinear effects in ultrasound propagation," Ultrasound in Medicine. Bristol, UK: Institute of Physics Publishing, 1998, F.A. Duck, A.C. Baker, and H.C. Starritt, Eds., pp. 23-38.

[7] G.R. Harris, "Pressure pulse distortion by hydrophones due to diminished low frequency response," *IEEE Trans. UFFC*, vol. 42, pp. 989-992, 1995.

[8] G.R. Harris, "Are current hydrophone low frequency response standards acceptable for measuring mechanical/ cavitation indices?," *Ultrasonics*, vol. 34, pp. 649-654, 1996.

[9] *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment*, Rev. 1, Am. Inst. of Ultrasound in Med., Laurel, MD; Nat. Electr. Manu. Assoc., Rosslyn, VA (NEMA Publ. UD 3), 1998.

[10] J. Abbott, "Rationale and derivation of MI and TI - A review," *Ultrasound in Med. & Biol.*, vol. 25, pp. 431-441, 1999.

[11] *Acoustic output measurement standard for diagnostic ultrasound equipment*, Am. Inst. of Ultrasound in Med., Laurel, MD; Nat. Electr. Manu. Assoc., Rosslyn, VA (NEMA Publ. UD 2, Rev. 2), 1998.

[12] *Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0.5 MHz to 15 MHz*, IEC, Geneva, Publ. IEC 61102, 1991.

[13] S.P. Robinson, "A comparison of the frequency response of membrane and needle probe PVDF hydrophones," *Physics in Medical Ultrasound II*. York, UK: Institute of Physical Sciences in Medicine, 1988, D. Evans and K. Martin, Eds.,pp. 79-86.

[14] B. Fay, G. Ludwig, C. Lankjaer, and P.A. Lewin, "Frequency response of PVDF needle-type hydrophones," *Ultrasound in Med. & Biol.*, vol 20, pp. 361-366, 1994.

[15] G.R. Harris and P.M. Gammell, "Sensitivity measurements of piezoelectric polymer hydrophones from 0.2-2 MHz using a broadband pulse technique," *J. Acoust. Soc. Am.*, vol. 105, pp. 725-731, 1999.

[16] P.A. Lewin, R. Bautista, and V. Devaraju, "Voltage sensitivity response of ultrasonic hydrophones in the frequency range 0.25-2.5 MHz," *Ultrasound in Med. & Biol.*, vol. 25, pp. 1131-1137, 1999.

[17] P.M. Gammell and G.R. Harris, "Time delay spectrometry for hydrophone calibrations below 1 MHz," *J. Acoust. Soc. Am.* (ARLO - in press) 1999.

[18] A.R. Selfridge and J.P. Goetz, "Ellipsoidal hydrophone with improved characteristics," *Proc. 1999 IEEE Ultrason. Symp.*

[19] *Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment*, IEC, Geneva, Publ. IEC 61157, 1992.

[20] *Acoustic output labeling standard for diagnostic ultrasound equipment: A standard for how manufacturers should specify acoustic output data*, Am. Inst. of Ultrasound in Med., Laurel, MD, 1998.

[21] T. Christopher and E.L. Carstensen, "Finite amplitude distortion and its relationship to linear derating formulae for diagnostic ultrasound devices," *Ultrasound in Med. & Biol.*, vol. 22, pp. 1103-1116, 1996.

[22] World Federation for Ultrasound in Medicine and Biology: Conclusions and recommendations on thermal and non-thermal mechanisms for biological effects of ultrasound. S.B. Barnett, Ed., *Ultrasound in Med. & Biol.*, vol. 24, suppl. 1, p. S47, 1998.

[23] E.L. Carstensen, D. Dalecki, S.M. Gracewski, and T. Christopher, "Nonlinear propagation and the output indices," *J. Ultrasound Med.*, vol. 18, pp. 69-80, 1999.

[24] T.L. Szabo, F. Clougherty, and C. Grossman, "Effects of nonlinearity on the estimation of in situ values of acoustic output parameters," *J. Ultrasound Med.*, vol. 18, pp. 33-41, 1999.

[25] F.A. Duck, "Estimating *in situ* exposure in the presence of acoustic nonlinearity," *J. Ultrasound Med.*, vol. 18, pp. 43-53, 1999.

[26] R.C. Preston, A. Shaw, and B. Zeqiri, "Prediction of *in situ* exposure to ultrasound: An acoustical attenuation method," *Ultrasound in Med. & Biol.*, vol. 17, pp. 317-332, 1991.

[27] R.C. Preston, A. Shaw, and B. Zeqiri, "Prediction of *in situ* exposure to ultrasound: A proposed standard experimental method," *Ultrasound in Med. & Biol.*, vol. 17, pp. 333-339, 1991.

[28] M.C. Macdonald and E.L. Madsen, "Acoustic measurements in a tissue mimicking liquid," *J. Ultrasound Med.*, vol. 18, pp. 55-62, 1999.

[29] R.T. Hekkenberg, W.A. Oosterbaan, and C.J.P.M. Teirlinck, "Handling IEC1157: complicated output measurements - a challenge," *Ultrasonics*, vol. 34, pp. 139-145, 1996.

[30] J. Henderson, J.R. Jago, K. Willson, and T.A. Whittingham, "Towards a protocol for measurement of maximum spatial peak temporal average acoustic intensity from diagnostic B mode ultrasound scanners in the field," *Phys. Med. Biol.*, vol. 38, pp. 1611-1621, 1993.

[31] T.A. Whittingham, "The purpose and techniques of acoustic output measurement," Ultrasound in Medicine. Bristol, UK: Institute of Physics Publ., 1998, F.A. Duck, A.C. Baker, and H.C. Starritt, Eds., pp. 129-148.

[32] A. Eisenberg, K. Mengedoht, M. Krix, and H.G. Trier, "Acoustic field parameter measurements performed on medical multi-mode array systems," *Proc. 1995 Ultrasonics World Congress*, ISBN 3-9805013-0-2, pp. 919-922.

[33] A. Shaw and R.C. Preston, "The NPL ultrasound beam calibrator - cost effective measurements to IEC 1157," *Proc. 1995 Ultrasonics World Congress*, ISBN 3-9805013-0-2, pp. 923-926.

[34] A. Hurrell and F. Duck, "A two-dimensional hydrophone array using piezoelectric PVDF," *IEEE Trans. UFFC*, submitted for Special Issue on PVDF.

[35] B. Schneider and K.K. Shung, Quantitative analysis of pulsed ultrasonic beam patterns using a schlieren system, *IEEE Trans. UFFC*, vol. 43, pp. 1181-1186, 1996.

[36] T.A. Pitts, R.R. Kinnick, and J.F. Greenleaf, "Optical measurement of wideband ultrasonic fields via Gabor holography," *Proc. 1997 IEEE Ultrason. Symp.*, pp. 761-764; T. Pitts, Optical Measurement of Wide Bandwidth Ultrasound Fields. Ph.D. Thesis, Mayo Graduate School, Dept. of Physiology and Biophysics, Rochester, MN, 1998.

[37] C.I. Zanelli and M.M. Kadri, "Measurements of acoustic pressure in the non-linear range in water using quantitative schlieren," *Proc. 1994 IEEE Ultrason. Symp.*, pp. 1765-1768.

[38] A. Shaw, N.M. Pay, R.C. Preston, and A.D. Bond, "Proposed standard thermal test object for medical ultrasound," *Ultrasound in Med. & Biol.*, vol. 25, pp. 121-132, 1999.

[39] A. Shaw, R.C. Preston, and D.R. Bacon, "Perfusion corrections for ultrasonic heating in nonperfused media," *Ultrasound in Med. & Biol.*, vol. 22, pp. 203-16, 1996.

[40] *Ultrasonic power measurement in liquids in the frequency range 0,5 MHz to 25 MHz*, IEC, Geneva, Publ. IEC 61161, 1992.

[41] K. Beissner, W.A. Oosterbaan, R.T. Hekkenberg, and A. Shaw, "European intercomparison of ultrasonic power measurements," *Acustica - acta acustica*, vol. 82, pp. 450-458, 1996.

[42] S.E. Fick and F.R. Breckenridge, "Ultrasonic power output mesurement by pulsed radiation pressure," *J. Res. Natl. Inst. Stand. Technol.*, vol. 101, pp. 659-669, 1996.

[43] B. Fay, M. Rinker, "Determination of the absolute value of ultrasonic power by means of thermoacoustic sensors," *Acustica - acta acustica*, vol. 82, pp. 274-279, 1996.

[44] M. Rinker and B. Fay, "Thermoacoustic calibration of ultrasonic transducers," *Proc. 1995 Ultrasonics World Congress*, ISBN 3-9805013-0-2, pp. 911-914.

[45] T. Esward, "An assessment of medical ultrasonic field measurement methods: final technical report for EC contract no. MAT1-CT940064," NPL Report CMAM 17, Teddington, UK: 1998, ISSN 1369-6785.

[46] K. Beissner, "Intercomparison of acoustic output measurements of a diagnostic ultrasound device," *Ultrasound in Med. & Biol.*, vol. 25, pp. 629-636, 1999.

[47] H.R. Gallantree and R.A. Smith, "Small area membrane hydrophones", *Proc. 1987IEEE Ultrason.Symp*, pp. 761-764.

[48] P. Lum, M. Greenstein, C. Grossman, and T.L. Szabo, "High-frequency membrane hydrophone," *IEEE Trans. UFFC*, vol. 43, pp. 536-544, 1996.

[49] R.C. Preston, D.R. Bacon, A.J. Livett, and K. Rajendran, "PVDF membrane hydrophone performance properties and their relevance to the measurement of the acoustic output of medical ultrasonic equipment". *J. Phys. E: Sci. Instrum.* vol. 16, pp 786-796, 1983.

[50] *Ultrasonics - Hydrophones - Characteristics and calibration in the frequency range from 15 MHz to 40 MHz*, IEC, Geneva, Future Publ. IEC 62092.

[51] T.J. Esward and S. P. Robinson, "Extending the frequency range of the NPL primary standard laser interferometer for hydrophone calibrations to 60 MHz". *IEEE Trans.* UFFC, vol. 46, pp. 737-744, 1999.

[52] R.C. Preston, S.P. Robinson, B. Zeqiri, T.J. Esward, P.N. Gélat, and N.D. Lee, "Primary calibration of membrane hydrophones in the frequency range 0.5 MHz to 60 MHz", *Metrologia*, vol. 36, no. 4, 1999.

[53] C. Koch and W. Molkenstruck, "Primary calibration of hydrophones with extended frequency range 1-70 MHz using optical interferometry," *IEEE Trans. UFFC* (in press).

[54] L. Filipczynski, T. Kujawska, R. Tymkiewicz, and J. Wojcik, "Nonlinear and linear propagation of diagnostic ultrasound pulses," *Ultrasound in Med. & Biol.*, vol. 25, pp. 285-299, 1999.

[55] H.J. Bleeker and P.A. Lewin, "A novel method for determining calibration and behavior of PVDF ultrasonic hydrophone probes in the frequency range up to 100 MHz," *IEEE Trans. UFFC*, submitted for Special Issue on PVDF.

[56] A. Selfridge and P.A. Lewin, "Wideband spherically focused PVDF acoustic source for calibration of ultrasound hydrophone probes," *IEEE Trans. UFFC*, submitted for Special Issue on PVDF.

[57] C.A. Bernier, L. Huntsman, and R. Martin, "A practical approach to measuring an intravascular ultrasonographic imaging system beam pattern," *J. Ultrasound Med.*, vol. 14, pp. 367-372, 1995.

[58] K. Raum and W.D. O'Brien, "Pulse-echo field distribution measurement technique for high-frequency ultrasound sources," *IEEE Trans. UFFC*, vol. 44, pp. 810-815, 1997.

[59] *Ultrasonics - Fields - Guidance for the measurement and characterization of ultrasonic fields generated by medical ultrasonic equipment using hydrophones in the frequency range 0,5 MHz to 15 MHz*, IEC, Geneva, Publ. IEC 61220Tr, 1993.

[60] B. Zeqiri and A.D. Bond, "The influence of waveform distortion on hydrophone spatial-averaging corrections - Theory and measurement," *J. Acoust. Soc. Am.*, vol. 92, pp. 1809-1821, 1992.

[61] *Ultrasonics - Pressure pulse lithotripters - Characteristics of fields*, IEC, Geneva, Publ. IEC 61846, 1998.

[62] *Medical electrical equipment - Part 2: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy*, IEC, Geneva, Publ. IEC 60601-2-36, 1997.

[63] P.A. Lewin and M.E. Schafer, "Shock wave sensors: I. Requirements and design," *J. Lithotripsy and Stone Disease*, vol. 3, pp. 3-17, 1991.

[64] F. Ueberle, "Aspects of pressure pulse lithotripter measurements," *Collected Papers, ASA/EAA/DAGA Meeting, Berlin, March, 1999*(ISBN 3-9804568-5-4).

[65] D.S. Campbell, H.G. Flynn, D.T. Blackstock, C. Linke, and E.L. Carstensen, "The acoustic fields of the Wolf electrohydraulic lithotripter," *J. Lithotripsy and Stone Disease*, vol. 3, pp. 147-156, 1991.

[66] M.R. Bailey, D.T. Blackstock, R. Cleveland, and L.A. Crum, "Comparison of electrohydraulic lithotripters with rigid and pressure-release ellipsoidal reflectors. I. Acoustic fields," *J. Acoust. Soc. Am.*, vol. 104, pp. 2517-2524, 1998.

[67] B. Granz, R. Holzapfel, and G. Köhler, "Measurement of shock waves in the focus of a lithotripter," *Proc. 1989 IEEE Ultrason. Symp.*, pp. 991-4.

[68] D. Cathignol, "PVDF hydrophone with liquid electrodes for shock wave measurements," *Proc. 1990 IEEE Ultrason. Symp.*, pp. 341-344.

[69] N. Inose and M. Ide, "A miniature hydrophone for high acoustic pressures," *Jpn. J. Appl. Phys.*, vol. 31, Suppl. 31-1, p. 272-273, 1992.

[70] E.C. Everbach, "An inexpensive wide-bandwidth hydrophone for lithotripsy research," *J. Acoust. Soc. Am.*, vol. 87, suppl. 1, p. S128, 1990.

[71] M. Schafer, T. Kraynak, and V. Krakhman, "Development of a cost-effective shock wave hydrophone," *Proc. 1994 IEEE Ultrason. Symp.*, pp. 1805-1808.

[72] J. Tavakkoli, A. Birer, and D. Cathignol, "Development of a PVDF low-cost shock-wave hydrophone," *Shock Waves*, vol. 5, pp. 369-374, 1996.

[73] R.L. Bedi and A.R. Selfridge, "Spot poled reflector style hydrophone for shock wave measurements," *Proc. 1991 IEEE Ultrason. Symp.*, 1141-45.

[74] L. Filipczynski and J. Etienne, "Capacitance hydrophones for pressure determination in lithotripsy," *Ultrasound in Med. & Biol.*, vol. 16, pp. 157-165, 1990.

[75] J. Etienne, L. Filipczynski, T. Kujawska, and B. Zienkiewicz, "Electromagnetic hydrophone for pressure determination of shock wave pulses," *Ultrasound in Med. & Biol.*, vol. 23, pp. 747-754, 1997.

[76] S.D. Pye, N.J. Parr, E.G. Munro, T. Anderson, and W.N. McDicken, "Robust electromagnetic probe for the monitoring of lithotriptor output," *Ultrasound in Med. & Biol.*, vol. 17, pp. 931-939, 1991.

[77] J. Staudenraus and W. Eisenmenger, "Fiber-optic probe hydrophone for ultrasonic and shock-wave measurements in water," *Ultrasonics*, vol. 31, pp. 267-273, 1993.

[78] T. Reuner, G. Buchholz, J. Oesterle, and U. Schatzle, "The fiber-optic hydrophone - A new quality in measuring lithotripter shock waves," *Proc. 1995 Ultrasonics World Congress*, ISBN 3-9805013-0-2, , pp. 939-942.

[79] C. Wurster, M. Kohler, R. Pecha, et al., "Negative pressure measurements of water using the glass fiber optic hydrophone," *Proc. 1995 Ultrasonics World Congress*, ISBN 3-9805013-0-2, pp. 635-638.

[80] C. Koch and R. Reibold, "Interferometric fiber-optic sensor for measurement of lithotripter shock waves," *Proc. 1995 Ultrasonics World Congress*, ISBN 3-9805013-0-2, pp. 931-934.

[81] C. Koch, "Measurement of ultrasonic pressure by heterodyne interferometry with a fiber-tip sensor," *Appl. Optics*., v. 38, pp. 2812-2819, 1999.

[82] C. Koch, W. Molkenstruck, and R. Reibold, "Shock-wave measurement using a calibrated interferometric fiber-tip sensor," *Ultrasound in Med. & Biol.*, vol. 23, pp. 1259-1266, 1997.

[83] P.C. Beard and T.N. Mills, "Extrinsic optical-fiber ultrasound sensor using a thin polymer film as a low-finesse Fabry-Perot interferometer," *Appl. Optics*, vol. 35, pp. 663-675, 1996.

[84] C. Koch, "Coated fiber-optic hydrophone for ultrasonic measurement," *Ultrasonics*, vol. 34, pp. 687-689, 1996.

[85] A.J. Coleman, E. Draguioti, R. Tiptaf, N. Shotri, and J.E. Saunders, "Acoustic performance and clinical use of a fibreoptic hydrophone," *Ultrasound in Med. & Biol.*, vol. 24, pp. 143-151, 1998.

[86] Y. Uno and K. Nakamura, "Pressure sensitivity of a fibre-optic microprobe for high frequency ultrasonic field," *Jpn. J. Appl. Phys.*, vol. 38, pp. 3120-3123, 1999.

[87] P.C. Beard, A. Hurrell, and T.N. Mills, "Characterization of a Parylene film optical fibre hydrophone for use in the range 1-20 MHz: A comparison with PVDF needle and membrane hydrophones," *IEEE Trans. UFFC*, 2000, in press.

[88] V. Wilkins and C. Koch, "Fiber-optic multilayer hydrophone for ultrasonic measurement," *Ultrasonics*, vol. 37, pp. 45-49, 1999.

[89] W. Folberth, G. Kohler, A. Rohwedder, and E. Matura, "Pressure distribution and energy flow in the focal region of two different electromagnetic shock wave sources," *J. Stone Disease*, vol. 4, pp. 1-7, 1992.

[90] T. Dreyer, R.E. Riedlinger, and E. Steiger, "Experiments on the relation of shock wave parameters to stone disintegration," *Proc. 16th Internat. Congress on Acoust. & 135th Meet. of ASA*, pp. 2811-2812, 1998.

[91] M.T. Carnell, R.D. Alcock, and D.C. Emmony, "Optical imaging of shock waves produced by a high-energy electromagnetic transducer," *Phys. Med. Biol.*, vol. 38, pp. 1575-1588, 1993.

[92] P.C.M. Galloway, R.C. Preston, and D.R. Bacon, "Velocity interferometer for measurement of high-amplitude acoustic pulses," *Proc. 1995 Ultrasonics World Congress* ISBN 3-9805013-0-2, pp. 935-938.

[93] C.R. Hill, I. Rivens, M.G. Vaughan, and G.R. ter Haar, "Lesion development in focused ultrasound surgery: A general model," *Ultrasound in Med. & Biol.*, vol. 20, pp. 259-269, 1994.

[94] L. Chen, G. ter Haar, D.Robertson, J.P.M. Bensted, and C.R. Hill, "Histological study of normal and tumor-bearing liver treated with focused ultrasound," *Ultrasound in Med. & Biol.*, vol. 25, pp. 847-856, 1999.

[95] S. Vaezy, R. Martin, H. Yaziji, et al., "Hemostasis of punctured blood vessels using hign-intensity focused ultrsound," *Ultrasound in Med. & Biol.*, vol. 24, pp. 903-910, 1998.

[96] S. Poliachik, W. Chandler, P. Mourad, et al., "Effect of high-intensity focused ultrasound on whole blood with and without microbubble contrast agent," *Ultrasound in Med. & Biol.*, vol. 25, pp. 991-998, 1999.

[97] N.T. Sanghvi, R.S. Foster, F.J. Fry, et al., "Ultrasound intracavity system for imaging, therapy planning, and treatment of focal disease." *Proc. 1992 IEEE Ultrasonics Symp.*, pp. 1249-1253.

[98] J.Y. Chapelon, J. Margonari, D. Cathignol, et al., "Thresholds for tissue ablation by focused ultrasound," *Proc. 1990 IEEE Ultrason. Symp.*, 1653-57.

[99] C.I. Zanelli, C.W. Hennige, and N.T. Sanghvi, "Design and characterization of a 10 cm annular array transducer for high intensity focused ultrasound (HIFU) applications," *Proc. 1994 IEEE Ultrason. Symp.*, pp. 1887-1890.

[100] Y. Sharf, G.T. Clement, and K. Hynynen, "Absolute measurements of ultrasonic pressure by using high magnetic fields," *IEEE Trans.* UFFC, (in press).

[101] *Ultrasonics - Physiotherapy systems - Performance requirements and methods of measurement in the frequency range 0,5 MHz to 5 MHz*, IEC, Geneva, Publ. IEC 61689, 1996.

[102] R.T. Hekkenberg, R. Reibold, and B. Zeqiri, "Development of standard measurement methods for essential properties of ultrasound therapy equipment," *Ultrasound in Med. & Biol.*, vol. 20, pp. 83-98, 1994.

[103] B. Zeqiri and M. Hodnett, "A new method for measuring the effective radiating area of physiotherapy treatment heads," *Ultrasound in Med. & Biol.*, vol. 24, pp. 761-770, 1998.

[104] L. Crum, M. Bailey, P. Kaczkowski, et al., "Therapeutic ultrasound: A promising future in clinical medicine," *Proc. 16th Internat. Congress on Acoust. & 135th Meet. of ASA*, pp. 719-720, 1998.

[105] X. Zhang, G.H. Harrison, and E.K. Balcer-Kubiczek, "Exposimetry of unfocused pulsed ultrasound," *IEEE Trans. UFFC*, vol. 41, pp. 80-83, 1994.

[106] *Ultrasonics - Surgical systems - Measurement and declaration of the basic output characteristics*, IEC, Geneva, Publ. IEC 61847, 1998.

[107] M.E. Schafer and A. Broadwin, "Acoustical characterization of ultrasonic surgical devices," *Proc. 1994 IEEE Ultrason. Symp.*, pp. 1903-6.

[108] I.R.S. Makin and E.C. Everbach, "Measurement of pressure and assessment of cavitation for a 22.5-kHz intra-arterial angioplasty device," *J. Acoust. Soc. Am.*, vol. 100, pp. 1855-1864, 1996.

[109] D. Swiney and W.D. O'Brien, Jr., "Human fetal diagnostic ultrasound exposimetry system," *Proc. 1996 IEEE Ultrason. Symp.*, pp. 1167-1169.

[110] M.E. Schafer, T.L. Kraynak, and P.A. Lewin, "Design of a miniature *in-vivo* shock wave hydrophone," *Proc. 1990 IEEE Ultrason. Symp.*, pp. 1623-1626.

[111] R.O. Cleveland, D.A. Lifshitz, B.A. Connors, A.P. Evan, L.R. Willis, and L.A. Crum, "*In vivo* pressure measurements of lithotripsy shock waves in pigs," *Ultrasound in Med. & Biol.*, vol. 24, pp. 293-306, 1998.

[112] C.L. Walker, F.S. Foster, and D.B. Plewes, "Magnetic resonance imaging of ultrasonic fields," *Ultrasound in Med. & Biol.*, vol. 24, pp. 137-142, 1998.