# Development of a High Intensity Focused Ultrasound (HIFU) Hydrophone System

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In the past few years, High Intensity Focused Abstract Ultrasound (HIFU) has developed from a scientific curiosity to an accepted therapeutic modality. Concomitant with HIFU's growing clinical use, there has been a need for reliable, economical and reproducible measurements of HIFU acoustic fields. A number of approaches have been proposed and investigated, most notably by Kaczkowski et al [Proc. 2003 IEEE Ultrasonics Symposium, 982-985]. We are developing a similar reflective scatterer approach, incorporating several novel features which improve the hydrophone's bandwidth, reliability, and reproducibility. For the scattering element, we have used a fused silica optical fiber with a polyamide protective coating. The fused silica core is 73 microns in diameter with a 5 micron thick polyamide coating for a total diameter of 83 microns. The fiber was prepared by cleaving to yield a perpendicular/flat cut. The fiber is maintained in position using a capillary tube arrangement which provides structural rigidity with minimal acoustic interference. The receiver is designed as a segmented, truncated spherical structure with a 10cm radius; the scattering element is positioned at the center of the sphere. Each segment is approximately 6.3 cm square. The receiver is made from 25 micron thick, biaxially stretched PVDF, with a Pt-Au electrode on the front surface. Each segment has its own high impedance, wideband preamplifier, and the signals from multiple segments are summed coherently. As an additional feature, the system is designed to pulse the PVDF elements so that the pulse-echo response can be used to align the fiber at the center. This is important when the need arises to change the fiber due to, for instance, cavitation damage. The hydrophone can also be designed with a membrane structure to allow the region around the scatterer to be filled with a fluid which suppresses cavitation. Initial tests of the system have demonstrated a receiver array sensitivity of -279 dB re 1 microVolt/Pa (before preamplification), with a scattering loss at the fiber of approximately 39dB, producing an effective sensitivity of -318 dB re 1 microVolt/Pa. The addition of the closely coupled wideband preamplifiers boosts the signal to a range which is sufficient for the measurement of HIFU transducers. The effective bandwidth of the system exceeds 15MHz, through careful design and the use of PVDF as a sensor material. In order to test the system, a HIFU transducer in the 4.0MHz frequency range was tested at low output settings using a conventional PVDF membrane hydrophone. The prototype system was then used to characterize the same HIFU transducer at full power. The results showed good correlation between waveforms and cross-axis beam measurements, taking into account the additional shock losses at higher output settings.

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## I. INTRODUCTION

High Intensity Focused Ultrasound (HIFU) is a novel technology for the destruction of cancerous tumors or other tissue structures within the body using ultrasound. The ultrasound fields are of sufficiently high intensity that the temperature in the targeted tissue is raised well above 45°C, at which point proteins within the tissue denature and the cells within the tissue die. The ultrasound is focused so that this destructive energy is directed only at a specific region (volume) within the patient. The principal problem with the measurement of HIFU fields is that the ultrasound field is of sufficient intensity that it can destroy or significantly alter the properties of the measurement device. The measurement device must have the capability of repeatedly measuring ultrasound fields over a wide frequency range with relatively flat frequency response (from 500kHz to 20MHz, when harmonics are included), with small apertures (less than 0.5mm), at high intensities (over 50W/cm<sup>2</sup>).

There is a need to quantify these fields for the purposes of instrument development, on-going quality assurance and to meet various governmental regulatory requirements. The fields must be quantified with respect to their distribution in space (spatial measurement), their extent in time (temporal measurement), and their frequency content. The latter requirement is due to the non-linear nature of wave propagation within tissue.

The bandwidth and linearity requirements would generally be met using a piezopolymer material, such as polyvinylidene difluoride (PVdF). This material, however, is relatively fragile, and would literally melt or would otherwise be damaged if directly exposed to the intensity levels produced by HIFU devices.

The general requirements for sensors to be used in high energy ultrasound fields were presented by Schafer and Lewin [1]. Although that paper was specific to short time duration wave fields (such as those from lithotripters), the general information regarding bandwidth, size, etc, are applicable in this case.

Several different approaches have been tried with the goal of repeatable, inexpensive measurements of high intensity ultrasound fields.

One uses a disposable piezopolymer film, which is designed to be self-monitoring [2]. This approach solves the problem of bandwidth and linearity (using the piezopolymer film), and addresses the issue of changes in the sensitivity in the material caused by exposure to the high intensity ultrasound. When the piezopolymer film is exposed to shock waves, the electrode material which conducts the electrical charge produced by the film is slowly eroded away. This erosion induces a change in resistance, and therefore a change in sensitivity. This change in resistance through the electrodes is remotely monitored, allowing the operator to cease the measurement program (and replace the disposable element) when the resistance (and therefore the sensitivity) has changed a predetermined amount. Additional details of this approach can be found in [3].

Another approach which uses a piezopolymer film [4] has the film disposed between two other, conductive films, eliminating the need for any electrode directly on the piezopolymer film itself. Therefore there are no electrodes which could be affected by the action of the ultrasound field.

The disposable piezopolymer film approach is more suited to exposure to short duration shock waves, as in those produced by shock wave lithotripters (kidney stone crushers). These short duration shock waves produce cavitation damage to the piezopolymer film, but do not produce any heating. In this regime, the hydrophone element may last for thousands of shock wave exposures, sufficient to characterize the shock wave field. However, in a HIFU field, there is both cavitation and heating, and the longer duration of the exposure (multiple seconds for HIFU, at up to 100% duty cycle, whereas lithotripter shock fields are microseconds in duration, with less than 1% duty cycle) would cause the piezopolymer to be destroyed within the first few seconds of exposure. This is not enough time to complete a characterization.

Similarly, the hydrophone film, which does not have any electrodes would also be subject to heating by the HIFU field. It has the further drawback that it has no provision for quick substitution or replacement of the active piezopolymer film. It does describe a controlled liquid environment around the scatterer. By controlling the properties of this liquid, it is possible to suppress cavitation, or alter the acoustic transmission properties in the region.

Thus, any design which places the piezopolymer film directly in the high intensity field is subject to rapid deterioration from the intense cavitation and thermal effects present in HIFU. Therefore another approach [5] uses a small reflective scatterer to reflect the ultrasound energy in a controlled manner. The reflected signal is then detected by a separate PZT receiver placed some distance away. This approach removes the actual detector from the region of high energy (and thereby, from the region of potential destruction). The description includes methods of producing the scatterer (a drawn wire or drawn glass pipette), and a block diagram which shows the scatterer, the receiver, and an adjunct piezopolymer receiver close to the scatterer used for calibration purposes. This calibration receiver (hydrophone) is also separated from the scatterer so that it is out of the HIFU field during full power exposure. Calibration is done by exposing the piezopolymer

hydrophone only to low level ultrasound fields, and comparing those hydrophone results to those from the receiver which senses the reflected energy from the scatterer.

The reflective scatter approach [5] does have a few limitations. First, the alignment process for the target is not well defined, except as an arbitrary position near the focal position of the receiver. Once an arbitrary alignment has been made, a cross calibration is required with a needle-type hydrophone which is attached to the same support structure. No optimization of the alignment is described. While it is mentioned that the measurements can be conducted in "in water or other fluids", there is no specific description of enveloping the scatterer in a specific fluid which would suppress cavitation or otherwise improve the measurement process. The scatterer, receiver, and support frame, which rigidly connects the two are open to the entire liquid environment, and are not conducive to making an isolated fluid region.

## II. MATERIALS AND METHODS

We have combined the attributes of these different concepts, and are developing a reflective scatterer approach as proposed by Kaczkowski et al [5], incorporating several novel features which improve the hydrophone's bandwidth, reliability, and reproducibility. Instead of a single, circular receiver element, we are developing an array of spherically shaped PVdF receivers oriented about a single reflector, in the shape of a truncated sphere. Figure 1 below is an illustration of the concept.



Figure 1. Schematic Diagram of HIFU Hydrophone Concept.

In this figure, the HIFU beam intercepts a reflective target in the center of the receiver array. By combining the output from the individual receivers, the overall signal strength and positional sensitivity are improved, permitting the use of a smaller reflector element. In addition, the system can be aligned by using the individual receiver elements as pulse-echo transducers, such that when the overall time alignment is uniform across all elements, the reflector is perfectly centered within the structure.

For the work reported upon here, the prototype consisted of a single concave receiver made from 25 micron thick, biaxially stretched PVdF, with a Pt-Au electrode on the front surface. The PVdF was stretched and bonded to the spherically curved segment using a compliant pressing fixture with controlled temperatures (below the Curie point) and pressures. The film was bonded using Epotek 310. By observing the proper pressing techniques, it was possible to get a thin, uniform bond of the PVdF to the backing surface. (However, no special attempts were made to seal the edges of the PVdF, and during testing the edges lifted from the backing in the corners. This will be addressed in future designs.) The initial backing surface was anodized aluminum, which also served as a ground plane. A separate preamplifier module was used with a 4cm cable. The preamplifier had uniform gain up to about 30MHz, with a slow roll-off beyond this frequency.

For the scattering element, we have used a fused silica optical fiber with a 73 micron core diameter and a 5 micron thick polyamide coating for a total diameter of 83 microns. The fiber was prepared by cleaving to yield a perpendicular/flat cut. The fiber was held using a capillary tube arrangement which provides structural rigidity with minimal acoustic interference. The capillary tube was then held in place by a collet arrangement on an adjustable arm extending from the receiver structure. The entire assembly was attached to another anodized aluminum support frame for suspension in the water tank.



Figure 2. Photograph of the prototype in the water tank. Note the test transducer on the upper right, the PVdF receiver array on the left, and the preamplifier module at the upper left.

### III. RESULTS

Figure 2 shows the assembled unit with a 35mm diameter, 4MHz test transducer, which was selected to be comparable to a commercial HIFU system.

One of the first tests involved using the PVdF receiver as a pulse-echo transducer in order to align the glass fiber target. The preamplifier was disconnected and a Panametrics 5052R pulser was connected instead. Figure 3 shows the resulting maximal pulse-echo response. The signal-to-noise is relatively poor; this was traced to grounding issues with the aluminum backing structure. A second unit was built using ABS as a backing, which improved the SNR, but with a slight loss of sensitivity, and increased construction complexity.



Figure 3. Pulse Echo response to the glass fiber target

Once the pulse-echo signal was maximized, this indicated that the glass fiber reflector was centered at the geometric focal region of the PVdF receiver. In the final design, this would be repeated for all the array elements, leading to a significant focal gain when all the elements are connected in parallel.

The next series of tests involved the 4MHz test transducer as shown in Figure 2. The transducer was driven with a long burst sine wave excitation, similar to that used in HIFU. Again, because of the grounding issues with the aluminum backing, there was electrical interference which influenced measurements taken in Continuous Wave (CW) mode. More specifically, it was difficult to scan the ultrasound beam out to the lower sidelobe levels, because these low acoustic signals were smaller than the electrical interference signal. Using the long burst mode, it was possible to time gate out the interference.

The output of the transducer was set to a relatively low level and the signals from the HIFU hydrophone were compared to those measured with a reference bilaminar hydrophone (Sonora Medical Systems, Model S5). The low level was used in order to not damage the reference hydrophone. The acoustic beam was used to insonify both the fiber reflector, and also the PVdF receive structure directly. In this way it was possible to estimate the receiver sensitivity and the scattering loss of the fiber. The receiver element sensitivity was -279 dB re 1 mV/Pa, with a scattering loss at the fiber of approximately 39dB, producing an effective sensitivity of -318 dB re 1 mV/Pa.

The final series of tests involved driving the test transducer at levels more typical of HIFU systems. Waveform capture and beam scanning measurements were taken. It was noted, however, that the laboratory transducer system probably did not reach the same levels as a commercial HIFU system, as there was negligible cavitation detected in the water tank, even at the highest safe (for the transducer) output setting.

Nonetheless, the results indicated that the system has excellent signal fidelity to the non-linear harmonic generation typical of high intensity ultrasound, as well as good spatial resolution. The spatial measurements are shown in the figures below.



Figure 4. Cross-Axis scan results



Figure 5. Raster Scan results.

In this prototype configuration, with the limited output of the transmit transducer, the small optical fiber did not always provide a sufficiently strong reflection to measure the beam pattern to the -26dB level; this required the use of a larger, metallic target. Further, the initial design of the PVdF receiver was very susceptible to electrical interference, which can be quite strong with high voltage, HIFU systems. There were also a number of spurious signals which were traced to internal echoes from within the aluminum structure. Therefore a second version of the hydrophone was built which used ABS rather than aluminum as the curved backing surface. This required using a separate ground connection scheme and PVDF with electrodes on both sides. It did allow the preamplifier to be built into a cavity milled into the back of the ABS plastic structure, which reduced the cable length and improved reliability. Having a lower impedance, lossy backing did reduce the sensitivity by several dB, but the improved noise immunity more than compensated for this signal loss. It is clear that the final version, now in development, must incorporate additional receivers to allow for a wide range of output conditions.

## IV. DISCUSSION AND CONCLUSIONS

The concept demonstrated here shows the promise of providing both a reliable and economic means of measuring HIFU fields, by combining the best attributes of the reflector technique [5], with the receive capabilities of PVdF. Further, the utility of using a pulse-echo approach for target alignment was demonstrated.

However, the prototype system was not without its limitations, and these are being addressed as the HIFU hydrophone system is further developed.

The conclusions from this work are: 1) the PVdF receiver segment shows high signal fidelity; 2) silica fiber provides a relatively inexpensive and straightforward approach to creating a reproducible reflector element; 3) PVdF can be formed into the necessary shape, if the proper design methods are followed; 4) the initial reflector element size, while suitable for the final, multi-receiver application, provides insufficient signal for the single receiver prototype; 5) the initial aluminum backing, while simplifying the grounding approach introduced too much stray noise pickup and a non-conductive (ABS plastic) backing provided better overall performance at a slight cost in sensitivity; 6) multiple receivers are required to obtain the desired signal-to-noise performance.

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