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14. ABSTRACT This report contains a description of an investigation of the physiological effects of underwater low frequency sound. The work described includes the design, fabrication, and testing of a travelling wave tube for the controlled insonification of small animals under representative conditions. It also contains a description of an experiment conducted on divers in a hyperbaric chamber to determine the frequency response of the human lung and the effects of depth on this frequency response.					
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Final Report for

Navy Contract N0014-97-1-0949

**Measurement of Lung Vibration from Low Frequency
Underwater Sound in an Animal Model and Divers Using
NIVAMS**

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October 31, 1999

Measurement of Lung Vibration from Low Frequency Underwater Sound in an Animal Model and Divers Using NIVAMS

Final Report

I. Introduction:

Active sonar systems have been developed by the Navy which operate in frequency ranges substantially lower than those used by preexisting active systems. The low frequency active (LFA) sonar systems are intended for use in both deep ocean and littoral waters. It is therefore quite likely that both recreational and Navy divers will be exposed to the acoustic energy produced by LFA sonars. Previous work [Pestorius 1996] suggested that the initial safe exposure guidelines which had been proposed for these systems (160 dB re $1\mu\text{Pa}$, 100-500 Hz, no depth or duration restrictions) were too liberal. This work, however, was not sufficient to establish a new guideline for safe exposure.

The focus of the research effort described in this report has been to aid in the establishment of exposure guidelines. The intended procedure through which these guidelines were to be established was as follows:

- Determine the lowest exposure level which produces measurable damage in small mammals by experimentally examining the damage thresholds of various candidate systems (lung, vestibular system, brain, etc.).
- Determine the mechanism responsible for each form of damage (strain, displacement, velocity, pressure, etc.).
- Establish the scaling laws necessary to extrapolate the various thresholds to a human in order to determine the limiting system for humans and the damage threshold.

Different aspects of this effort were addressed simultaneously by several institutions. There were two primary tasks which were undertaken at Georgia Tech and are described within this report. The first of these was the development of a technique and an apparatus to expose small mammals to a known underwater low frequency sound (ULFS) dose and to distinguish between the acoustic velocity and the pressure related effects which it produced. The second task was to determine the ULFS induced displacement response of the human lung as a function of both depth and frequency for the determination of scaling laws and to provide the ability to extrapolate data taken at surface pressure to the range of depths at which divers are likely to be exposed.

II. Design, construction, and testing of a chamber for the controlled exposure of small animals to underwater low frequency sound

A. Problem statement

The acoustic field is defined by the pressure and the velocity which are functions of location and time (or location and frequency). For an acoustic field which is characterized by propagating planar wave fronts the acoustic pressure is in phase with and proportional to the acoustic particle velocity (which is in the direction of propagation). The proportionality constant is called the plane wave impedance. It is a function only of the properties of the medium in which the wave propagates. This relationship may be written as follows:

$$\frac{p}{\vec{v} \cdot \vec{n}} = \rho c$$

Equation 1: Plane Wave Impedance Relationship

In this equation p is the acoustic pressure, \vec{v} is the particle velocity, \vec{n} is a unit vector in the propagation direction and ρ and c are the density and sound speed of the medium respectively. This relationship is generally a good approximation for a variety of cases in which wave fronts are not truly planar. Far from an LFA source in open water would be such a case. Unfortunately the sort of case for which this relationship is valid does not lend itself to laboratory experimentation. The open water (free field) assumption requires that the body of water be much larger than a wavelength. Thus any energy reflected from tank boundaries may be time gated out of a measurement or attenuated at the boundaries. For full scale LFA frequencies this implies minimum tank dimensions on the order of tens of meters. In smaller tanks the boundary reflections form a standing wave field in which the pressure and velocity are in quadrature (rather than in phase as in equation 1) and the magnitude of the impedance is dependant on frequency. The proposed solution for this dilemma was the construction of a travelling wave tube (TWT). This is a tube with a sufficiently small cross section that field uniformity (planarity) can be maintained and active control of the terminations at both ends where in a travelling wave produced by the drive at one end is completely absorbed at the other. Such tubes have been built in the past for transducer calibrations and the study of material properties. An advantage to this scheme is that alternate drive types for the terminations can be chosen which lead to either a pure pressure (zero velocity) or pure velocity (zero pressure) condition at the tube center. This permits the physiological effects of each of these components of a travelling wave to be studied separately. The design of the TWT for these experiments was unique in that these are not usually constructed for the insonification of compliant objects (such as an animal with an air filled lung) or of living creatures.

B. Modeling and conceptual design

The conceptual design for the animal exposure chambers is detailed in the interim report entitled "Test Chambers for LFS Animal Exposures" which is included in Appendix A of this report. The interim report details the theoretical

study which validated the TWT concept for the animal exposure chamber and identified the critical design parameters. Primary among these were the requirements that the tube walls and end caps be rigid and immovable; that the driver responds with a prescribed force of sufficient amplitude to generate the desired pressure levels; that all tube dimensions be kept as small as possible; and that the pistons be sufficiently large, low in mass, and softly suspended that they do not adversely affect the fluid load on the animals lung. Several of the design requirements compete and limits are imposed on all parameters by the need to work with readily available components. A parametric study of these constraints led to the decision to use commercially available 110 lb. electrodynamic shakers connected to 5.5" diameter pistons as the drives for the two active ends. It was decided that the tube should be 14" long with a 10" internal diameter and 3" thick 304 stainless steel walls.

C. Final design and fabrication

The initial testing of the animal exposure chamber revealed several flaws in the original design. The pistons demonstrated an unpredicted 1500 Hz resonance in the absence of fluid loading. The effect of the fluid load would have been to downshift this closer to the band of interest. The original seal design proved to be impossible to assemble because it required tighter mechanical tolerance on the shaker suspension than the manufacturer was able to achieve. The result of this was an interference between the piston and the bore in the end cap which substantially distorted the signal from the shaker when the device was driven. To eliminate these problems the seals, pistons and end caps were redesigned. The double sliding seals were replaced with a single membrane seal and the cylindrical syntactic foam piston was replaced with a two piece conical aluminum piston. Machine drawings for both the original and final chamber designs are included in Appendix B.

Three animal exposure chambers were constructed. Each chamber was mounted in a rolling frame which incorporated a water heater and circulation system, a winch for opening the chamber lid, and a sealed top tank to permit the chamber to be opened and closed without the introduction of air. Each chamber was also equipped with a PC based data acquisition and signal generation system which included 250 kHz analog to digital conversion, a calibrated hydrophone and accelerometer, a borescope system, and two 3KW power amplifiers. A complete system is depicted in figure 1.

D. Device testing

The testing of the exposure chambers was undertaken using a B&K 8103 hydrophone and a Kistler Picotron accelerometer. The accelerometer was embedded in a syntactic foam sleeve to make it neutrally buoyant and was softly suspended using nylon fishing line to ensure that it would move in unison with the surrounding water. Both the hydrophone and the accelerometer were located near the center of the midplane of the tube.

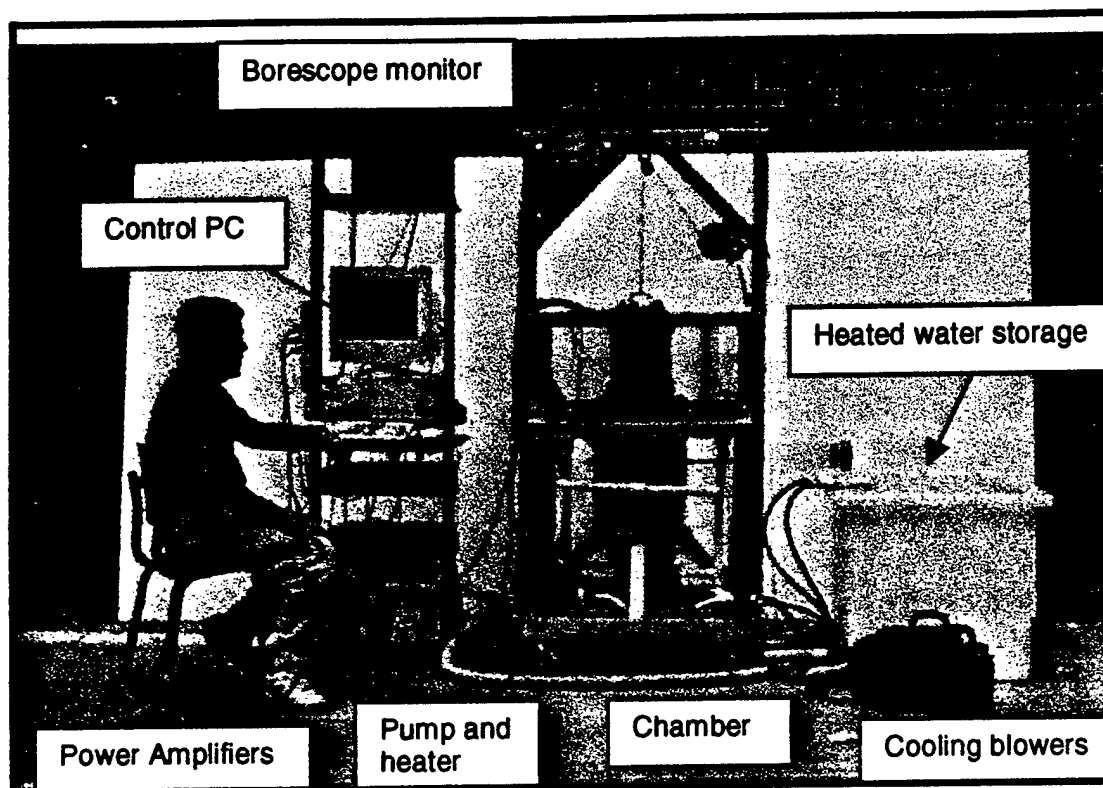


Figure 1: Animal Exposure Chamber and Support Equipment

Figure 2 shows the pressure and velocity which were measured by these devices over to 100 – 1000 Hz band when both shakers were driven in phase with equal amplitude. The sharp resonance that was observed at 800 Hz is predicted by the model detailed in the interim report to occur at 1140 Hz. The lower frequency observed in the experiment can be explained by the added compliance of the redesigned membrane seal. A much smaller resonance is observable around 340 Hz. This can be explained by a suspension resonance in the shaker mounting system. The effect is small because this effect can only manifest in the fluid pressure to the extent that the motion of the shaker tail mass generates a fluid pressure. This is only coupled to the piston through the relatively soft shaker suspension. Over the entire frequency range of this experiment the impedance relation (p/v) is roughly 15-20 dB higher than for a plane wave of similar level. This had previously been established as sufficient to define an experimental "pure pressure condition". It should be noted that the drive level for this test was set well below the maximum to permit measurements at resonance. It should also be noted that the impedance relation could be further improved if the drive signals accounted for the slight mismatch between the two shakers which were used. This adjustment can be easily done experimentally.

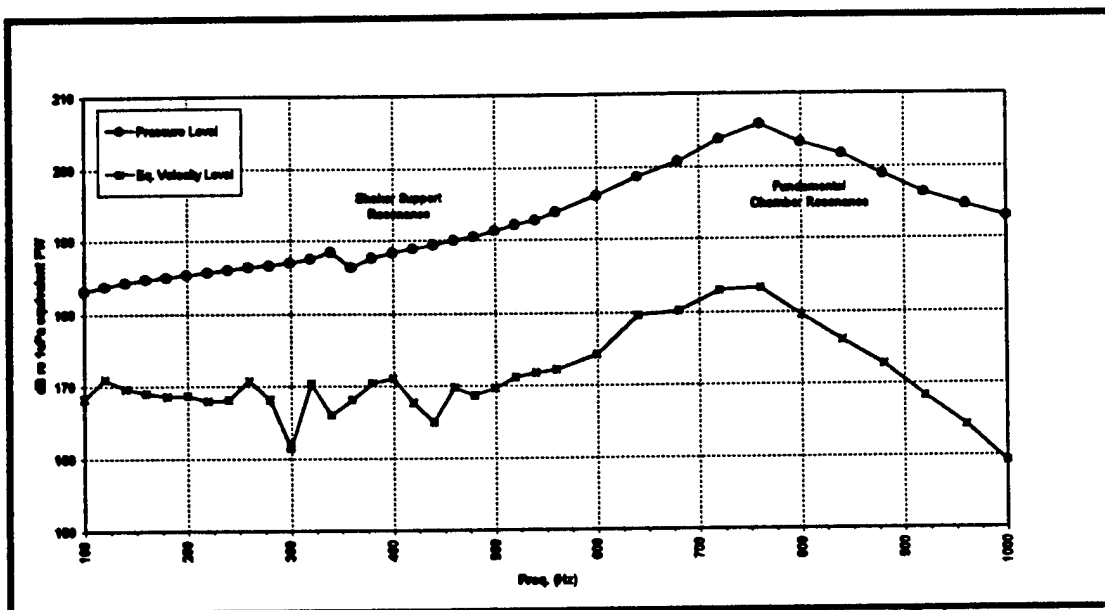


Figure 2: Exposure Chamber Response to Balanced Drive

Figure 3 shows the response of the chamber under the opposite drive condition to that depicted in figure two. In this unbalanced drive condition both shakers were driven with equal amplitude 180° out of phase with each other.

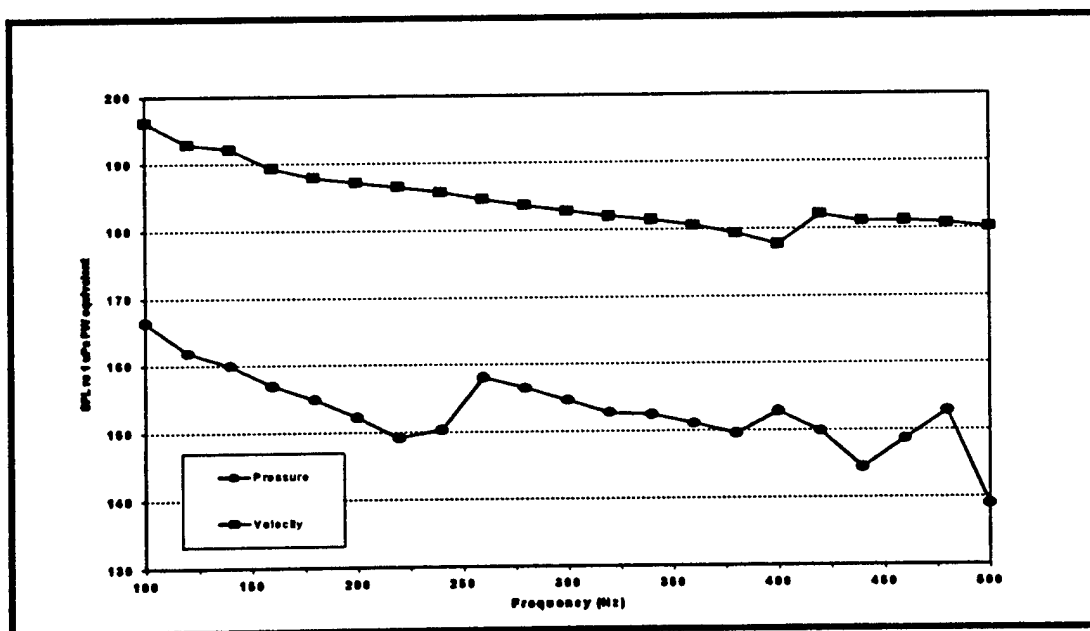


Figure 3: Pressure and Velocity in Primary Band for Unbalanced Drive

The data shows at least a 20 dB reduction in the impedance relative to the plane wave case over the entire primary band of 100- 500Hz. This is the full scale frequency range and was chosen for initial testing because it fell well below the fundamental resonance and it was the range of focus for all the animal experiments undertaken in 1997-8.

Figure 4 depicts a similar set of data taken when the shaker drives were phased so as to create a plane wave condition. This was done by adjusting the relative amplitude and phase of one of the shakers so that the measured acceleration and pressure in the tube midplane would be in phase quadrature (and therefore the pressure and velocity would be in phase). The data is plotted here as both the phase and the magnitude of the measured impedance. There was no relevant measure of phase for the previously plotted cases. From the data it can be seen that the impedance is within 20% of the desired value ($1.5 \text{ MRayl} \approx \rho c$ for water) and that the phase is within 14° of the desired value. This is within the parameters of the design.

The nature of animal studies which were going on simultaneously with the development of these exposure chambers gave rise to concern over maximum achievable pressure levels within the primary band. The data in figure 5 represents an attempt to measure the maximum pressure level which could be achieved in the exposure chamber. For this measurement a balanced drive was used and the chamber was assumed to be overdriven either when the power amplifiers indicated overload or when the received pressure signal was distorted such that the level of the first harmonic of the drive frequency was within 20 dB of the fundamental. The maximum achievable level was found to be on the 206 – 210 dB re $1 \mu\text{Pa}$ over the primary band with the exception of the 300–400 Hz range which was limited by the 340 Hz shaker mounting resonance. This increased the harmonic level and caused an audible rattle during the 340 Hz drive for fundamental levels higher than 190 dB. The nature of this resonance implies that the actual equivalent levels which could be achieved with a compliant animal in the tube are much higher than those depicted in the 300–400 Hz range.

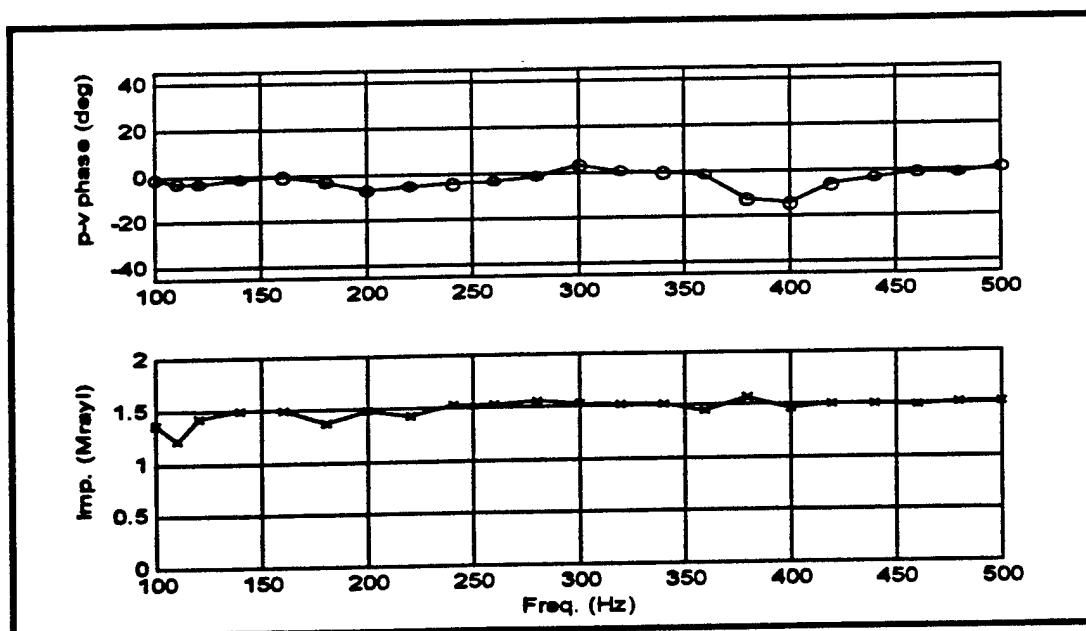


Figure 4: Impedance at Tube Midplane for Plane Wave Drive @180 dB

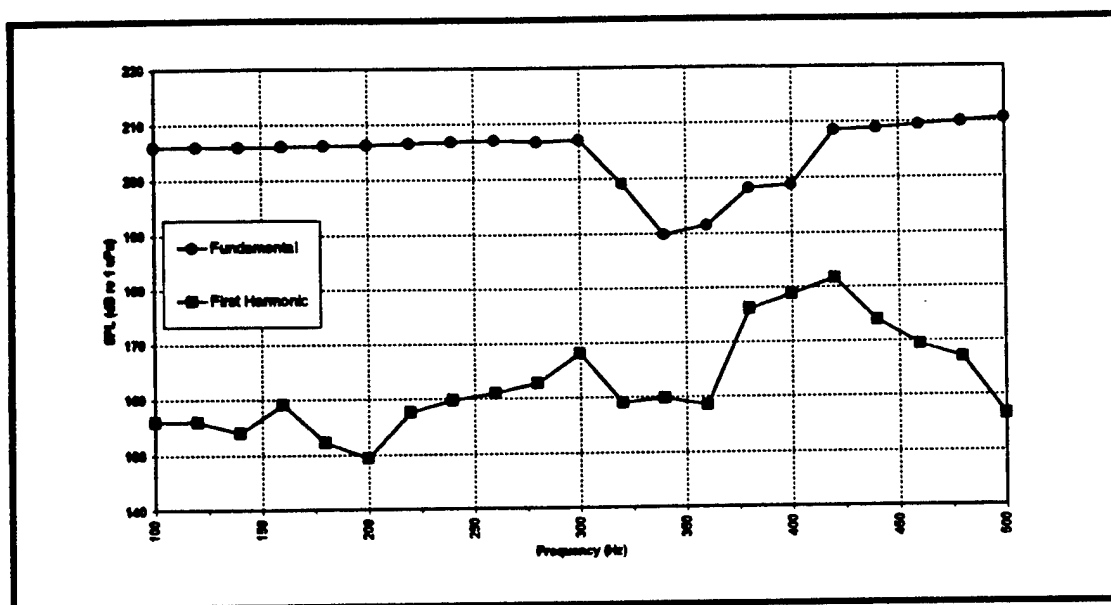


Figure 5: Maximum Pressure Measured in Chamber Using Balanced Drive

E. Open loop active mass control

The minimization of piston mass was one of the few design parameters for which there were no tradeoffs other than the inherent impracticality of requiring an object to be both light weight and rigid. In general, the lighter the piston becomes the higher the fundamental resonance will be and the more realistic the radiation loading on the animal will be. The pressure level in the chamber below resonance is independent of the piston mass and is dictated only by the piston's surface area. The mass of the piston as built was 500g, however the effective dynamic mass of the piston also included the 455g armature mass of the shaker and the radiation mass load imposed on the wet side of the piston. The latter two contributions were unalterable since the first was specified by the shaker manufacturer and the second was dictated by the laws of physics. The addition of stiffness to the dry side of the shaker could have increased the observed fundamental chamber resonance, but the tradeoff for this would have been an unacceptable loss of pressure level inside the chamber and an unrealistic radiation impedance for the animal.

A solution to this conundrum was identified which provided a feasible way in which to realize an effectively massless piston. The proposed scheme involved summing the output of piston mounted accelerometers back into the drive signal prior to the power amplifier. Since the amplifier was effectively linear and the shaker was well characterized as a force driver the net effect of this additional drive term was to appear as a mass in the equations of motion for the system. This mass, unlike a physical mass, can have a negative value since its

magnitude is dependant only on the gain of a preamplifier before the summation stage. Symbolically this may be represented as follows:

The one dimensional representation of Newton's 2nd law :

$$F = ma$$

Is modified by the additional drive term:

$$F = F_{Drive} + Ga$$

To give:

$$F_{Drive} = (m_{actual} - G)a$$

This relationship contains a term which is functionally identical to a mass but can be arbitrarily modified by control of the preamplifier gain (G):

$$m_{effective} = m_{actual} - G$$

Initially this modification may seem to be a unnecessary complication which is functionally equivalent to turning down the drive level at resonance. However, the importance of the feedback loop is that the piston mass is reduced not only as seen by the drive but also as seen from the wet side which includes the enclosed animal. It therefore satisfies the end conditions necessary for the correct radiation loading on the animal which a predetermined frequency dependence of the drive level could not do.

This scheme was implemented on a bread board. The measured pressure transfer functions are displayed in figure 6. It is apparent from the figure that the system resonance has been shifted upward with a decreasing effective mass. It is also apparent that the resonant Q has become progressively sharper. This is because the accumulation of delays and phase errors in the acceleration feedback loop give rise to a negative damping term in addition to the negative mass. Thus, as mass is decreased, damping is also and the effective Q goes up with resonance. This feature of the system is problematic because it gives rise to feedback instabilities in what is conceptually a stable system. As the net damping term, which is quite small in the absence of the loop, is driven to zero (or beyond) the loop goes unstable. This happens well before a zero net mass condition is achieved. The problem is further complicated by the fact that the phase responses of the power amplifiers in the system are temperature dependant. The temperature dependence gives rise to the marginally stable case depicted in figure 6. Here the loop remains stable until the power amplifiers have heated up. Once unstable, stability cannot be recovered since the power requirements of the instability keep the amplifiers overloaded and, therefore, hot. Data for the

marginally stable case had to be collected before the loop drifted into oscillation and is therefore confined to the region around resonance.

A scheme has been devised, although not yet implemented, for dealing with this instability. This scheme involves summing a time integrated accelerometer signal into the drive and gained accelerometer signal. The integration should create a damping term that can be used to compensate for the loop delay and maintain stability.

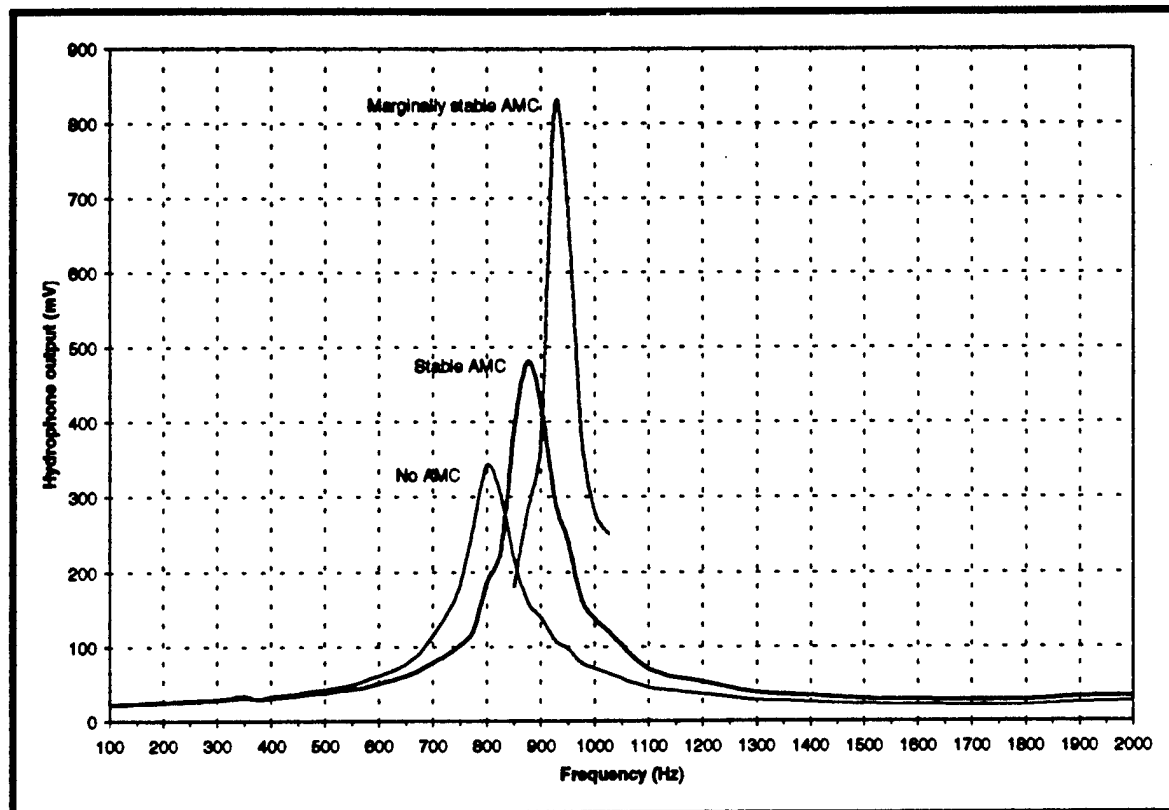


Figure 6: Chamber Resonance Shift Produced by Active Mass Control

III. Measurement of the frequency response of the human lung to ULFS in the 30 – 500 Hz frequency range

A. Problem statement

Below 500 Hz the largest features to be expected in the response to ULFS of human systems are the fundamental resonances of large air filled spaces such as the lungs. A previous study [Rogers, 1994] reported resonances in the 60 – 500 Hz frequency range that manifest in lung and chest wall motion. These resonances were observed above 100 Hz and were not believed to be the fundamental resonance of the lungs. No measurements of a verifiably fundamental resonance of the human lung underwater have previously been made. Theory and past experiments point to a lung resonance below the primary 100 – 500 Hz band. It is important to note that a fundamental lung resonance should have a strong depth dependence. It could, therefore, easily impinge on the primary band within the normal depth range seen by recreational divers. It should also be noted the damage produced in small mammals during G-40 experiments was inflicted at or near resonance frequencies [Dilecki 1998]. This information could not be scaled to human thresholds without a valid frequency scaling of the resonance. Thus, the problem which was addressed in the experiment described in this report was to determine the frequency response of the lung exposed to ULFS below 500 Hz as a function of depth and frequency. This information should provide both the appropriate scaling information for data from animal models and permit an assessment of the potential risks from ULFS associated with depths beyond the range which has been directly examined.

In the simplest analysis the lungs may be considered to be a single compliant object whose stiffness is governed by the fixed volume air contained within them. They are driven uniformly by the oscillating pressure of the low frequency acoustic stimulus and their motion is mediated by the radiation loading of the surrounding fluid (radiation mass and radiation resistance). If one imposes the additional simplification of assuming a virtually spherical geometry then the first lung resonance would be expected to occur between 20 and 100 Hz and to be predicted by the equation:

$$f_n = \frac{1}{d_{lung}} \sqrt{\frac{3\gamma_{air}P_{ambient}}{\pi^2\rho_{water}}}$$

Equation 2: Simple Bubble Resonance Frequency

Where γ_{air} is the ratio of specific heats for the gas entrained gas in the lungs (about 1.4 for air), $P_{ambient}$ is the ambient static pressure, ρ is the density of the subscripted quantity, and d_{lung} is the equivalent lung diameter. The simple bubble model is loosely in agreement with the data from small animals. Since a more accurate analytical model is not available, the bubble approximation was used as a baseline for the design of this experiment.

This analysis is functionally identical to assuming that the lung is a single degree of freedom harmonic oscillator with mass, stiffness, and damping as follows:

$$M_{rad} = 3\rho_{water} V_{lung}$$

Equation 3: Radiation Mass Load on a Spherical Lung at Low Frequency

This is the radiation mass load on a uniformly oscillating spherical lung of any size. This is strictly applicable to spherical objects and may not be correct to better than an order of magnitude for the lung. It also neglects any mass loading effects of the chest wall, rib cage, and lung tissue.

$$K_{lung} = \rho_{air} c_{air}^2 \frac{A_{lung}^2}{V_{lung}}$$

Equation 4: Stiffness of a Uniformly Dilating Air Cavity

This is the stiffness of confined gas in a lung of any shape undergoing small uniform oscillation. This is generally a good approximation provided that surface motion is uniform dilation (change in size not accompanied by a change in shape). It neglects any contribution to the stiffness of the lung by the chest wall. Of the three terms which define the simple bubble system this is the only one with a significant ambient pressure dependence. The leading term (air density) is directly related to ambient pressure through the ideal gas equation.

$$R_{rad} = \frac{\pi \rho_{water} f^2 A_{lung}^2}{c_{water}}$$

Equation 5: Radiation Resistance for a Monopole Lung

The equivalent resistance of the radiated acoustic energy for a lung which is much smaller than a wavelength in the surrounding medium. This is probably a very poor approximation for the damping of lung system. It seldom constitutes the dominant form of damping at low frequencies. The true source of lung damping is more likely to be a viscous effect of the surrounding tissues.

In these equations A_{lung} and V_{lung} are the surface area and volume of the lung, ρ is the density of the subscripted quantity, and c is the adiabatic speed of sound of the subscripted quantity. The resonance frequency of this system is determined from the square root of the ratio of K/M . This gives the same result shown in the first equation since the specific heat ratio is related to the sound speed and the gas density relates to the ambient pressure. The Q of the resonance is inversely proportional to R .

For a lung that could be described by these simplified assumptions the frequency response curve shows a single resonance, a flat displacement response below resonance, and a 12 dB/octave rolloff (flat acceleration) above resonance. The predicted frequency response for such a spherical lung exposed at a sound pressure level of 140 dB is shown in figure 7.

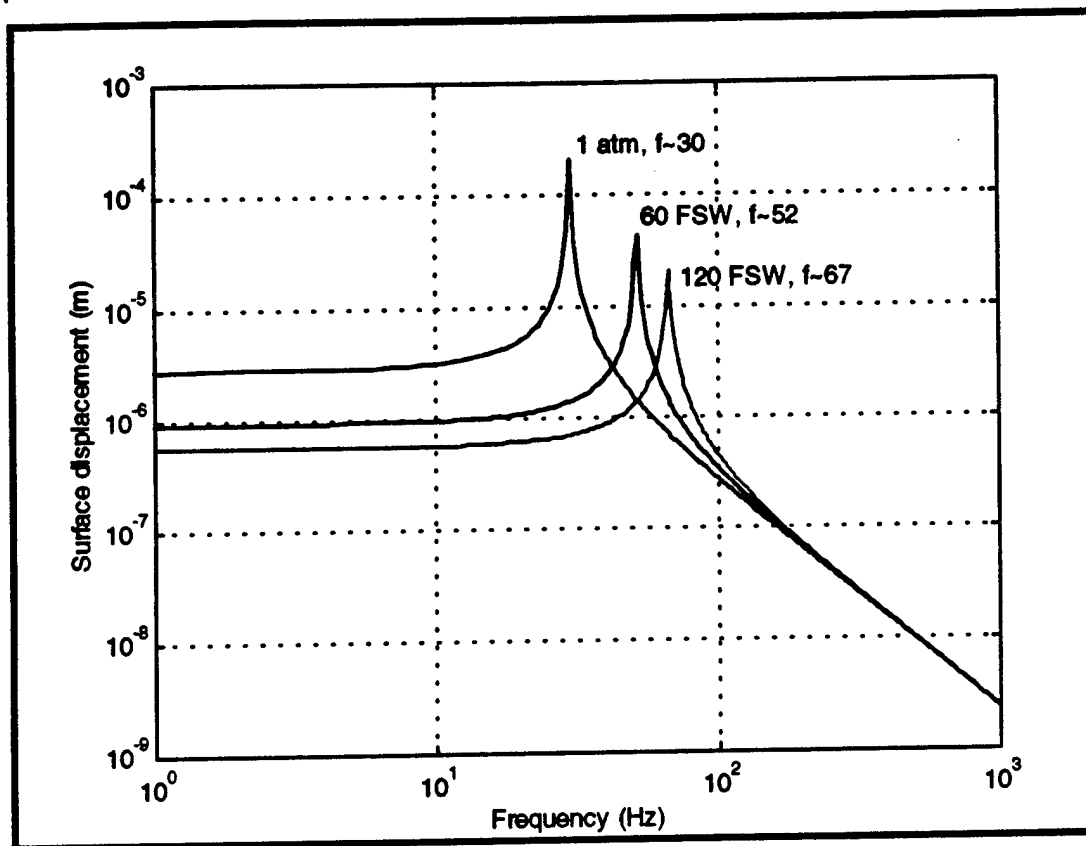


Figure 7: Frequency Response of a 4L Spherical Air Bubble

The anticipated validity, or lack of validity, of the various assumptions in this simplified model was intended to be a focus of the experiment reported here. The data was planned to provide a fairly direct measure of lung stiffness, an indirect measure of the source of that stiffness from its depth dependence, an indirect measure of radiation mass through stiffness and resonance frequency, a measure of nonradiational damping (which was expected to be the dominant form of loss), and a response curve which would show if the lungs actually behaved as a system with a single degree of freedom.

B. Experimental apparatus and procedure

This experiment was performed between Nov. 2 and Nov. 11 1998 in the 1100 gallon tank housed in the Genesis hyperbaric chamber at the Naval Submarine medical Research Lab in Groton Connecticut. Appendix C contains the experimental protocol which describes the experimental procedures. Several procedural changes were made following the preparation of the protocol as initial

testing revealed deficiencies in the planned procedure. The most notable changes were that all subjects were seated during the test and the ultrasound transducers and hydrophones were mounted on the chair in which they were seated. This was done because the subjects were unable to hold sufficiently still for the measurements without a fixed reference frame. The test pressures were changed to 120, 60, 10 and 0 FSW to accommodate diver decompression. And the divers only examined a single point on the lung's surface in order to save decompression time. The experimental configuration is shown in figure 8. The acoustic source was provided by two USRD J11 type electrodynamic transducers. These were chosen because they produced the fixed force required for testing in the transducer's near field (an identical restriction to the chamber transducers described in section II and appendix A) and because they provided sufficient volume velocity to achieve the desired source level over the frequency range of interest. Two transducers were used because the lung response was expected to be largely a pressure response. Previous measurements had shown that a single J-11 generated abnormally large acoustic velocities in the water and poor pressure uniformity over the volume to be occupied by the subjects chest. In a tank this small the entire water content of the tank acts as a mass load on the transducer. The pressure falls off rapidly away from the source and the pressure is directly proportional to the particle acceleration throughout the fluid. Although far from optimal, the use of two J-11's provided significantly better uniformity and lower overall velocities (with two transducers the center of the tank is a velocity null). Further significant improvements would have required a larger tank. Figure 9 shows the pressures measured at the center of the tank.

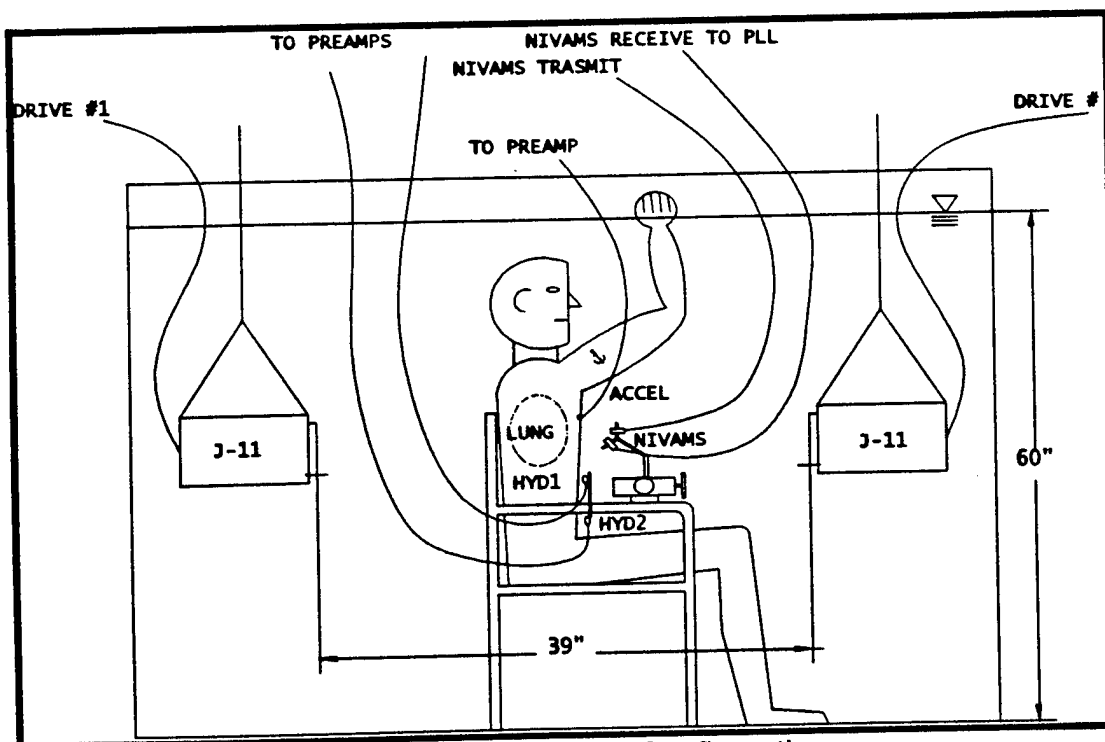


Figure 8: Experimental Configuration

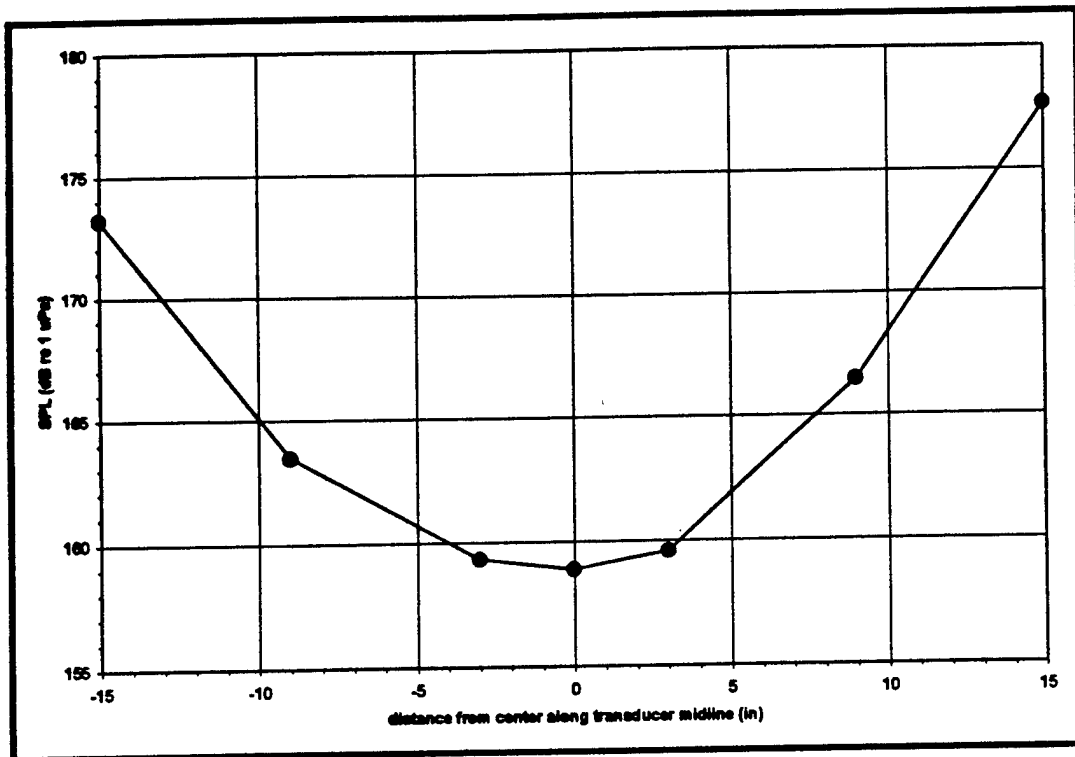


Figure 9: Pressures in Tank Using 2 J-11's Driven in Phase

C. Incident signals

Since the desired data from this experiment was in the form of frequency domain transfer functions the actual shape of the incident pressure signals in the time domain was of little significance from the standpoint of data validity provided that those signals consisted of a suitable frequency content to examine the band of interest. Pulsed signals are generally well suited for this purpose. The signals which were chosen were $\frac{1}{2}$ second long windowed frequency modulated chirps. An example of one of these signals and its spectrum is shown in figure 10. It can be seen from the figure that the signal content is fairly flat from below 50 to about 400 Hz. Increasing the low frequency content of the signal would have required overdriving the J-11s increasing the high frequency was unnecessary and risked exciting a strong tank resonance around 900 Hz. The pulses were presented to the subject as a sequence of 16 over 8 seconds. During this time each subject was required to hold his breath and maintain body position. The level of the signals was designed to be 140 dB re 1 μ Pa rms over the $\frac{1}{2}$ second signal length measured at the center of the subject's intended location at surface pressure.

The actual incident pressure signals were considerably different from the drive signal shown in figure 10. This can be seen in figure 11 which shows the actual incident signals measured at each depth. The reason for this difference was that the low frequency resonance of the J-11's was effected by the depth dependent

stiffness of the transducer's air spring suspension. At surface pressure the incident signal spectrum cuts off just below the J-11 resonance around 30 Hz. As the ambient pressure increases the resonance shifts into the signal band and there is significant amplification at the lower end of the band due to this resonance. There is also an up shift in the cutoff frequency from 30 to 45 Hz. This can be seen in the comparison of incident spectra shown in figure 12. In principle, the depth dependence of the incident can be compensated for by making incident signal measurements at each depth. However, the up shift in cutoff frequency resulted in an unacceptable low frequency signal to noise ratio and, as a consequence, measurements below 45 Hz at 120 FSW (feet of sea water) and 35 Hz at 60 FSW could not be made.

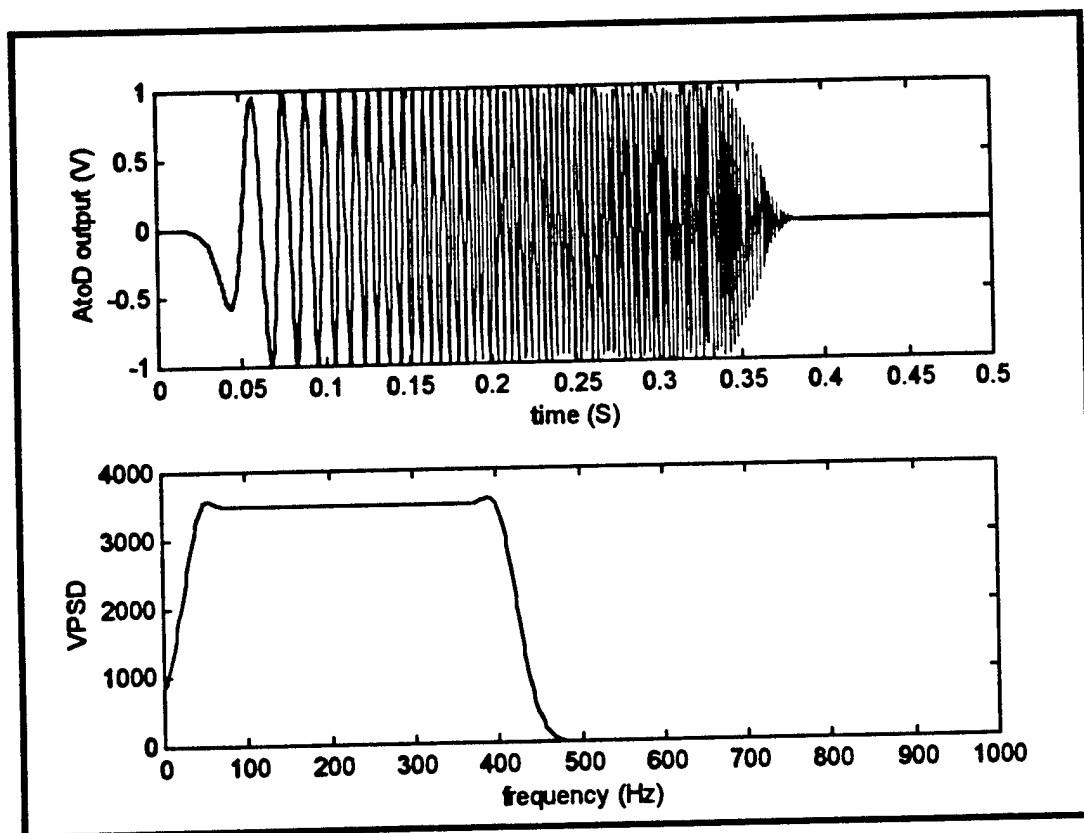


Figure 10: FM Chirp Drive Signal and Spectrum

D. Data acquisition and post processing

During the experiment data was acquired simultaneously on 4 channels. One of these was a hydrophone (denoted hydrophone 1) located just below the subject's sternum. This hydrophone was intended to measure the total pressure very close to the subject's lung. If this hydrophone were sufficiently close it could be considered to measure lung surface pressure which is directly proportional to lung surface displacement. The constant of that proportionality is the lung stiffness. On the second channel was a hydrophone (denoted hydrophone 2)

located 15 " horizontally away from the first. This hydrophone was roughly midway between the subject and the tank wall and was intended to measure (after the subtraction of the incident signal) the pressure scattered by the lung which is proportional to lung surface acceleration. The third channel monitored the output of a phase locked loop (PLL) connected to the NIVAMS (non invasive vibration amplitude measurement system) ultrasonic receiver. The function of the NIVAMS system has previously be described [Rogers and Cox 1987]. As it was configured here two 5 MHz ultrasound transducers were used. One transducer was operated as a transmitter and the other as a receiver. The transducers were fixed in a positioner so their beams crossed at an angle of 60°. Their position was adjusted so that the beams crossed at the lung surface and the receiver signal was dominated by the specular reflection of the transmit signal from the lung. Position adjustments were made by the subjects who were shown a display of the receiver output on an underwater television. The received signal was phase modulated by any motion of the reflecting surface. This signal was mixed down to 1 MHz and frequency demodulated in the PLL. The PLL output was directly proportional to the velocity of lung surface motion. The fourth channel monitored the output of a small accelerometer taped to the subject's chest in the symmetrically opposite location to that which was interrogated using NIVAMS. This was intended as a second direct measure of motion to determine the extent to which the lung and chest wall moved in unison. Also, the accelerometer offered better signal to noise at high frequencies than the NIVAMS system.

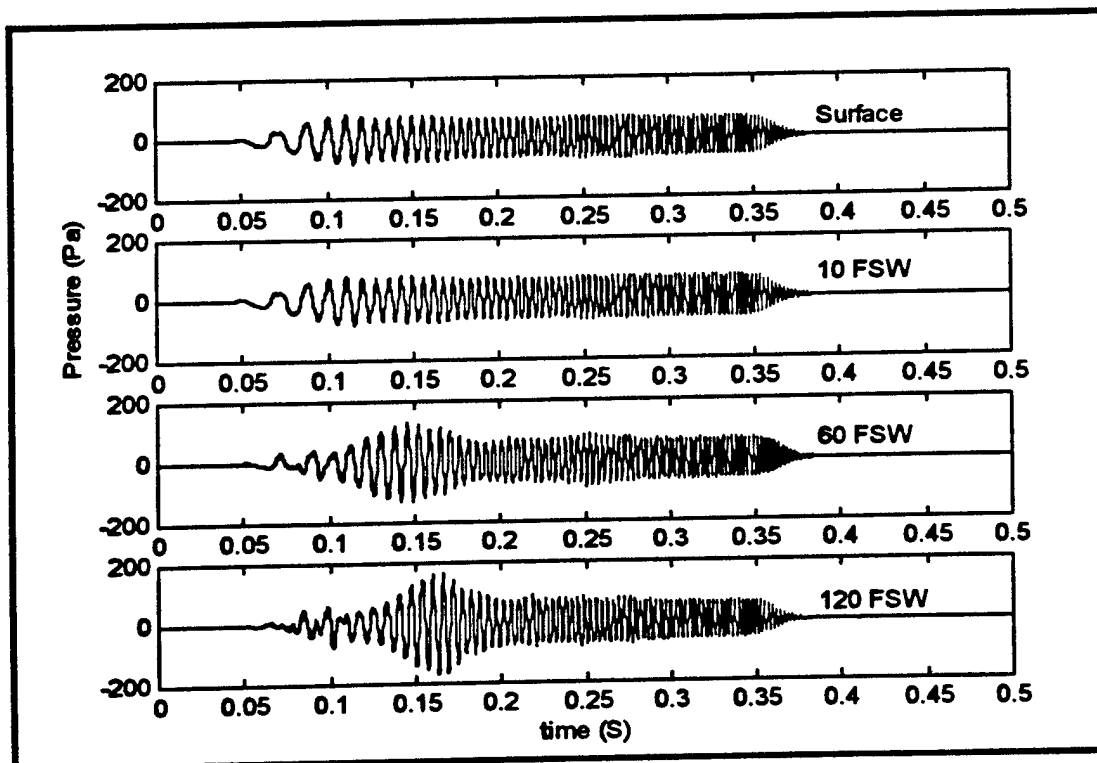


Figure 11: Incident Pressure Signals Measured on Hydrophone #1

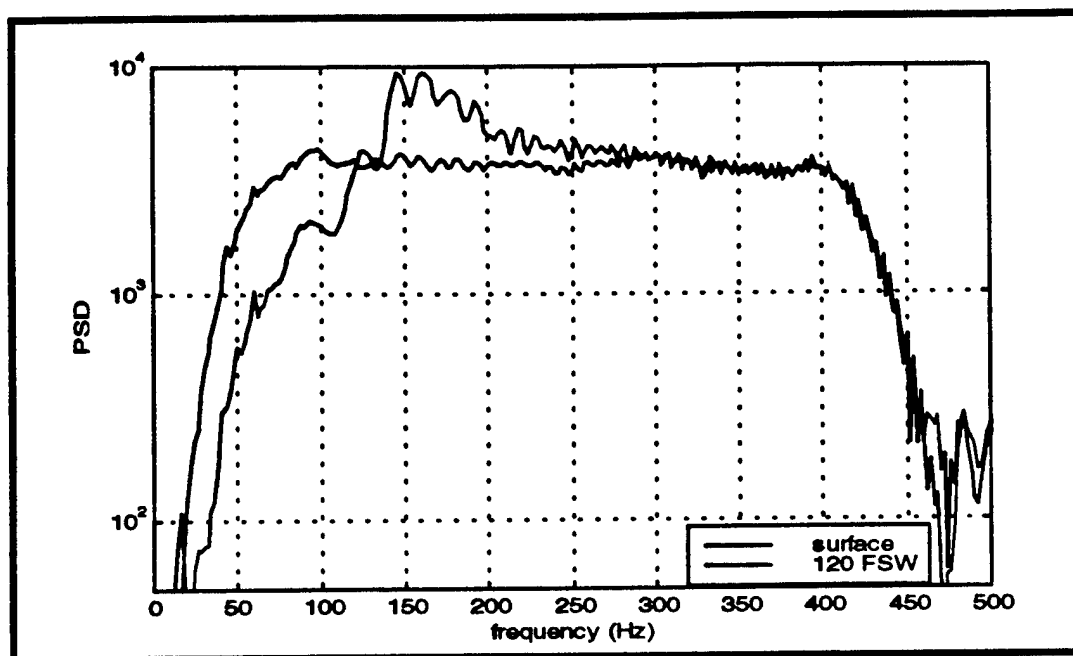


Figure 12: Comparison of Incident Spectra at Different Depths

All 4 input channels were triggered simultaneously at the onset of the acoustic stimulus and recorded continually for the 8 sec signal duration. Signals were digitized at 40 kHz with 12 bits resolution. Each measurement set in its raw form (including a record of the trigger and drive signal) constituted roughly 18 MB of information. In the post processing of the data each of the 16 pulses were averaged into a single signal which was resampled at 4KHz 32 bit resolution. All of the data contained substantial electromagnetic components at power line harmonic frequencies (60,120,180Hz....). This was particularly problematic since the frequencies fell within the band of interest. Grounding and shielding options were explored during the experiment, but improvements were small at best. In the signal post processing a time domain subtraction was performed to remove these components without corrupting the corresponding acoustic components in the data. The algorithm which was used was to sample the signal precursor as background. This was acausally comb filtered to leave only the power line components and then subtracted from each signal prior to averaging. Figure 13 shows a comparison between an unprocessed NIVAMS signal and one which was post processed in the way described. Noise floors were taken with subjects in position with no drive signal going through the J-11's. These were processed in an identical manner and used to determine the useable frequency range in the measured signals.

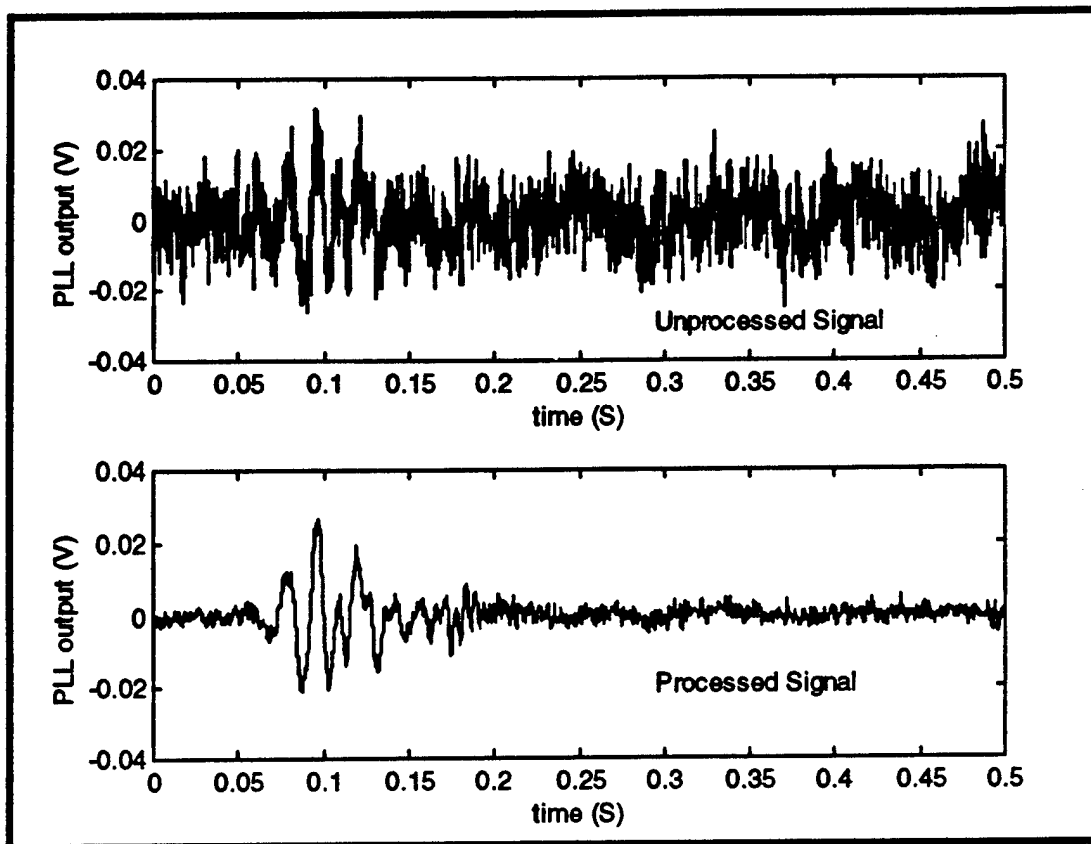


Figure 13: Comparison of NIVAMS Signals before and After Postprocessing
Subject D, Run 1, Set 1, 10 FSW

E. Analysis of experimental data

A total of 10 subjects were each tested on 2 different days. Also, two pilot subjects were tested once each. This gave a total of 22 test runs. For each subject at each depth at least two and as many as six signal sequences (the actual number was a function of the subjects ability to hold the focus of the NIVAMS transducers steady) consisting of 16 pulsed chirps each were recorded on 4 measures. Each of these measures were post-processed as described previously leaving four $\frac{1}{2}$ second signal measures per sequence. No attempt was made to average signals between sequences or between runs because of the relatively high variability associated with the amount of air in the subject's lungs on each breath hold. Two accelerometers failed during the experiment and, as a consequence, accelerometer data was absent for 2 runs.

For analysis purposes each signal was transformed into the frequency domain and normalized by the measured incident spectrum taken at the same depth immediately after the data run. In this way transfer functions were created for each of the measured signals.

Figure 14 shows the transfer functions measured on each of the 4 channels for a single signal measured at 120 FSW. It is apparent that there is a resonance in the 70 – 80 Hz range on all the measures and that it is the dominant feature of the spectrum below 300 Hz. This peak appears to be the fundamental lung resonance. Above 300 Hz the measured NIVAMS signal drops into the noise floor, however the hydrophones and accelerometer indicate that there are no other significant features below 450 Hz. Below 45 Hz the transfer function blows up because there is no energy in the incident.

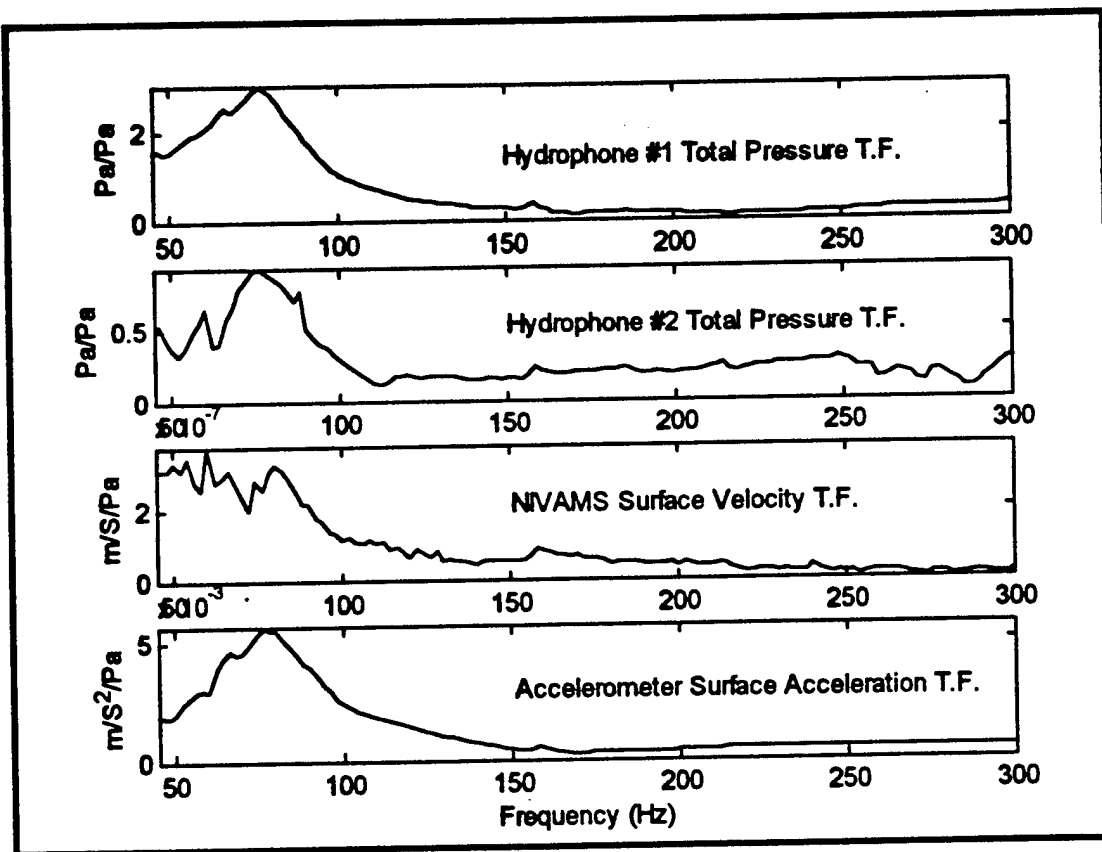


Figure 14: Comparison of simultaneously Measured Transfer Functions
Subject E, Run 1, Set 1, 120 FSW

In several of the data sets it is apparent that the fundamental lung resonance is below the band for which the transfer function can be constructed. Figure 15 shows an example of this. It is apparent that the magnitude of the transfer function is rising toward a peak below 30 Hz, however the actual location of this peak is obscured by the loss of incident signal energy at the low frequency. Post processing options are currently being explored to recover the fundamental resonance frequency from the available trend in transfer functions such as the one shown in figure 15. The resonances apparent in this transfer function and others like it were not scored in the compiled data presented in this report.

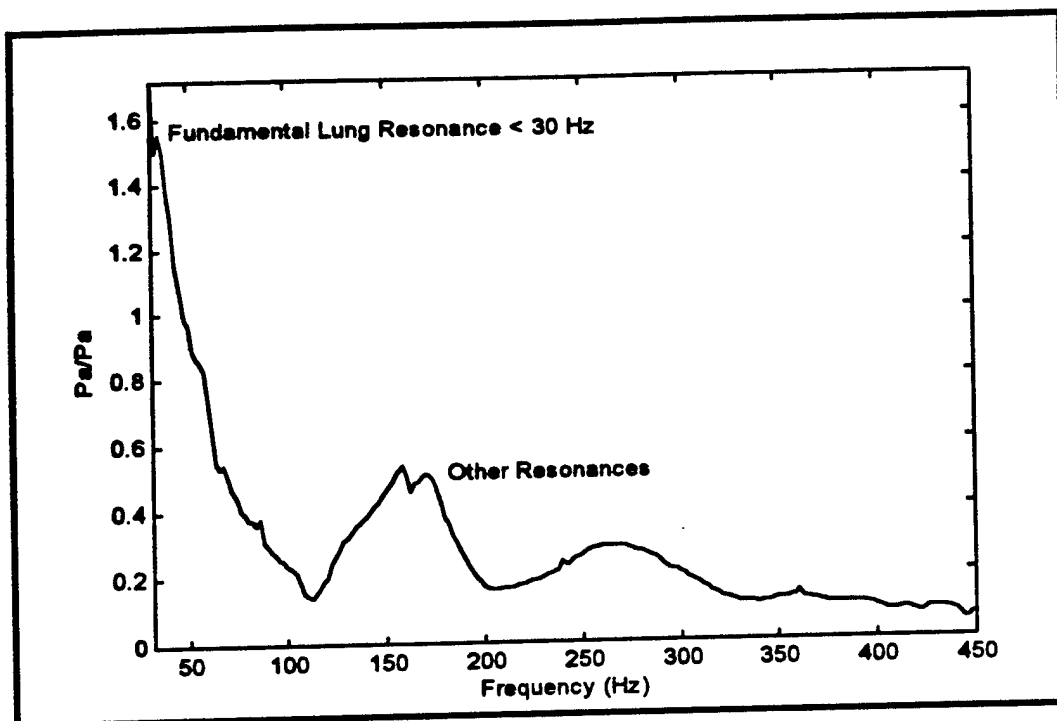


Figure 15: Total Pressure Transfer Function From Hydrophone #1 Showing Low Frequency Trend Without Peak Subject D, Run 2, Set 6, Surface Pressure

An interesting feature of the transfer function in figure 15 is the low amplitude resonance which occurs around 180 Hz. This was a ubiquitous feature of transfer functions measured at surface pressure and at 10 FSW, but was rare in the measurements made at higher pressures. Figure 16 shows two other transfer functions measured at surface pressure and 10 FSW in which a fundamental lung resonance at 36 Hz is obvious in the surface transfer function and the 180 Hz resonance is again apparent indicating that the two are, in fact, independent phenomena. Two features of this higher resonance give clues to its possible source. First, the resonance is most commonly and most strongly apparent in the measurements made on the sub sternum hydrophone indicating that it either involves a structure lower in the torso than the lungs or that it involves a dominantly vertical motion to which the accelerometer and NIVAMS system are insensitive. Second, the resonance shows a very strong depth dependence shifting upward by nearly 70% in the transition from the surface to 10 FSW as can be seen in Figure 16. This is unlikely to be a lung resonance. If lung stiffness is assumed to be dominated by the depth dependent stiffness of the air within the lungs then lung resonance would not be expected to shift by more than 15% with this change in depth. These features of the data could be explained, however, if the resonance were due to a closed gas cavity in the gastro-intestinal (GI) system where the gas pressure equilibrated through a change in volume rather than being compensated at a fix volume from an outside source of gas as the lungs are and a portion of the gas is assumed to go into solution in the surrounding liquids. A spherical bubble permitted to contract with ambient

pressure would be expected to shift its fundamental resonance by about 30% with a 10 FSW depth change due to its change in size (size is related to radiation mass) and gas stiffness. The remainder of the change might be accounted for by assuming that roughly 1/3 of the original gas content of the bubble goes into solution. Since the depth change is made gradually there is sufficient time (several minutes) for this sort of diffusion process to occur.

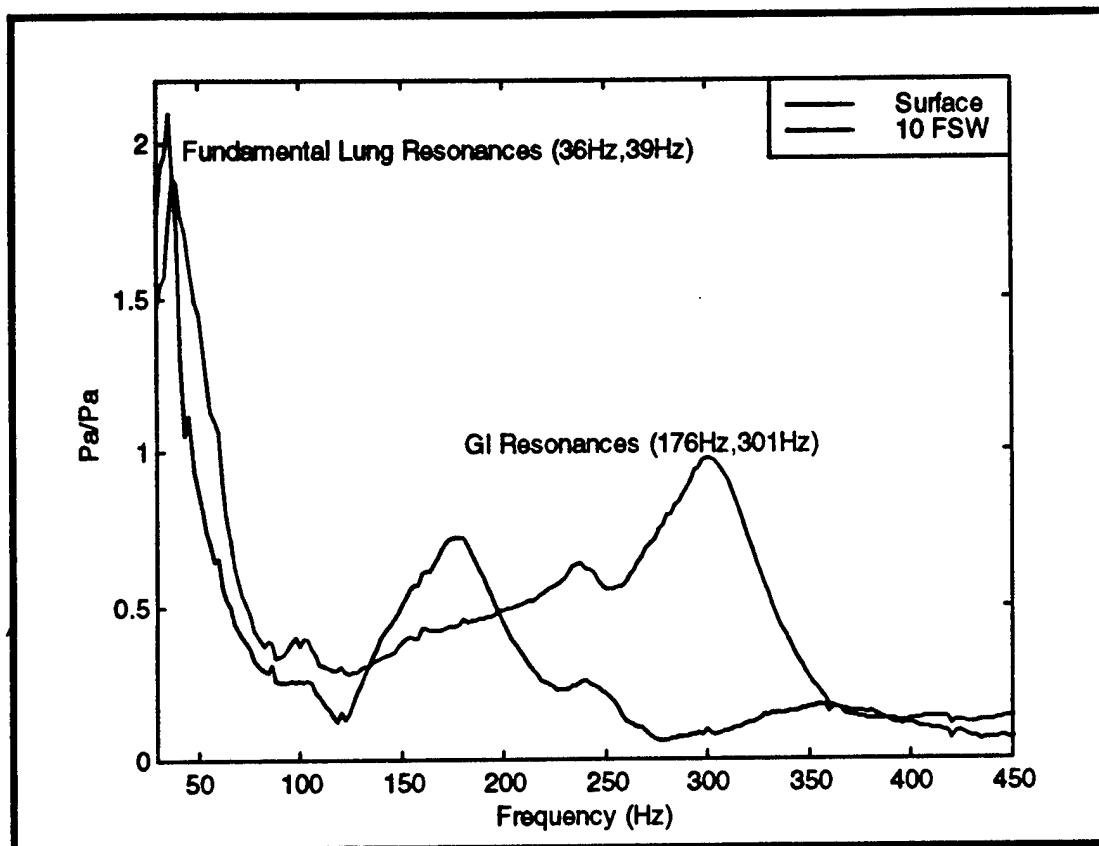


Figure 16: Total Pressure Transfer Functions from Hydrophone #1 Showing GI Resonances: Subject A, Run 1, Sets 2 and 2, depths 0 and 10 FSW

Other than the apparent GI resonance and some small and inconsistent features of the measured transfer functions there is little evidence that the lungs move with more than one degree of freedom below 500 Hz. A notable exception to this observation are a few instances in which the sub sternum hydrophone total pressure transfer function shows two distinct peaks near the fundamental resonance. Such a case is depicted in figure 17. This transfer function shows the GI resonance up shifted to about 320 Hz at 10 FSW and two distinct peaks of roughly equal amplitude below 60 Hz. This may be an indication that the measured fundamental resonances are due to two well coupled systems with very similar properties (the right and left lung) rather than a single system. Alternately, it may be an indication of a recurring low frequency resonance that does not normally result in large lung surface displacements.

In order to compile all the measured data into a model for lung behavior each transfer function was manually evaluated for the frequency and Q of the fundamental resonance. An automated scheme would have been preferable to eliminate any scoring bias and one is currently being developed. Similar schemes involving best fits to single degree of freedom models have been employed successfully in the past [Lewis 1994]. The situation is complicated by the GI resonances and dependence of the frequency range of the data and such a system is not yet available. Figure 18 shows the compilation of the manually evaluated data. The apparent upturn in resonance frequency at low depth is an artifact of the inability to score resonances below 30 Hz. The two stray data points in the 30 – 40 Hz range at 120 FSW are the result of division by nulls in the incident. There was no actual energy in the incident at these frequencies (the low frequency cutoff at 120 FSW was 45 Hz). All transfer functions were evaluated over the same frequency range to minimize scoring bias. There is a clear trend in the data toward increasing resonance frequency with depth. This is consistent with a lung stiffness controlled by the enclosed air.

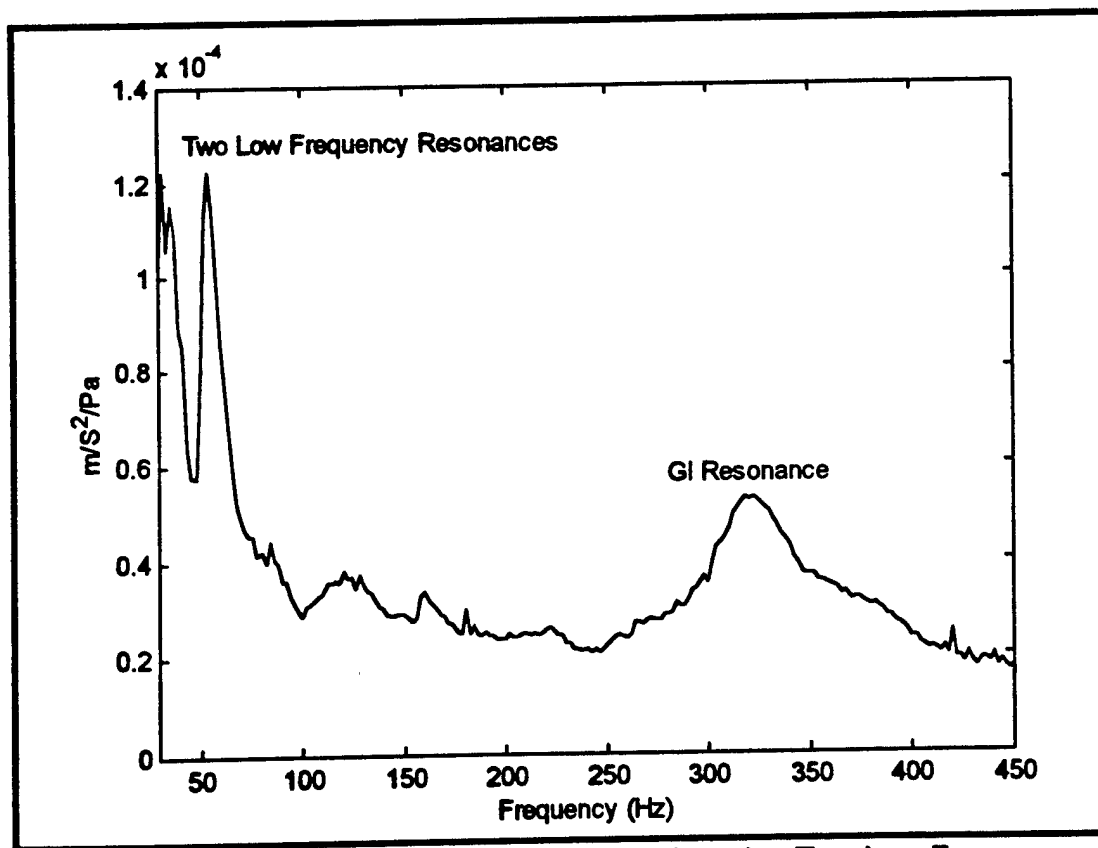


Figure 17: Acceleration Transfer Function Showing Two Low Frequency Resonances Subject F, Run 2, Set 2, Depth 10 FSW

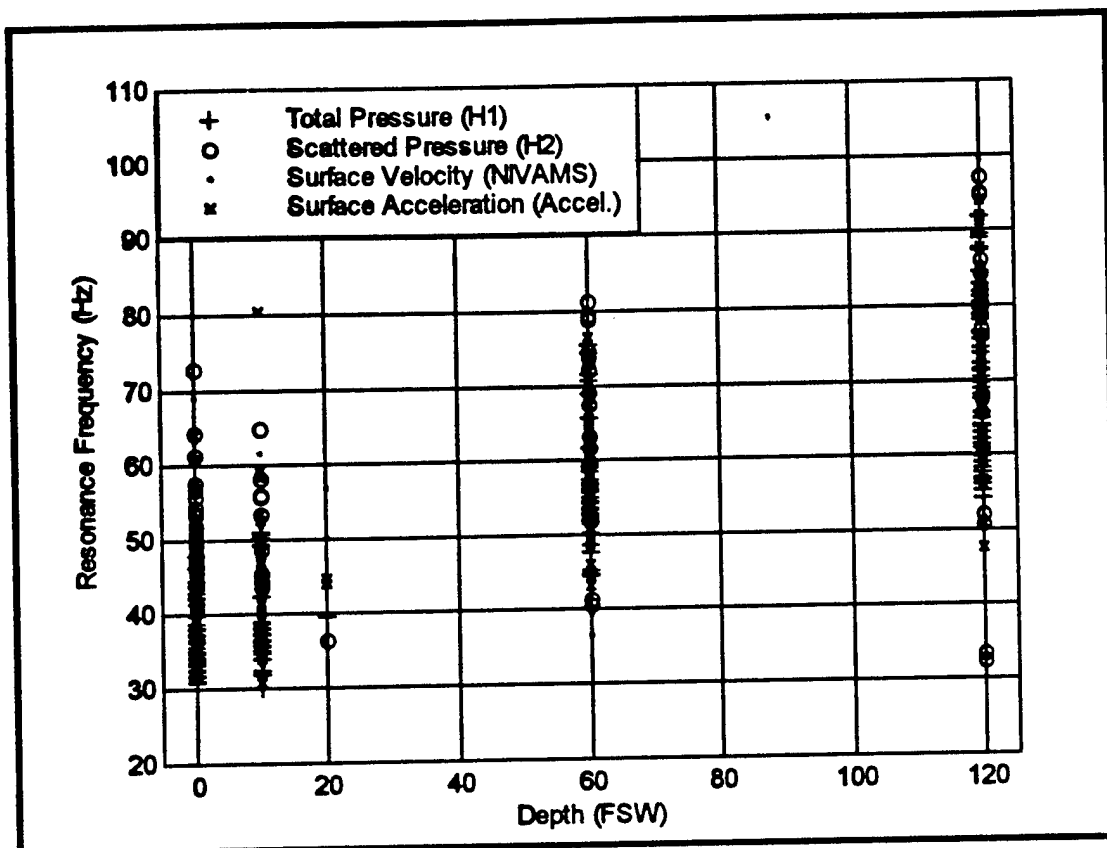


Figure 18: Compilation of All Measured Fundamental Lung Resonances

Figure 19, constructed from the resonance data on all the divers, shows resonances frequency as a function of depth for the three best measures. The data from the second hydrophone (15" from the diver) has been omitted because it was particularly noisy and resulted in relatively few scored resonances. The error bars indicate \pm one standard deviation of the mean. It is clear from the figure that the depth dependant trend of the resonance is reproduced on each of the three measures plotted. It is interesting to note that the resonances scored from the hydrophone data are constantly lower than those observed on the accelerometer. It can be seen from the error bars that this is a statistically significant difference. The resonances scored from the NIVAMS data cross both curves and therefore do little to validate one measure over the other. If the sub sternum hydrophone were truly measuring displacement the discrepancy might be accounted for by the two time derivatives associated with relating this to acceleration. However, the manual evaluation of the resonance Qs gave values in the range of 5 to 7. These were too high to permit explanation of the discrepancy in terms of the time derivative. Such an explanation would have required Qs of less than 3.

The model fit data depicted in figure 19 results from the following equation:

$$f_{res}(z) = f_0 \sqrt{\frac{p(z)}{p(0)}} + \eta$$

Equation 5: Depth Dependence of Lung Resonance

Where f_{res} is the lung resonance frequency, z is the depth and p is the absolute ambient pressure. f_0 and η are empirically determined constants found to be 32.2 and 0.39 respectively. The constant η represents the depth independent portion of the lung's stiffness (about 1/3 of the total stiffness at surface pressure). This is probably due to the stiffness contribution of the chest wall. The constant f_0 represents the air spring resonance of the lung at surface pressure. It is quite close to the predicted value from figure 7.

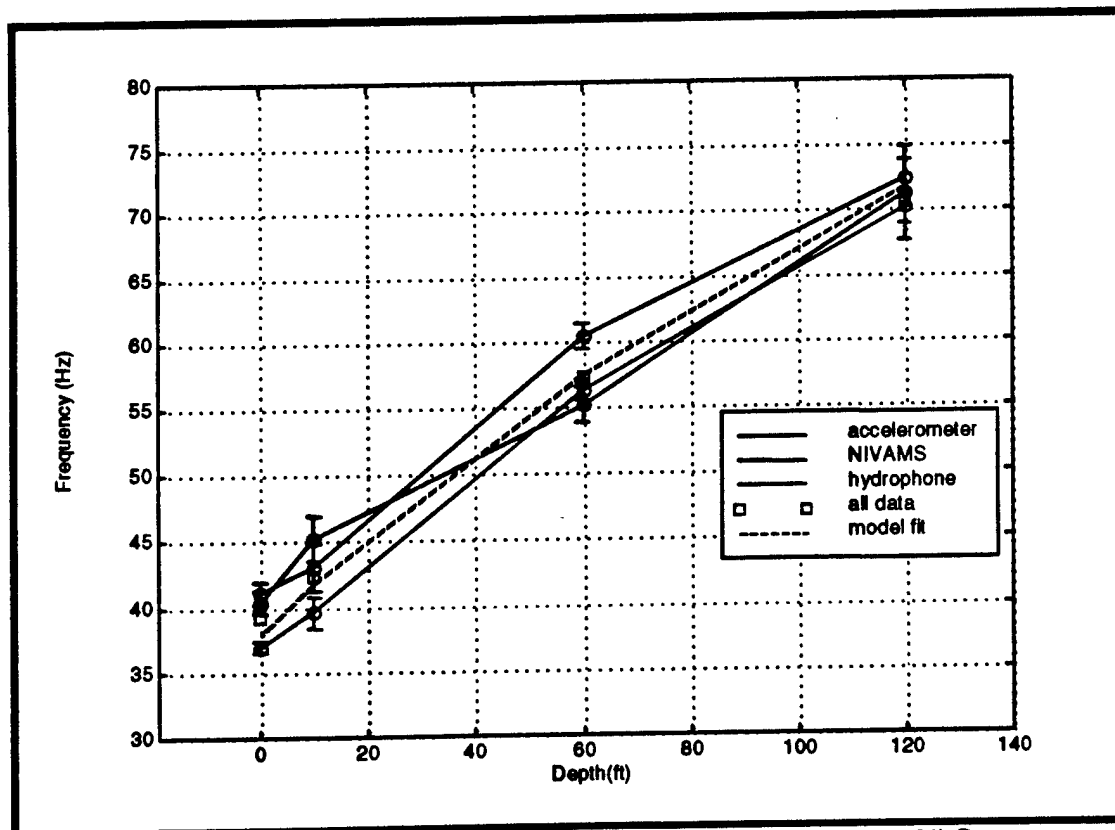


Figure 19: Mean Resonance Frequencies for All Divers on All Sensors

Using the empirical relationship from equation 5 it is possible to extrapolate the measured resonances to the entire range of recreational diving depths. Such an extrapolation can be seen in figure 20. As this figure shows resonant excitation of the lungs in the primary band of interest, 100 – 500 Hz, will only occur at depths below 275 FSW.

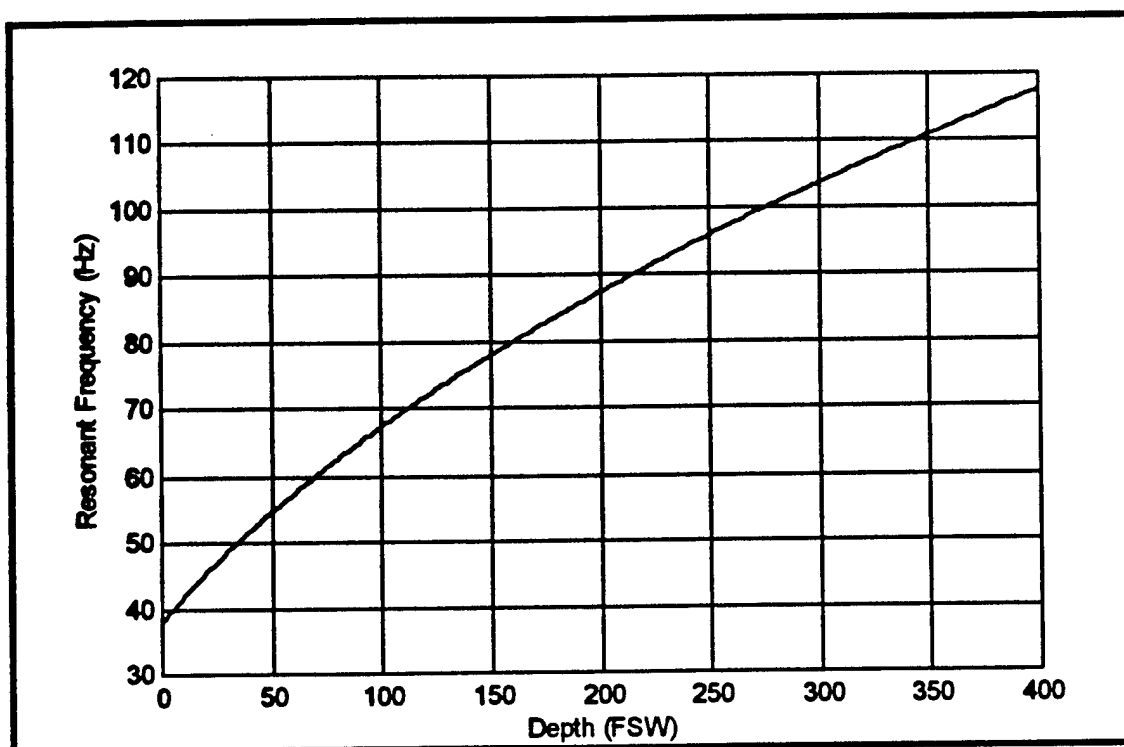


Figure 20: Extrapolation of Resonant Frequency as a Function of Depth

During this experiment questions were raised regarding the linearity of the measured transfer functions. The design of the experiment presumed this linearity and the experiment was not intended to validate this assumption. An additional test was performed on a pilot subject during the last day of the experiment to provide such a validation. The subject was chosen to be the test subject who had shown the greatest proficiency in aligning the NIVAMS transducers since this was the most noise susceptible measure to be tested. The test was particularly difficult to design because the dynamic range of the measurement system was limited at the high end by the signal level restrictions imposed by the protocol and at the low end by the noise floor. This defined a range of less than 20 dB. In the absence of such restrictions the measurement could have been made by increasing the incident level by 20–40 dB and checking for a corresponding 20–40 dB increase in each of the measured signals. Since linearity inherently breaks down at high drive levels it is always preferable to increase the drive over the level used for measurements when attempting to validate linearity. Since this was not an option, it was instead decided to decrease the incident level by 6 dB and look for a corresponding 6 dB decrease in the measurements.

An ad hoc evaluation of the measured wave forms lead to the decision to test over a 6dB range as a suitable compromise between dynamic range and noise floor requirements. It should be noted that it is not sufficient to make this sort of measurement just above the noise floor, since it must be far enough above the

noise that the effects of noise do not masquerade as non linearity. Previously, a relatively high level of inter-signal and inter-run variation had been noted as a consequence of the subjects body position and the amount of air in the subject's lungs during breath hold. It was, therefore, decided to provide both the normal amplitude and the reduced amplitude excitation in a single pulse sequence with identically shaped alternating amplitude chirps. These signals were then post processed as the previous signals had been and averaged into single 1 second long sequences of large then small chirp for each signal. An example of one of these can be seen in figure 21. To validate linearity these pulses were then autocorrelated and the ratios of the two correlation peaks were used to compute the relative amplitudes of the two pulses. Tight band pass filters were used on all the signals to minimize the effects of noise on the correlation.

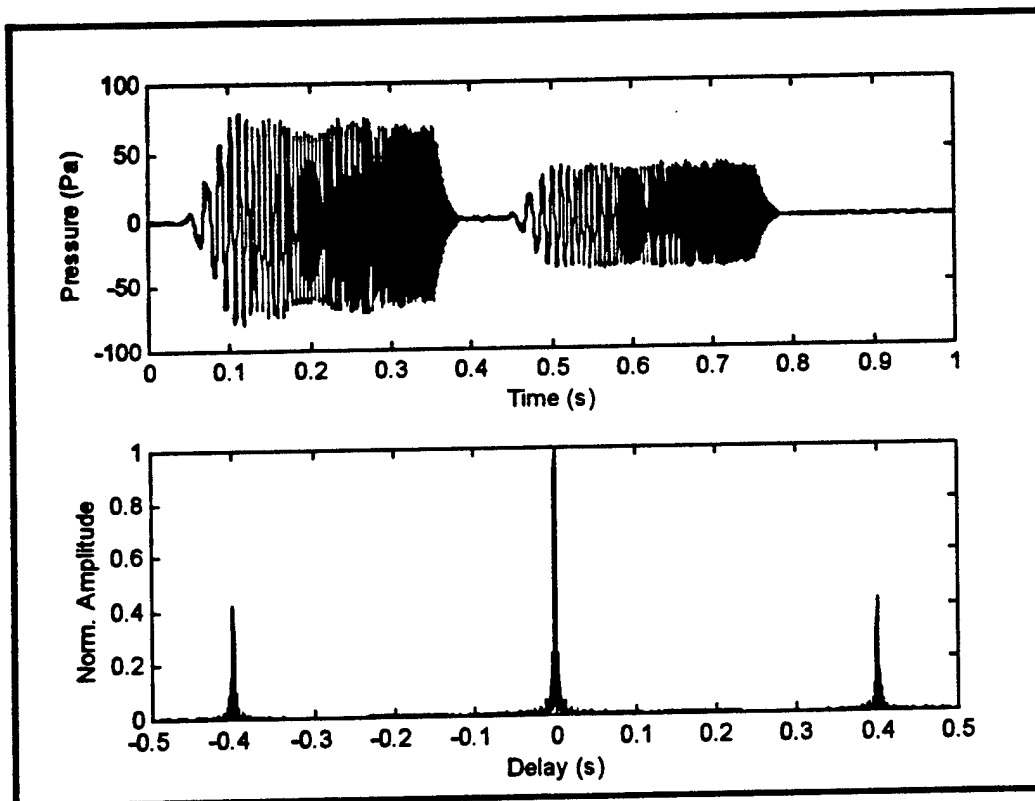


Figure 21: Linearity Test Pressure Incident Signal and Autocorrelation, 0 FSW

The results of these correlations can be seen in table 1. It should be noted that the strongest nonlinearity noted was not in the measured transfer functions but rather in the drive system and this needed to be corrected for in the data. Although the second pulse was exactly $\frac{1}{2}$ the size of the first at the digital to analog converter, the ratio of the pulses in the measured incident pressures was around 1.8:1 and showed a depth dependence. Thus each measured amplitude ratio had to be compared with a corresponding incident ratio rather than the intended factor of two.

Depth FSW	Incidence Ratio	Name	Amplitude Ratios			
			Hyd. 1	Hyd. 2	NIVAMS	Accel.
0	1.8407	k10001g	1.8099	1.7874	2.598**	1.8064
0		k10002g	1.8034	1.7897	2.2195	1.8244
0		k10003g	1.8101	1.7895	2.1877	1.7884
0		k10004g	1.7999	1.7927	2.1496	1.8502
0		k10005g	1.7863	1.7884	2.0751	1.8395
60	1.8947	k10601g	1.7856	1.7727	2.0303	1.8138
60		k10602g	1.7853	1.8314	2.3191	1.7991
120	1.7767	k11201g	1.7314	1.7796	1.8747	1.7461
120		k11202g	1.7542	2.7459*	2.0874	1.7219

Table 1: Correlated Amplitude Ratios from Linearity Test

* Preamplifiers Clipped during this data set

** Signal to noise was particularly poor in this set

It was noticed that the worst comparisons occurred in the noisiest measures. To qualify this effect mock drive signals were constructed for each measure by generating a proportionately smaller replica of the larger received chirp and summing it with the larger chirp using an appropriate delay the sum was then added to a post-processed noise floor from the same sensor taken at the end of this test. This mock signal was then autocorrelated and used to generate the data shown in table 2. Although the distribution of values is somewhat tighter in table two (probably because the same noise signal was used in the generation of all the mock signals) it accounts well for the discrepancies in table 1. It can reasonably be asserted that within the limits imposed by the nature of this test no non linearities were found.

Depth FSW	Incidence Ratio	Name	Amplitude Ratios			
			Hyd. 1	Hyd. 2	NIVAMS	Accel.
0	1.8407	mk10001g	1.8465	1.842	2.0365	1.8413
0		mk10002g	1.8378	1.8389	2.1052	1.8471
0						
0		mk10004g	1.8379	1.8356	2.0912	1.8491
0		mk10005g	1.8396	1.8386	2.0509	1.8516
60	1.8947	mk10601g	1.8915	1.8954	2.2806	1.8985
60		mk10602g	1.8939	1.8982	2.2961	1.8929
120	1.7767	mk11202g	1.7754	1.7787	2.2576	1.7794
120		mk11201g	1.7765	1.7786	2.0601	1.7795

Table 2: Mock Correlation Amplitude Ratios Constructed with an Assumption of Linearity Using Measured Noise

F. Implications for the determination of human exposure thresholds

In General, it is not possible to use the data collected in this experiment alone to establish human exposure thresholds. The resonance frequency data does, however, provide the necessary frequency scaling for measurements made on animals. i.e. If a damage threshold is known to be lowered in an animal at the animal's lung resonance then it is reasonable to assume that a human will be most sensitive to similar damage at the scaled resonance frequencies described in this report. If the damage mechanism in the animal were known then an actual threshold for the human could also be extrapolated from the animal data using this scaling. Unfortunately, this information is not currently available. A second use for this data is in establishing the depth dependencies of exposure thresholds measured or inferred for humans. Since the pressure and velocity at any point on the torso which result from a ULFS exposure are likely to be dominated by the lung response, it is reasonable to assume that any threshold measured off resonance may safely be applied to the range of depths for which resonance will not occur at the threshold frequency. It is also reasonable to extrapolate a threshold to a depth where the effect will occur at resonance if that threshold is reduced by a factor equivalent to the resonant Q of 5 to 7.

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Appendix A:
Interim Report:
Test Chambers For LFS Animal Exposures

Test Chambers for LFS Animal Exposures

by

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and

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In order to determine the effects of low frequency underwater sound on small animal models the test animals must be exposed to well characterized fields which closely simulate the (locally) plane-wave-like stimulus which the LFA produces in the ocean at long ranges. In addition it would also be desirable to be able to produce pure pressure and pure velocity stimuli in order to isolate the biological effects of the individual components of the acoustic plane wave. It is also necessary to be able produce these fields with sufficient strength to enable damage thresholds to be determined.

The range of frequencies over which such stimuli must be produced is quite broad. since must include the actual band of interest, (nominally 100 - 500 Hz) in order to be able to examine damage on a cellular and tissue level, as well as a scaled frequency band (approximately 550 - 3000 Hz for a 400g animal ; 1350 - 6500 kHz for a 30 g animal) in order to be able to examine the effects the sound on the organs. Although all of these conditions could be realized in the free field, it would be difficult and costly since it would require sources at least as large and powerful as the LFA itself. Moreover, because of the large wavelengths involved, to obtain free-field conditions an enormous amount of water would be needed and the animals would have to maintained at significant depths. It would be far more desirable to be able to produce the required fields in a small test chamber.

This paper proposes (and analyzes) a design for test chamber which should be suitable for this purpose. The problem is considerably more subtle than one might imagine because of the high compliance of the test animals resulting from the air in their lungs. The lungs will obviously drastically alter the acoustic field in the chamber and change the loading on the sources and, conversely, the chamber could potentially alter the vibrational response of the lung. Careful consideration is required to ascertain how valid measurements can be made in a small chamber and to determine the true effective sound pressure level.

Our emphasis is on the obtaining the correct behavior of the lung because it dominates the response of the animal and because the presence of the lung drastically effects the sound field

everywhere in the body. For example, in the free-field the presence of the lung will cause the acoustic pressure at the head to be much smaller than the free-field pressure and will cause the acoustic particle velocity at the head to be much larger and in a different direction than the free-field acoustic particle velocity. If we get the response of the lung correct, we will get the response of the head correct also.

The use of plane wave tubes for calibrating hydrophones is a well accepted technique which is especially useful when hydrophone sensitivities are needed as a function of temperature and/or pressure. The hydrophone is placed inside a rigid walled tube. The tube is operated at frequencies below the cutoff of the first (non plane wave) mode so only plane wave propagation is possible. A piston source at one end generates a plane wave. And a piston at the other end is driven in such a way as to completely absorb the wave (i.e. no reflected wave). In this way, a true traveling wave is generated and the hydrophone's response to this wave is measured.

The same apparatus can also be used to generate a predominantly pressure field by driving the two projectors in phase with equal amplitude and to generate a predominantly velocity field by driving them 180° out of phase. Such field conditions may be useful in isolating the mechanism of any observed damage.

Inherent in the theory of such devices are three assumptions: (1) that the relatively stiff and small hydrophone does not significantly alter the field in the tube, (2) that the presence of the hydrophone does not effect the motion of sources and (3) that the tube itself does not effect the response of the hydrophones. When a small animal rather than a hydrophone is placed in such a chamber the high compliance of the animal's lungs causes assumption (1) to be obviously not valid and causes assumptions (2) and (3) to be mutually exclusive. [If the motion of the sources were unaffected by the lung, than the lung would have to actually compress the water in order to vibrate. This would obviously add an enormous of amount of stiffness to the system and remove much of the radiation mass as well. On the other hand, if the lung vibrates as it would in the free field in response to the sound, the transducer face would have to move much more than it does with the animal absent in order to conserve mass since the fluid is incompressible relative to the lung.] It turns out, however, that in a properly designed and operated chamber these problems are can be handled. The key is to choose the correct kind of driver, to properly size the tube and in using the correct effective pressure level in assessing the results.

Theory

Consider a water filled tube as shown in Fig. 1 below. On each end of the tube is a plane piston of area A_p which we label as surfaces S_1 and S_2 . The remainder of the inner surface of the tube (including the remainder of the endcaps) is denoted by S_3 . An air filled object (lung) within the tube has surface S_L . [The remainder of the animal's body is water-like and can be ignored in the analysis]. Let \mathbf{r}_1 , \mathbf{r}_2 , \mathbf{r}_3 and \mathbf{r}_L be vectors which define the surfaces S_1 , S_2 , S_3 and S_L and let \mathbf{r} be any point within the fluid.

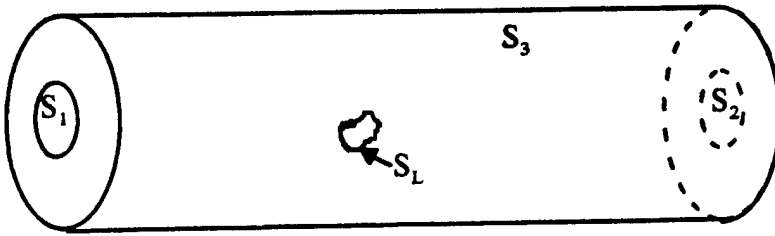


Fig. 1 Water filled tube with pistons S_1 and S_2 and air filled inclusion S_L

The surface $S = S_1 + S_2 + S_3 + S_L$ constitutes a "closed surface" which encloses all of the water. We assume sinusoidal excitation at frequency ω . Let $G(\mathbf{r}|\mathbf{r}_i)$ be the Green's function which vanishes on S_1 and S_2 whose normal derivative $G_n(\mathbf{r}|\mathbf{r}_i)$ vanishes on S_3 and S_L . Although we may not be able to determine $G_n(\mathbf{r}|\mathbf{r}_i)$, the function must always exist. [Since it is by definition the field at \mathbf{r} due to a point source at \mathbf{r}_i if S_3 and S_L were rigid and S_1 and S_2 were pressure release.] In terms of this Green's function the pressure anywhere in the water is given by

$$p(\mathbf{r}) = \iint G_n(\mathbf{r}|\mathbf{r}_1) p(\mathbf{r}_1) dS_1 + \iint G_n(\mathbf{r}|\mathbf{r}_2) p(\mathbf{r}_2) dS_2 \\ + i\omega\rho \iint G(\mathbf{r}|\mathbf{r}_3) v_n(\mathbf{r}_3) dS_3 + i\omega\rho \iint G(\mathbf{r}|\mathbf{r}_L) v_n(\mathbf{r}_L) dS_L \quad (1)$$

Equation (1) is exact. We now make the following assumptions:

1. The drivers are "force drivers". That is, they are assumed to produce a given force into any load. (The load, however, determines the displacement of the piston.) This implies that the mechanical impedance of the piston is low. Electrodynamic shakers approximate these conditions well.

2. Excluding the surfaces of the pistons, the walls of the chamber (surface S_3) are assumed to be rigid and immovable. The tube walls and endcaps must be made of a thick, stiff, material such as steel. The walls will be considered to be sufficiently rigid if the propagation speed for plane waves in the fluid waveguide is nearly equal to the speed of sound in water. The propagation speed for the lowest mode in water filled pipe is approximately given by

$$c_0 = \frac{c}{\sqrt{1 + \frac{2\rho c^2 a}{Yt(1 - 5d/6t)}}} \quad (2)$$

where a is the radius of the tube, t is its thickness and Y is Young's modulus for the tube material. ρ and c are the density and speed of sound of water. Obviously a large Young's modulus and as large a thickness to radius ratio as possible is needed.

3. The pistons are sufficiently small to be able to replace the piston surface pressures $p(r_1)$ and $p(r_2)$ by their average values. Thus if shaker 1 generates force F_1 and shaker 2 generates F_2 we can replace $p(r_1)$ by F_1/A_p and $p(r_2)$ by F_2/A_p .

With these assumptions Eq.1 becomes

$$p(r) = \langle G_n(r|r_1) \rangle F_1 + \langle G_n(r|r_2) \rangle F_2 + i\omega\rho \iint G(r|r_L) v_n(r_L) dS_L \quad (3)$$

The first two terms are, by definition, the pressure which would be present in the tube if the lungs were rigid and immovable ($v_n(r_L) = 0$). Since the lung is much smaller than the tube in cross section, this is virtually the same field which would present when the animal is not in the tube.

The external forces acting on the lung are determined by $p(r_L)$ which is given by

$$p(r_L) = \langle G_n(r_L|r_1) \rangle F_1 + \langle G_n(r_L|r_2) \rangle F_2 + i\omega\rho \iint G(r_L|r_L) v_n(r_L) dS_L \quad (4)$$

The first two terms are the pressure at the location of the lung in the absence of the animal. The third term is the reaction pressure resulting from the motion of the lung. It is, by definition, the reaction pressure (primarily radiation mass) on S_L in a rigid walled tube with *pressure release* pistons on each end. The lung vibrates in response to all three terms. It will be demonstrated that the reaction forces with these boundary conditions closely approximate the free field reaction forces provided that the lung has a relatively small cross section, is located near the center of the chamber, the piston areas are not too small and that the frequency is far away from any resonance of the tube. Since the reaction force is the same as it is in the free field, the lung will vibrate as if it were in the free field responding to the pressure (and velocity) field which would be present in the tube in the absence of the animal. This assumes that the shakers can move with sufficient

amplitude to take up the volume displacement of the lungs and that the Q of the lung resonance is not excessively high. If the pistons are driven in such a way as to produce a plane traveling wave in the tube *in the absence of the animal* then the response of the lung will be the same as it would be in a free-field plane wave of the same amplitude. Thus, the response of the animal and all of its other organs and tissue, to the field in the tube should also be virtually identical to what it would be in a free-field plane wave of the same amplitude. The pressure in the tube with the animal ~~is~~ inside will, of course, be considerably lower than it is without the animal. The point is, that in a properly designed calibrator the animal's presence will lower the acoustic pressure in the tube in exactly the same way as it lowers the pressure in the vicinity of the animal in the free field.

According to the above analysis we need to show two things:

- 1) That we can generate a uniform traveling wave field with sufficiently large amplitude.
- 2) That the radiation reaction of an object the size of the animal's lung is substantially the same in the tube as it is in the free field.

The measure of the quality of the generated traveling wave field is the uniformity of the pressure field in the vicinity of the animal and how close the axial acoustic particle velocity is to $p/\rho c$ in both amplitude and phase. The measure of the adequacy of the impedance condition is how close the calculated value of $Z/i\omega$ is to the free-field radiation mass of the object.

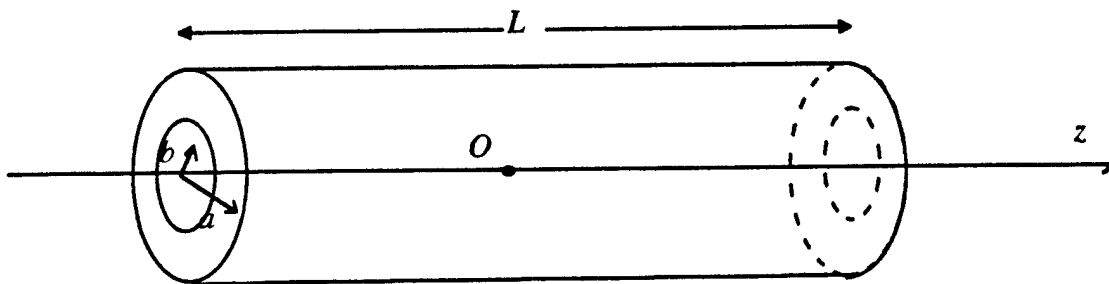


Fig. 2 Geometry of the test chamber

The acoustic field of a rigid walled tube of length L and radius a driven by shaker driven pistons of radius b at either end (as shown in Fig. 2) is easy to calculate. The axisymmetric acoustic field inside a rigid walled tube of radius a can easily be obtained analytically. We chose the center of the tube to be the origin of a cylindrical coordinate system (r, z) . The general expression for the pressure is given by.

$$p(r, z) = A_0 e^{ikz} + B_0 e^{-ikz} + \sum_{n=1}^{\infty} \left(A_n J_0(\alpha_n r/a) e^{-\sqrt{(\alpha_n/a)^2 - k^2} z} + B_n J_0(\alpha_n r/a) e^{\sqrt{(\alpha_n/a)^2 - k^2} z} \right) \quad (5)$$

where $k = \omega/c$ and α_n is the n th root of J_1 (note that $-J_1$ is the derivative of J_0 so $J_0'(\alpha_n) = 0$.) The plane wave terms ($n=0$) in Eq. 6 always propagate. At frequencies below the cutoff for the second mode [$f_{cutoff} = \alpha_1 c / (2\pi a)$] all other modes are evanescent and rapidly decay with distance from the source. In order to assure only plane waves (i.e. uniform pressure and velocity) in the middle of the tube it is necessary to operate the tube at frequencies below the cutoff frequency for the $n=1$ mode. Since $\alpha_1 = 3.8317$, the cutoff frequency for a 6 inch diameter tube would be around 12kHz.

The z component of the acoustic particle velocity is obtained from (5) using Euler's equation:

$$v_z(r, z) = \frac{A_0}{\rho c} e^{ikz} - \frac{B_0}{\rho c} e^{-ikz} - \sum_{n=1}^{\infty} \left(A_n \frac{\sqrt{(\alpha_n/a)^2 - k^2}}{i\omega\rho} J_0(\alpha_n r/a) e^{-\sqrt{(\alpha_n/a)^2 - k^2} z} - B_n \frac{\sqrt{(\alpha_n/a)^2 - k^2}}{i\omega\rho} J_0(\alpha_n r/a) e^{\sqrt{(\alpha_n/a)^2 - k^2} z} \right) \quad (6)$$

The pistons are assumed to be rigid so the boundary conditions at the ends of the tube are given by

$$\begin{aligned} v_z(r, -L/2) &= v_1 & r < b \\ &= 0 & r > b \\ v_z(r, L/2) &= v_2 & r < b \\ &= 0 & r > b \end{aligned} \quad (7)$$

Where v_1 is the complex amplitude of the acoustic particle velocity of piston on the left and v_2 is the complex amplitude of the acoustic particle velocity of the piston on the right.

The coefficients of the expansion are obtained from the boundary conditions by substituting (6) in (7) multiplying both sides of the resulting equation by $J_0(\alpha_m r/a) r dr$ and integrating from 0 to a making use of the orthogonality relations

$$\begin{aligned} \int_0^a J_0(\alpha_n r/a) J_0(\alpha_m r/a) r dr &= 0 & m \neq n \\ &= \frac{a^2}{2} J_1^2(\alpha_n) & m = n \end{aligned} \quad (8)$$

along with the integral

$$\int_0^b J_0(\alpha_n r/a) r dr = ab J_1(\alpha_n b/a) / \alpha_n \quad (9)$$

The result is a set of linear equations relating A_m and B_m ($m = 0, 1, 2, \dots$) to the assumed values of v_1 and v_2 :

$$\frac{v_1 b^2 \rho c}{a^2} = A_0 e^{-\alpha_0 L/2} - B_0 e^{\alpha_0 L/2} \quad (10a)$$

$$\frac{v_2 b^2 \rho c}{a^2} = A_0 e^{\alpha_0 L/2} - B_0 e^{-\alpha_0 L/2} \quad (10b)$$

$$\frac{-2v_1 b \rho c J_1(\alpha_m b/a) i}{a \alpha_m J_0^2(\alpha_m) \sqrt{(\alpha_m/ka)^2 - 1}} = A_m e^{\sqrt{(\alpha_m/a)^2 - k^2} L/2} - \left[B_m e^{-\sqrt{(\alpha_m/a)^2 - k^2} L/2} \right] \quad (10c)$$

$$m = 1, 2, \dots$$

$$\frac{-2v_2 b \rho c J_1(\alpha_m b/a) i}{a \alpha_m J_0^2(\alpha_m) \sqrt{(\alpha_m/ka)^2 - 1}} = \left[A_m e^{-\sqrt{(\alpha_m/a)^2 - k^2} L/2} \right] - B_m e^{\sqrt{(\alpha_m/a)^2 - k^2} L/2} \quad (10d)$$

Since all modes with $m \geq 1$ are evanescent, the terms in "[]" on the right hand side of Eqs. 10c and 10d are negligible and will be discarded. Thus, Eqs. 10c and 10d can be used to find A_m and B_m directly in terms of v_1 and v_2

$$A_m = -\rho c v_1 \frac{2b J_1(\alpha_m b/a) i}{a \alpha_m J_0^2(\alpha_m) \sqrt{(\alpha_m/ka)^2 - 1}} e^{-\sqrt{(\alpha_m/a)^2 - k^2} L/2} \quad (11a)$$

$$m = 1, 2, \dots$$

$$B_m = \rho c v_2 \frac{2b J_1(\alpha_m b/a) i}{a \alpha_m J_0^2(\alpha_m) \sqrt{(\alpha_m/ka)^2 - 1}} e^{-\sqrt{(\alpha_m/a)^2 - k^2} L/2} \quad (11b)$$

There are thus just four unknowns v_1 , v_2 , A_0 and B_0 , since the other A_m and B_m coefficients are known from Eqs. 11a and 11b once v_1 and v_2 are known.

Equations 10a and 10b provide two of the four equations necessary to solve the problem. The form of the remaining two equations will depend on the desired drive conditions.

The most important drive condition is the traveling wave case where we wish to duplicate a free-field plane wave in the tube. For this case then we want to have a plane wave propagating in one direction only. Thus for the traveling wave condition we require that

$$B_0 = 0. \quad (12)$$

The fourth and final equation for this case comes from the driver. A sinusoidal voltage is applied to the shaker which drives the piston on the left. With this drive voltage the shaker is assumed to produce a sinusoidal force with complex amplitude F_I into any load. Thus from Newton's law

$$\begin{aligned} F_I &= (Z_M + Z_R)v_1 + Z_{MR}v_2 \\ &= Z_M v_1 = F_R \end{aligned} \quad (13)$$

where Z_M is the mechanical impedance of the piston-shaker armature assembly including both mass and stiffness effects, Z_R is the mechanical radiation impedance (*i.e.* the force exerted back on the piston due to the pressure generated by its motion) and Z_{MR} is the mutual radiation impedance (*i.e.* the force exerted on piston 1 due to the pressure generated by the motion of piston 2). The total radiation force, F_R , including both self and mutual impedance effects is by definition minus the integral of the pressure over the surface of the piston:

$$F_R = -Z_R v_1 - Z_{MR} v_2 = -2\pi \int_0^b p(r, -L/2) r dr \quad (14)$$

Substituting Eq. 5 for $p(r, z)$ into Eq. 14, neglecting the very small terms involving B_m for $m > 0$ and utilizing Eq. 9 for the resulting Bessel function integral we obtain:

$$\begin{aligned} F_R &= -2\pi \int_0^b p(r, -L/2) r dr = -\pi b^2 (A_0 e^{-ikL/2} + B_0 e^{ikL/2}) - 2\pi \sum_{n=1}^{\infty} \left(A_n e^{\sqrt{(\alpha_n/a)^2 - k^2} L/2} \int_0^b J_0(\alpha_n r/a) r dr \right) \\ &= -\pi b^2 (A_0 e^{-ikL/2} + B_0 e^{ikL/2}) - 2\pi ab \sum_{n=1}^{\infty} \left(A_n \left[\frac{J_1(\alpha_n b/a)}{\alpha_n} \right] e^{\sqrt{(\alpha_n/a)^2 - k^2} L/2} \right) \end{aligned} \quad (15)$$

Replacing A_m in Eq. 15 by the expression given in Eq. 11a we obtain

$$F_R = -\pi b^2 (A_0 e^{-ikL/2} + B_0 e^{ikL/2}) + 4\pi b^2 i \sum_{n=1}^{\infty} \left(\left[\frac{J_1(\alpha_n b/a)}{\alpha_n J_0(\alpha_n)} \right]^2 \frac{1}{\sqrt{(\alpha_n/ka)^2 - 1}} \right) \rho c v_1 \quad (16)$$

Finally substituting Eq. 16 for F_R into Eq. 13 we obtain the fourth equation

$$F_i = Z_M v_i + \pi b^2 (A_0 e^{-ikL/2} + B_0 e^{ikL/2}) - 4\pi b^2 i \sum_{n=1}^{\infty} \left(\left[\frac{J_1(\alpha_n b/a)}{\alpha_n J_0(\alpha_n)} \right]^2 \frac{1}{\sqrt{(\alpha_n/ka)^2 - 1}} \right) \rho c v_i \quad (17)$$

or

$$F_i = \pi b^2 (A_0 e^{-ikL/2} + B_0 e^{ikL/2}) + (Z_M + Z'_R) v_i \quad (18)$$

where Z'_R is given by

$$Z'_R = -4\pi \rho c b^2 i \sum_{n=1}^{\infty} \left(\left[\frac{J_1(\alpha_n b/a)}{\alpha_n J_0(\alpha_n)} \right]^2 \frac{1}{\sqrt{(\alpha_n/ka)^2 - 1}} \right) \quad (19)$$

The four equations can be written in matrix form as

$$\begin{pmatrix} e^{-ikL/2} & -e^{ikL/2} & -b^2 \rho c / a^2 & 0 \\ e^{ikL/2} & -e^{-ikL/2} & 0 & -b^2 \rho c / a^2 \\ 0 & 1 & 0 & 0 \\ \pi b^2 e^{-ikL/2} & \pi b^2 e^{ikL/2} & Z_M + Z'_R & 0 \end{pmatrix} \begin{pmatrix} A_0 \\ B_0 \\ v_1 \\ v_2 \end{pmatrix} = \begin{pmatrix} 0 \\ 0 \\ 0 \\ F_i \end{pmatrix} \quad (20)$$

The corresponding equations for the "pressure only" and "velocity only" drive cases are the same except for the third row. For the "predominantly pressure" case we want $v_1 = -v_2$, (symmetric drive condition) while for the "predominantly velocity" case we want $v_1 = v_2$, (antisymmetric drive condition).

Thus for the "predominantly pressure" case:

$$\begin{pmatrix} e^{-ikL/2} & -e^{ikL/2} & -b^2 \rho c / a^2 & 0 \\ e^{ikL/2} & -e^{-ikL/2} & 0 & -b^2 \rho c / a^2 \\ 0 & 0 & 1 & -1 \\ \pi b^2 e^{-ikL/2} & \pi b^2 e^{ikL/2} & Z_M + Z'_R & 0 \end{pmatrix} \begin{pmatrix} A_0 \\ B_0 \\ v_1 \\ v_2 \end{pmatrix} = \begin{pmatrix} 0 \\ 0 \\ 0 \\ F_i \end{pmatrix} \quad (21)$$

while for the "predominantly velocity" case

$$\begin{pmatrix} e^{-ikL/2} & -e^{ikL/2} & -b^2 \rho c / a^2 & 0 \\ e^{ikL/2} & -e^{-ikL/2} & 0 & -b^2 \rho c / a^2 \\ 0 & 0 & 1 & 1 \\ \pi b^2 e^{-ikL/2} & \pi b^2 e^{ikL/2} & Z_M + Z'_R & 0 \end{pmatrix} \begin{pmatrix} A_0 \\ B_0 \\ v_1 \\ v_2 \end{pmatrix} = \begin{pmatrix} 0 \\ 0 \\ 0 \\ F_i \end{pmatrix} \quad (22)$$

Equations 20 - 22 can be solved to obtain the acoustic fields within the tube for each of the three drive conditions. A fifth equation, similar to the fourth could be used to determine the drive

force (and hence the required drive voltage) needed for piston 2 to produce the required drive condition. In practice, however, the drive voltage to be applied to the second shaker would not be determined theoretically but empirically. An accelerometer and a hydrophone would be located near the center of the chamber. To achieve the "predominately pressure" condition the voltage applied to the second shaker would be adjusted until the accelerometer output was nulled. To achieve the "predominately velocity" condition the voltage applied to the second shaker would be adjusted until the hydrophone output was nulled. To achieve the traveling wave solution the amplitude and phase of the drive voltage would be adjusted until the accelerometer signal and the pressure signal were in quadrature.

The analysis presented thus far is adequate to determine the quality, strength and uniformity of the field in a proposed chamber. We also need to be able to determine whether the radiation reaction force on the lung in the chamber will be close to the free-field value. We cannot easily or accurately calculate the radiation reaction force on an object with a shape as complex as that of a lung in free space or in the chamber. We can, however, calculate the radiation reaction force on a two sided circular piston, with the same size and in the same location as the lung, both in the free-field and in the chamber. It is reasonable to expect that if the two calculated values are close for the piston they will also be close for the lung. We will therefore proceed to determine the radiation reaction force acting on a circular piston of radius d and (two sided velocity v_d located at

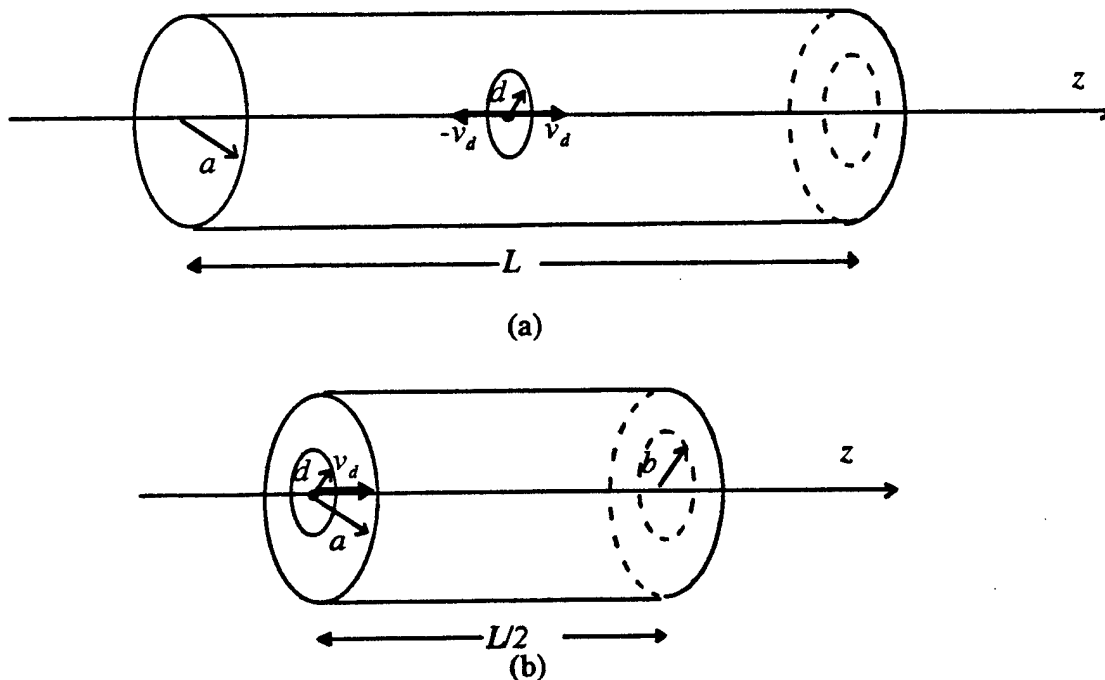


Fig. 3 By symmetry the reaction pressure on each side of the two sided piston in (a) above is the same as the reaction pressure on the one sided piston in (b) below

the center of the chamber as shown at the top of Figure 3. By symmetry this problem is mathematically identical to the problem illustrated in Fig. 3b.

The boundary conditions for the geometry shown in Fig. 3b are

$$\begin{aligned} v_z(r, 0) &= v_d & r < d \\ &= 0 & r > d \end{aligned} \quad (23)$$

$$\begin{aligned} v_z(r, L/2) &= v_2 & r < b \\ &= 0 & r > b \end{aligned}$$

Using Eqs. 5 and 6 and the above boundary conditions we obtain the following equation (analogous to Eq. 9)

$$\frac{v_d d^2 \rho c}{a^2} = A_0 - B_0 \quad (24)$$

$$\frac{v_2 b^2 \rho c}{a^2} = A_0 e^{ikL/2} - B_0 e^{-ikL/2} \quad (25)$$

$$\frac{-2v_d d \rho c J_1(\alpha_m d/a) i}{a \alpha_m J_0^2(\alpha_m) \sqrt{(\alpha_m/ka)^2 - 1}} = A_m \quad (26)$$

$$m = 1, 2, \dots$$

$$\frac{2v_2 b \rho c J_1(\alpha_m b/a) i}{a \alpha_m J_0^2(\alpha_m) \sqrt{(\alpha_m/ka)^2 - 1}} e^{-\sqrt{k^2 - (\alpha_m/a)^2} L/2} = B_m \quad (27)$$

In the impedance problem there are only three unknowns A_0 , B_0 and v_2 since v_d is known. Two of the required three equations are given by Eqs. 23 and 24. The third equation comes from the requirement analogous to Eq. 13 that at the far piston

$$0 = -F_R + Z_m v_2 \quad (28)$$

since $F_2 = 0$. Evaluating F_R at $z = L/2$ we obtain

$$\begin{aligned} F_R &= 2\pi \int_0^b p(r, -L/2) dr = \pi b^2 (A_0 e^{ikL/2} + B_0 e^{-ikL/2}) + 2\pi \sum_{n=1}^{\infty} \left(B_n e^{-\sqrt{k^2 - (\alpha_n/a)^2} L/2} \int_0^b J_0(\alpha_n r/a) r dr \right) \\ &= \pi b^2 (A_0 e^{ikL/2} + B_0 e^{-ikL/2}) + 2\pi ab \sum_{n=1}^{\infty} \left(B_n \left[\frac{J_1(\alpha_n b/a)}{\alpha_n} \right] e^{-\sqrt{k^2 - (\alpha_n/a)^2} L/2} \right) \end{aligned} \quad (29)$$

Substituting Eqs. 27 and 29 in Eq. 28 we obtain

$$0 = Z_M v_2 - \pi b^2 (A_0 e^{ikL/2} + B_0 e^{-ikL/2}) - 4\pi \rho c i b^2 \sum_{n=1}^{\infty} \left(\left[\frac{J_1(\alpha_n b/a)}{J_0(\alpha_n)} \right]^2 \frac{1}{\sqrt{1 - (\alpha_n/ka)^2}} \right) v_1 \quad (30)$$

or

$$0 = -\pi b^2 (A_0 e^{ikL/2} + B_0 e^{-ikL/2}) + (Z_M + Z'_R) v_1 \quad (31)$$

where Z'_R is

once again given by Eq. 19.

The three equations (Eqs. 24, 25 and 31) can be written in matrix notation as

$$\begin{pmatrix} 1 & -1 & 0 \\ e^{ikL/2} & -e^{-ikL/2} & -\rho c b^2 / 2a^2 \\ -e^{ikL/2} & -e^{-ikL/2} & Z_M + Z'_R \end{pmatrix} \begin{pmatrix} A_0 \\ B_0 \\ v_2 \end{pmatrix} = \begin{pmatrix} \rho c d^2 / 2a^2 \\ 0 \\ 0 \end{pmatrix} \quad (32)$$

where v_d , which is arbitrary, has been set equal to 1 m/sec.

The reaction force, F_d on the "lung piston", which is also the radiation reactance since $v_d = 1$ is given by

$$\begin{aligned} Z_d^{chamber} = F_d &= 2\pi \int_0^d p(r, 0) r dr = \pi b^2 (A_0 + B_0) + 2\pi \sum_{n=1}^{\infty} \left(A_n \int_0^d J_0(\alpha_n r/a) r dr \right) \\ &= \pi d^2 (A_0 + B_0) + 2\pi a d \sum_{n=1}^{\infty} \left(A_n \left[\frac{J_1(\alpha_n d/a)}{\alpha_n} \right] \right) \end{aligned} \quad (33)$$

Substituting Eq. 26 for A_m in Eq. 33 we obtain our final result:

$$Z_d^{chamber} = \pi d^2 (A_0 + B_0) - 4\pi \rho c d^2 i \sum_{n=1}^{\infty} \left(\frac{1}{\sqrt{(\alpha_n/ka)^2 - 1}} \left[\frac{J_1(\alpha_n d/a)}{J_0(\alpha_n)} \right]^2 \right) \quad (34)$$

which is to be compared with the free-field value of the radiation impedance for a circular piston of radius d . The free-field impedance of an acoustically small piston transducer is "mass-like"

$$Z_R^{freefield} = -i\omega m_R \quad (35)$$

where the free-field "radiation mass" of the piston is given by

$$m_R = (8/3)\rho d^3 \quad (36)$$

The test chamber results will closely approximate free-field results if the radiation impedance satisfies:

$$\frac{iZ_R^{chamber}}{\omega} \approx m_R \quad (37)$$

Parameters for the Proposed Chamber

Computer codes implementing the above theory were written and used to design a test chamber. The chamber was designed for a 30 g mouse about 10 cm in length. Such an animal would have a lung volume of about $1.5 \times 10^{-6} \text{ m}^3$. Assuming linear scaling, the scale factor between a 70kg human and a 30 g mouse is 13.25. We therefore chose 6.6 kHz as the upper frequency for the design with 100 Hz being the required lower frequency for any size animal.

A reasonable design was obtained after a few iterations. A number of compromises are necessary, e.g. a smaller piston diameter produces a higher pressure in the chamber but results in poorer adherence to Eq. 37. The piston mass should be as low as possible. The parameters chosen for the mouse test chamber were the following:

Table I: Mouse Test Chamber Parameters

Tube Dimensions:	length:	14 inch
	Inner diameter	10 inch
	wall thickness	1.5 inch
Tube material:	stainless steel	
Piston diameter:	5.5 inch	
Piston mass	.5 kg (includes shaker armature)	
Spring Constant of shaker	15,761 N/m (90 lb/inch)	
Shaker force	489N (110 lb)	

A sketch of the selected geometry approximately to scale is shown in Fig. 4 above. For this geometry, with steel construction, the plane wave speed in the tube is .959 times the speed of

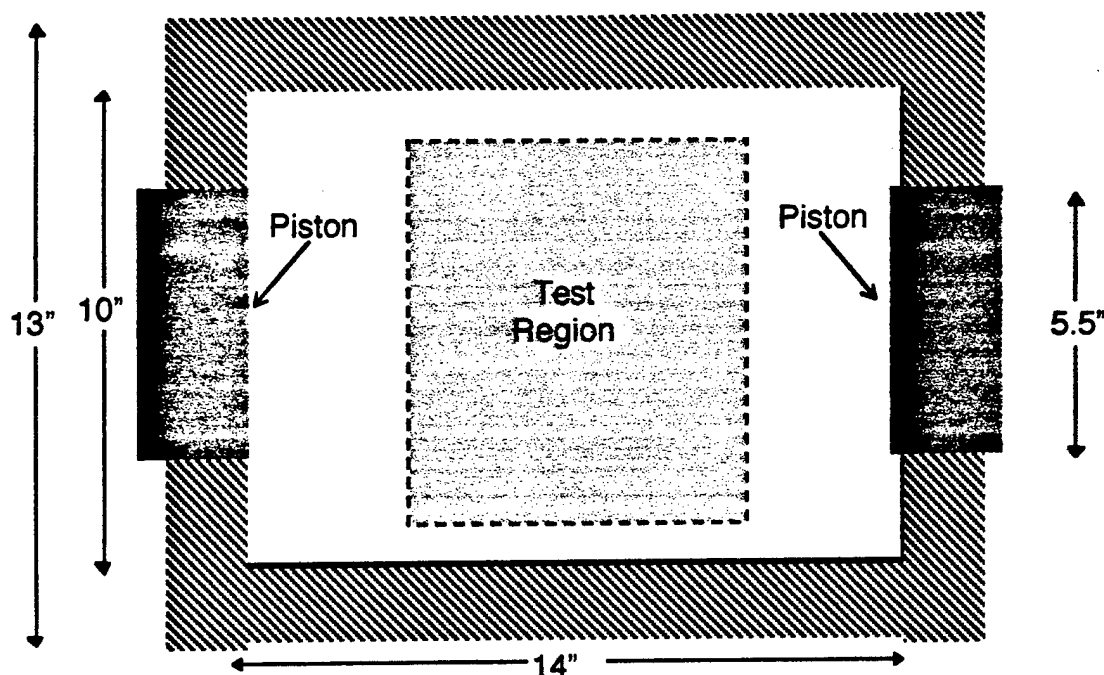


Fig. 4 Scale drawing of the "mouse" test chamber.

A sketch of the selected geometry approximately to scale is shown in Fig. 4 above. For this geometry, with steel construction, the plane wave speed in the tube is .959 times the speed of sound in water, hence, assumption 2 regarding the rigidity of the walls is valid. The cutoff frequency for mode 1 is 7120Hz, which is, as required, above the highest frequency of interest.

Predicted Performance

Theoretical results for the field inside a chamber with the parameters of Table I were obtained for all three drive conditions. We will show results for the traveling wave and predominant pressure drive conditions only. The predominantly velocity drive condition yields similar results (with the equivalent pressure being ρcv_x rather than p).

We begin by checking to see whether the chamber effects the radiation impedance of the lung. Recall, that to do this we will compare the impedance of a piston of radius d in the tube (Eq. 34) with its impedance in free space (Eq. 35). The first question is what is the appropriate value for d . The lung volume of a 30g mouse is estimated to be around $1.5 \times 10^{-6} \text{ m}^3$ which corresponds to a sphere of radius $d_0 = 0.76 \text{ cm}$. In Fig. 5 we plot the ratio of the impedance in the

tube to the free space impedance of pistons with radius d_o (.75 cm), $.9d_o$ (.68 cm) and $1.1d_o$ (.825 cm). The ratio is in the vicinity of unity except near resonances near 1140Hz and 4500Hz. Over the full scale frequency range of 100 to 500 Hz the ratio exceeds unity by just 11 to 15%. Over the scaled frequency range of 1325 to 6600 the ratio is within 20% of unity between 1640 and 4380Hz and between 4720 and 6600 Hz. If desired, the two missing bands (1325 - 1640Hz and 4380 - 4720 Hz) could be covered by moving the two resonance frequencies by altering the length of the tube or the mass of the piston.

The pressure at the center of the chamber for the traveling wave drive and "pressure only" condition are shown in Fig. 6. Note that for the "predominantly pressure" drive condition there are two resonances (at the same frequencies as those which appear in Fig. 5) while for the traveling wave drive condition there are none. This is because ~~the~~ with traveling wave drive the energy put in the tube by the piston on left side is removed by the piston on the right. There is no standing wave and hence no build up of amplitude at any resonance frequency. The increase in pressure which begins near 6600Hz for both drive conditions is due to the nearness of cut-off

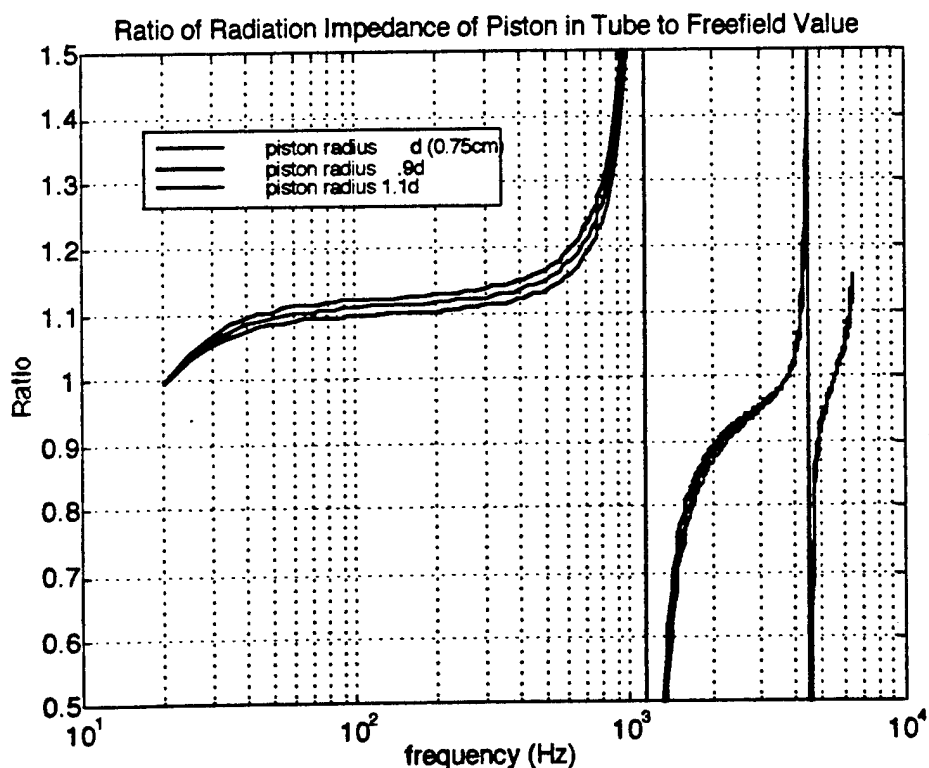


Fig. 5 The ratio of the impedance of a piston simulating a 30 g mouse in the "mouse" chamber to its free-field value. A value near one is desired.

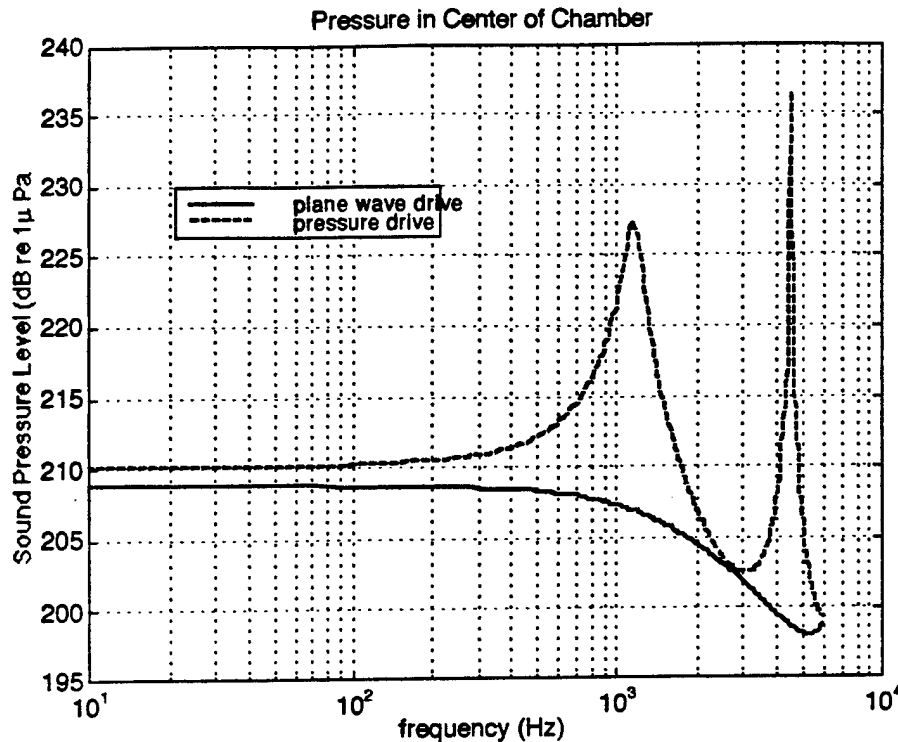


Fig. 6 Pressure in the center of the "mouse" chamber vs frequency for the two drive conditions

frequency for the first mode (7120 Hz). The sound pressure level exceeds 200 dB re $1\mu\text{Pa}$ for all frequencies below 4kHz. In the full scale frequency range 100 to 500 Hz the sound pressure level exceeds 209 dB re $1\mu\text{Pa}$.

The plane wave condition ($p = \rho cv$) is satisfied to within about 3% from 10Hz to 3325Hz and to within 10% to 4300. Beyond 4300 Hz the velocity term drops rapidly relative to the pressure term and is about 40% of its plane wave value at 6600Hz. The condition is thus well satisfied over the full scale frequency range of 100 to 500 Hz and reasonably well satisfied over more than half of the scaled frequency range.

The pressure uniformity in the chamber is shown in Figs. 7-10 for 100, 500, 3000 and 6000 Hz. The pressure is extremely uniform everywhere in the chamber at 100 and 500 Hz. The total variation at 100Hz is only .07dB over the *entire* chamber and less than .001 dB in the test region. At 3000 Hz the pressure variation is less than 1 dB over the test region. At 6000 Hz the pressure uniformity is about 4 dB.

We conclude that the chamber should work quite well over the full scale frequency range of 100 - 500Hz and reasonably well in the scaled range from about 1500 Hz to 4300 Hz. Above 4300 Hz the chamber is usable but far from ideal.

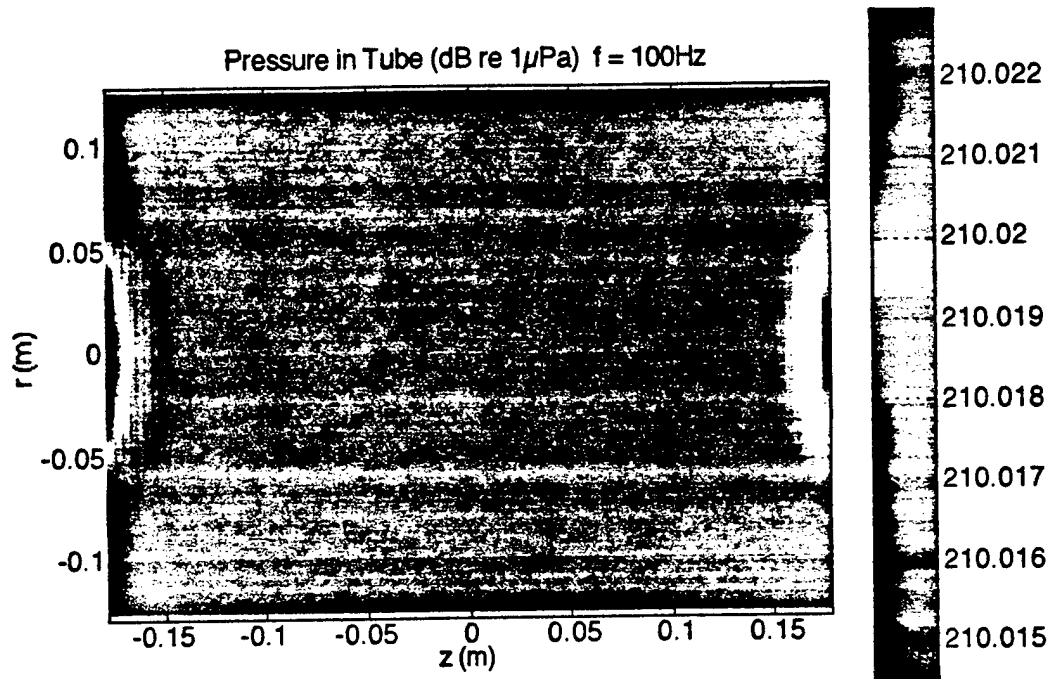


Fig.7 Acoustic pressure amplitude in "mouse" chamber at 100Hz for traveling wave

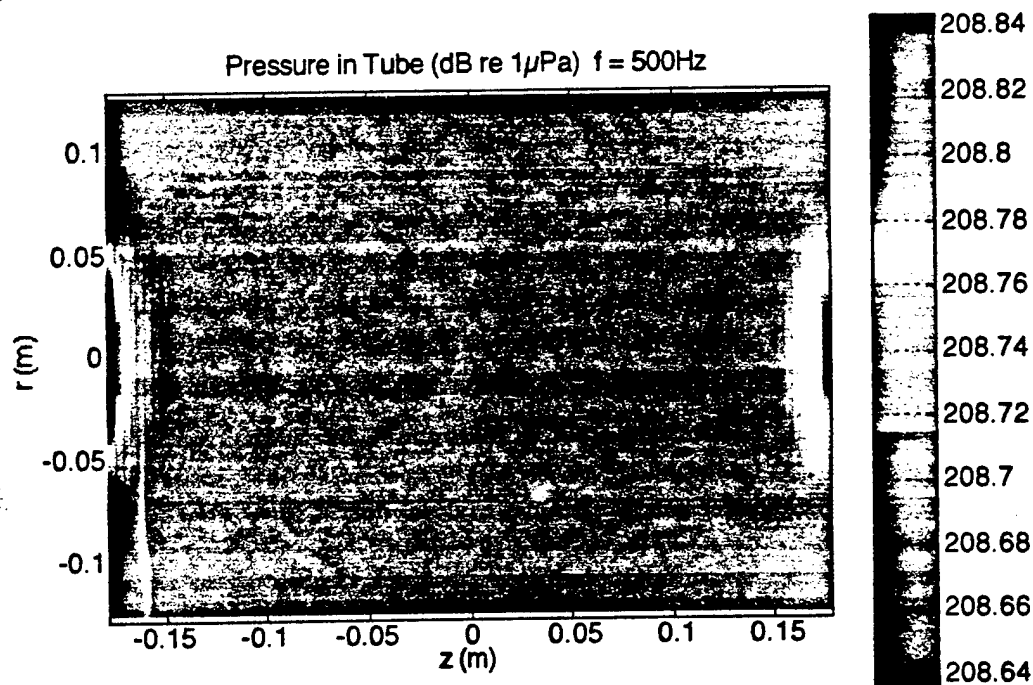


Fig.8 Acoustic pressure amplitude in "mouse" chamber at 500Hz for traveling wave drive

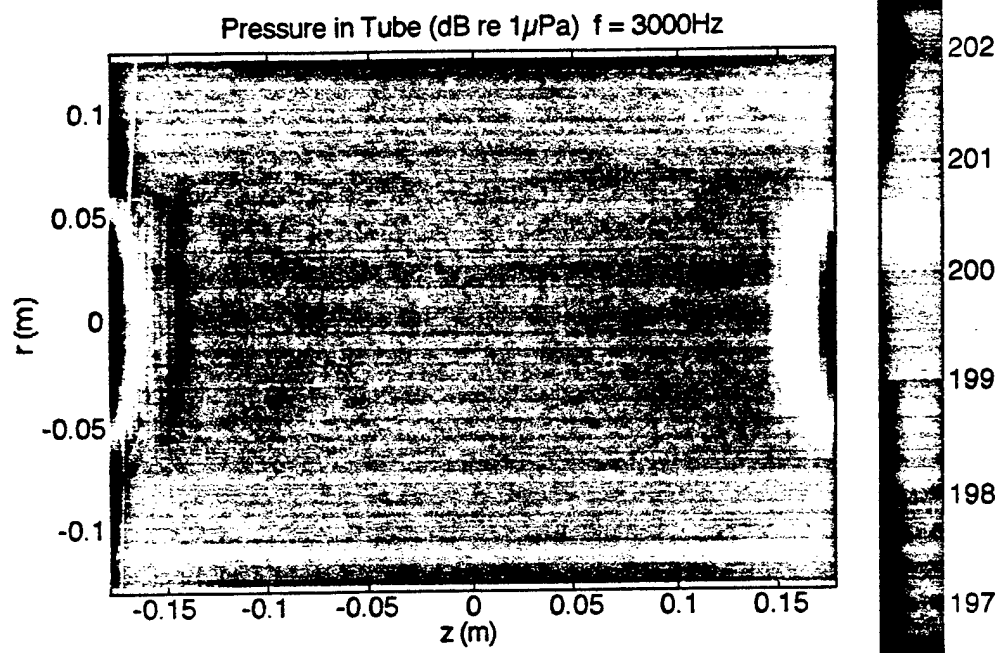


Fig.9 Acoustic pressure amplitude in "mouse" chamber at 3000Hz for traveling wave drive

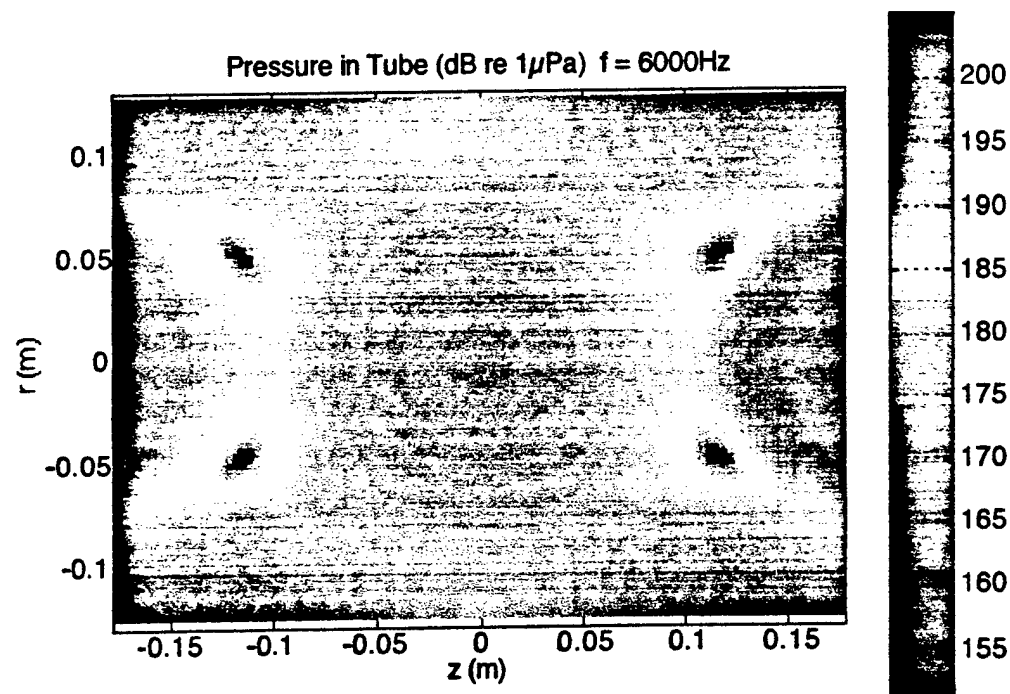


Fig.10 Acoustic pressure amplitude in "mouse" chamber at 6000 Hz for traveling wave drive

The "mouse" chamber could also be used for a larger animal in the 100-500 Hz full scale frequency range. All of the curves are the same except for the impedance ratio curve (Fig. 5)

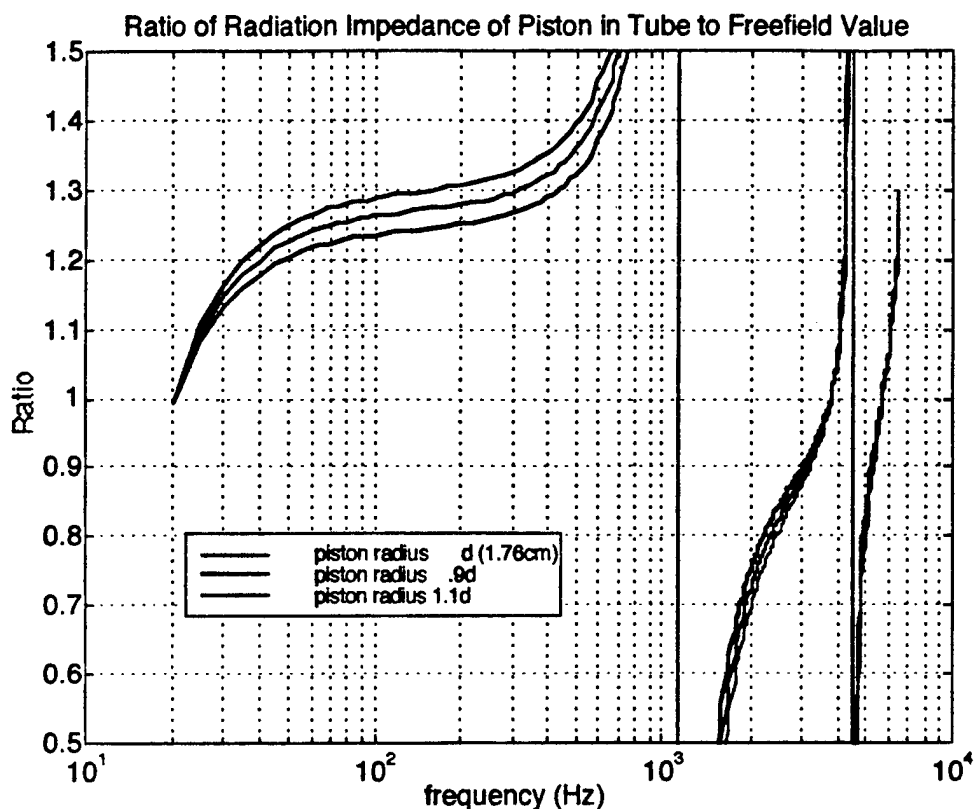


Fig. 11 The ratio of the impedance of a piston simulating a 400 g rat in the "mouse" chamber to its free-field value. A value near one is desired.

which is different because it depends on the size of the piston which simulates the animals lung. Note however that the scaled frequency range now will be lower. The impedance ratio curve for a 400 g rat in the "mouse" chamber is shown in Fig. 11. The performance is adequate (but not nearly as good as it is for the smaller animal) in the 100 - 500Hz range with radiation impedance exceeding the free-field values by as much as 35%. This may not be a serious problem since this frequency range is likely well below resonance where the impedance is dominated by the stiffness of the lung and not the radiation mass. In the scaled frequency range of 550Hz to 3000Hz the device is for the most part useless for the larger animal (except near the extremes of the range). A different design for the larger animal would be preferable.

A better chamber for the larger animal could be made by using a shorter tube with a wider piston. The shorter tube is needed to raise the resonance frequency. A larger piston is required to reduce the effect of the piston on the radiation impedance of the lung. A design for a 400 g rat might be as follows:

Table II: Rat Test Chamber Parameters

Tube Dimensions:	length:	10 inch
	Inner diameter	10 inch
	wall thickness	1.5 inch
Tube material: stainless steel		
Piston diameter:	7.0 inch	
Piston mass	.75 kg (includes shaker armature)	
Spring Constant of shaker	15,761 N/m (90 lb/inch)	
Shaker force	489N (110 lb)	

The larger mass is not desirable but is a concession to practicality. The impedance ratio for this chamber with a 400 g rat (effective piston size $d = 1.76$ cm) is shown in Fig. 12.

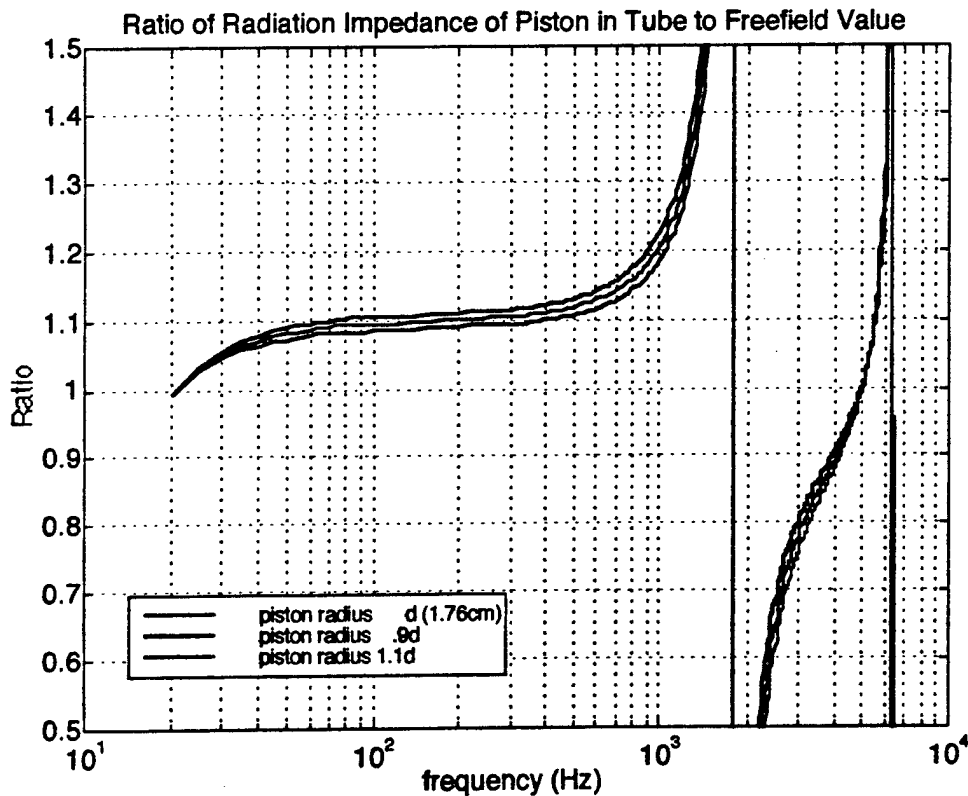


Fig. 11 The ratio of the impedance of a piston simulating a 400 g rat in the "rat" chamber to its free-field value. A value near one is desired.

The simulated lung impedance now exceeds the free field value by no more than 11% over the full scale frequency range (100 - 500 Hz) and good results could also be obtained for much of the scaled frequency range of 550 - 3000 Hz (i.e. from 550 to just over 1 kHz and above 2500 Hz).

The acoustic pressures in the "rat" chamber (Fig. 13) would be somewhat lower than in the "mouse" chamber but still around 205dB re $1\mu\text{Pa}$ for the full scale frequency range and over 200 dB re $1\mu\text{Pa}$ at all frequencies.

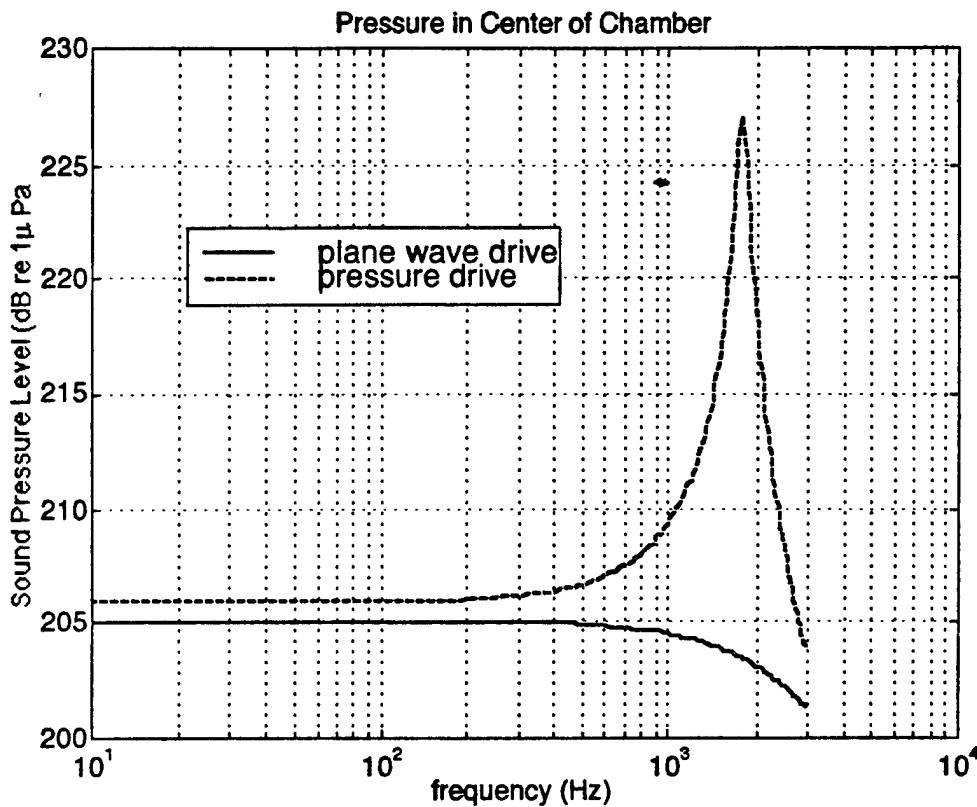


Fig. 12 Pressure in the center of the "rat" chamber vs frequency for the two drive conditions

Conclusions

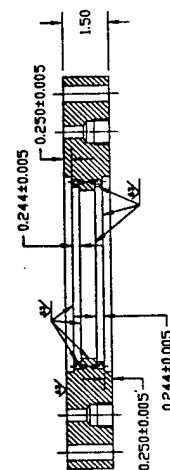
It has been demonstrated that it should be possible to build laboratory size chambers where small test animals can be exposed to traveling wave sound fields comparable to those encountered in the free field. The response of the lungs and other organs and tissue to these fields should also be comparable to what they would be under free field conditions. In assessing exposure levels the relevant field strength has been shown to be the field strength in the chamber when the animal is not present.

Appendix B:
Animal Exposure Chamber Shop Drawings

SCALE	1 / 2	MAIN TUBE DETAIL	
DIMENSIONS ARE IN INCHES		dB CHAMBER 1	
TOLERANCES			
FRACTIONS - 1/32			
DECIMALS - 0.005			
ANGLES - 10° 30'			
SURFACE FINISHES			
✓		SITE	111
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[illegible]

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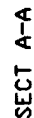
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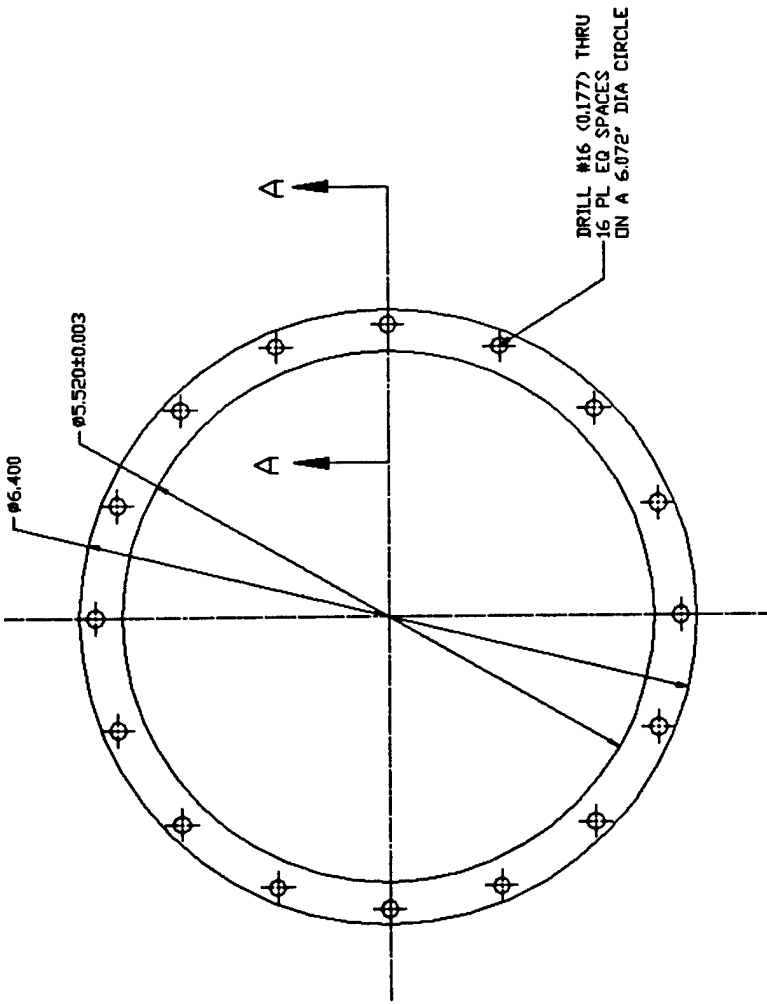
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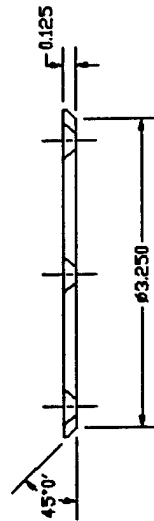


SECT A-A

NOTES: 1. FINISH ALL SURFACES TO 63.
CLEAR AND DIZE WITH A THICKNESS
OF 15 MICRONS OR GREATER.

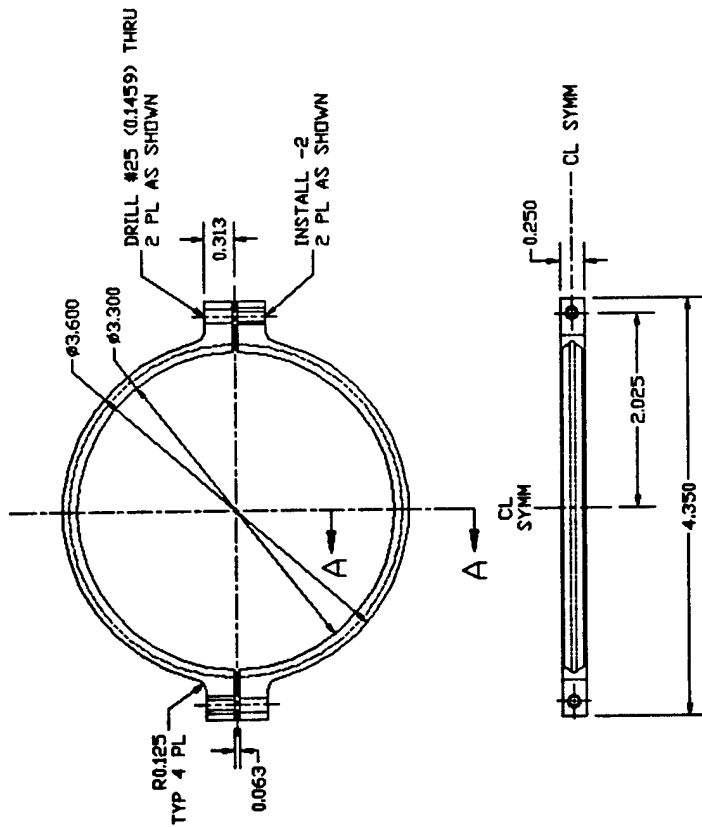
-1 SEAL RETAINER

-1	1	SEAL RETAINER		7075-T6S1 ALUM PLATE	SEE NOTE 1	E25A541370-1	6
PART NAME	DESCRIPTION		MATERIAL	FINISH	NEXT ASSEMBLY	QTY	
PARTS LIST							
DESIGN ENGINEER							
JOEY LLOYD							
404-657-0445							
6 NOV 97							
SCALE 1/1							
DIMENSIONS ARE IN INCHES							
TOLERANCES							
X=±.1							
XX=±.03							
XXX=±.005							
ANGLES ±0°30'							
SURFACE ROUGHNESS							
SEAL RETAINER							
ØB CHAMBER 1							
SIZE	C	E25A541374					
PAGE	1						1

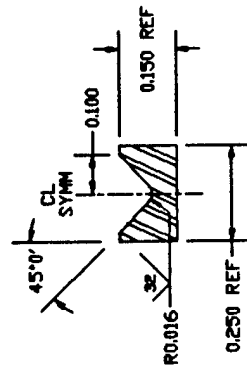


NOTES: 1. CLEAR ANDDIZE TO A THICKNESS OF 15 MICRONS OR MORE.

-1	1	PISTON ADAPTOR	7075 ALUMINIUM PLATE	SEE NOTE 1	E25A541370-1	3
PART NAME	DESCRIPTION	MATERIAL	FINISH	NEXT ASSEMBLY	QTY	
PARTS LIST						
DESIGN ENGINEER			GEORGIA INSTITUTE OF TECHNOLOGY			
JOEY LLOYD			MECHANICAL ENGINEERING			
404-657-0445						
13 NOV 97						
SCALE 1/1			PISTON ADAPTOR			
DIMENSIONS ARE IN INCHES			dB CHAMBER 1			
TOLERANCES						
X=.01						
XX=.003						
XXX=.005						
ANGLES 10°/30°						
SURFACE ROUGHNESS						
			✓			
SIZE			C		E25A541376	
PAGE			1		OF	1



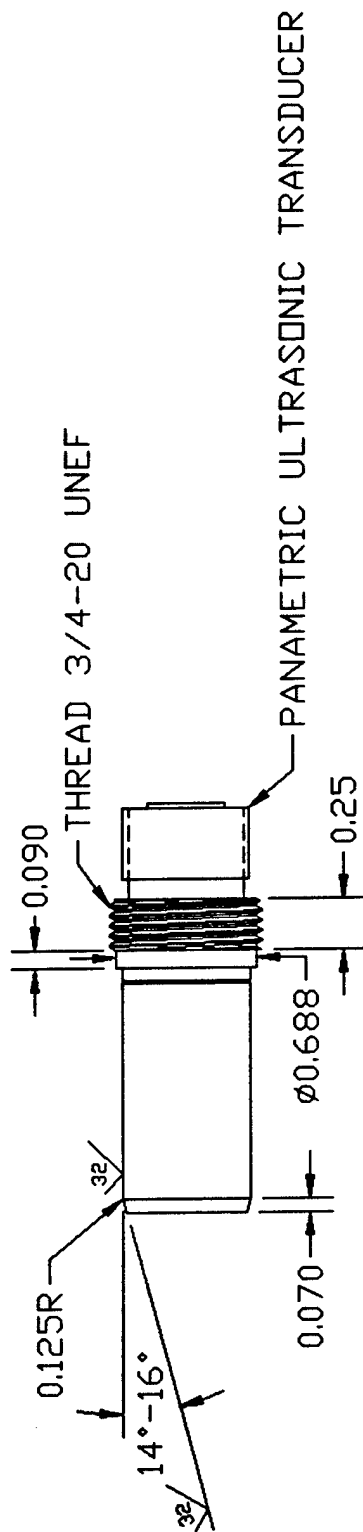
-1 PISTON CLAMP



SECT A-A
SCALE 4/1

NOTES: 1. CLEAR AND DIZE TO A THICKNESS OF 15 MICRONS OR MORE.

-2	1	INSERT	6-48 X 20 SS HELICOID	NA	-1	6
-1	1	PISTON ADAPTOR	7075 ALUMINUM PLATE	SEE NOTE 1	E25A54137D-1	3
PART	QTY	DESCRIPTION	MATERIAL	FINISH	NEXT ASSEMBLY	QTY
PARTS LIST						
DESIGN ENGINEER						
JOEY LLOYD						
404-657-0445						
14 NOV 97						
SCALE 1/1						
DIMENSIONS ARE IN INCHES						
TOLERANCES						
X=±.1						
XX=±.03						
XXX=±.005						
ANGLES 30°/30°						
SURFACE ROUGHNESS 63						
PISTON CLAMP						
dB CHAMBER 1						
SIZE	C	E25A541377				PAGE 1
DF	1					1

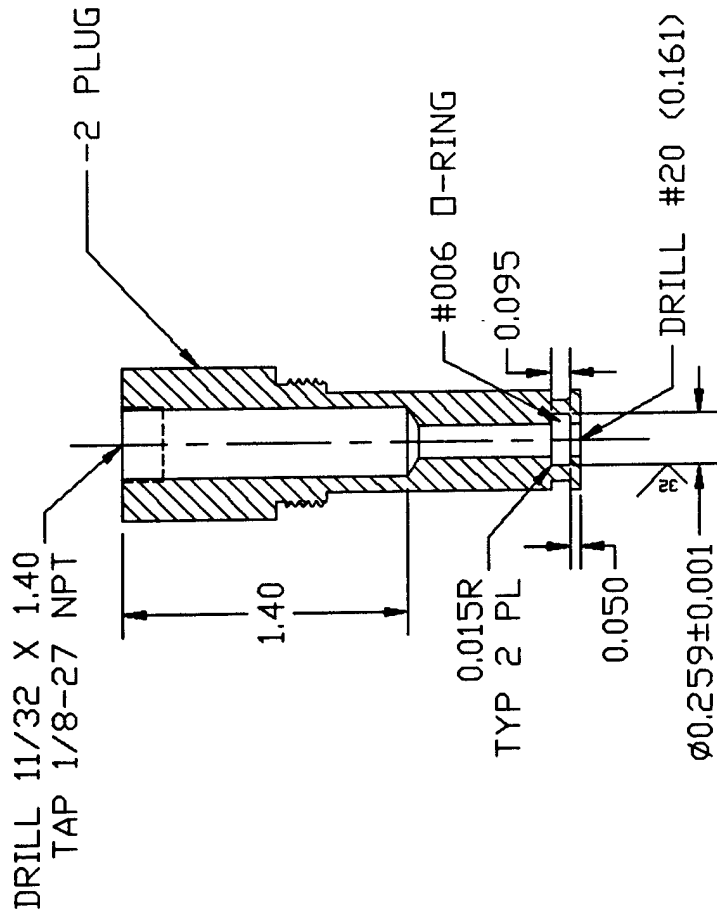


-1 TRANSDUCER

-1	1	TRANSDUCER	DESCRIPTION	PANAMETRICS A303S	END ARTICLE	2
PART	PAGE			MATERIAL OR MAKE FROM	FINISH OR NEXT ASSY. QTY	
PARTS LIST						
DESIGN ENGINEER				GEORGIA INSTITUTE OF TECHNOLOGY		
JOEY LLOYD				MECHANICAL ENGINEERING		
404-657-0445						
8 DEC 97						
SCALE 1 / 1				ULTRASONIC TRANSDUCER		
DIMENSIONS ARE IN INCHES				MODIFICATION		
TOLERANCES						
XX±.1						
XX±.03						
XXX±.005						
ANGLES 30°-90°						
SURFACE ROUGHNESS						
				SIZE	A E25A541368	PAGE 1
				DF		1



JAXXZJJ JXXZ±0.05 ANGLES 40°30' SURFACE ROUGHNESS 6.4	SIZE	E25A541378		PAGE	6
	A				6



-5 BORE SCOPE FEED

DESIGN ENGINEER

JOEY LLOYD
404-657-0445
4 DEC 97

SCALE 1 / 1

DIMENSIONS ARE IN INCHES
TOLERANCES
X=±1
XX=±0.03
XXX=±0.005

ANGLES ±0°30'

SURFACE ROUGHNESS 64

INSERTS
ØB CHAMBER 1

SIZE

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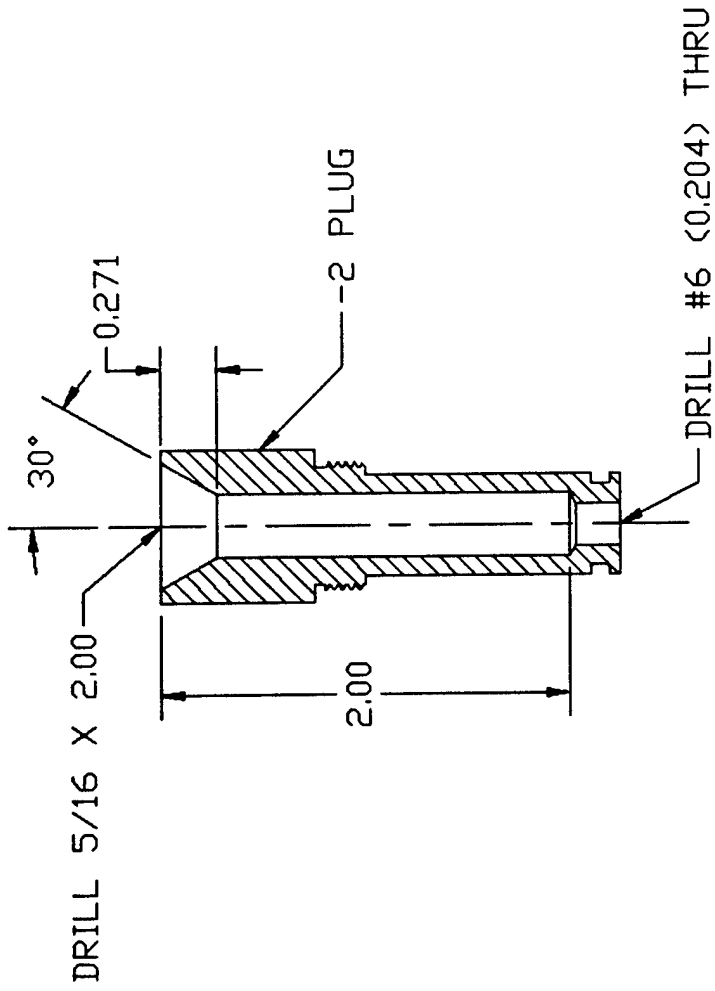
E25A541378

PAGE

5

OF

6



-4 AIR FEED

DESIGN ENGINEER

JOEY LLOYD
404-657-0445
4 DEC 97

SCALE 1 / 1

DIMENSIONS ARE IN INCHES

TOLERANCES

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XX=±.03

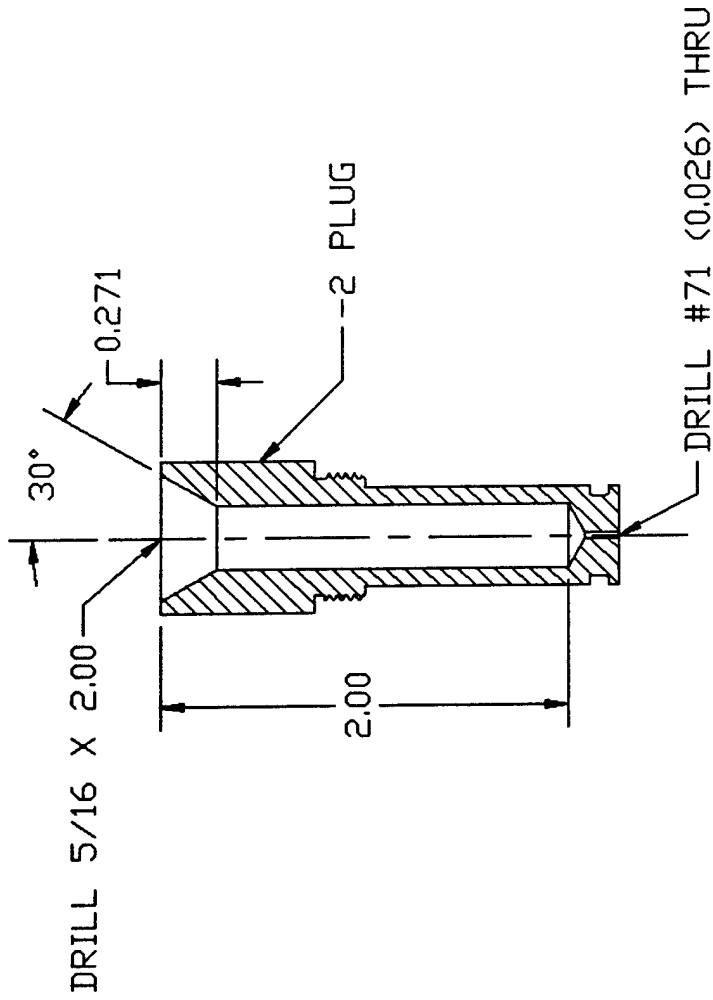
XXX=±.005

ANGLES 30°/30°

SURFACE ROUGHNESS 64

INSERTS
QB CHAMBER 1

SIZE	A	E25A541378	PAGE	4	OF	6
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-3 IV FEED

DESIGN ENGINEER

JOEY LLOYD
404-657-0445
4 DEC 97

SCALE 1 / 1

DIMENSIONS ARE IN INCHES
TOLERANCES
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XX=±.03
XXX=±.005
ANGLES 40°/30°

SURFACE ROUGHNESS 64/

INSERTS
ØB CHAMBER 1

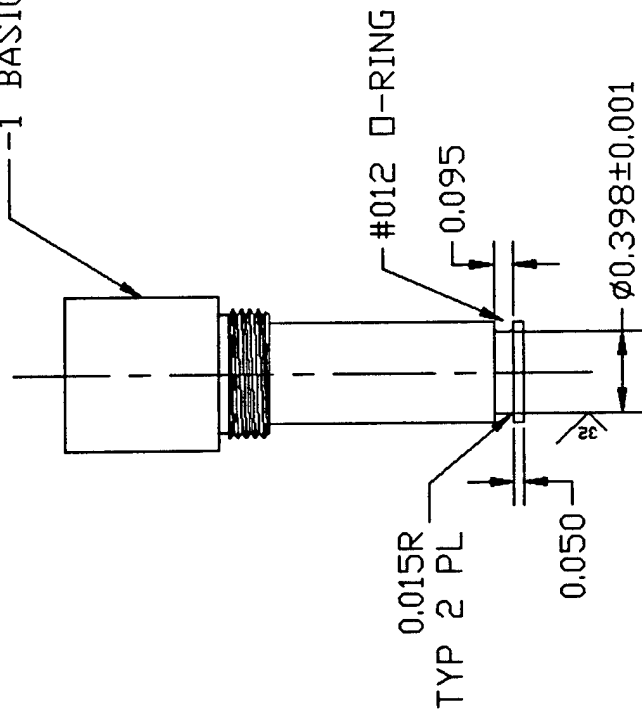
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PAGE 3

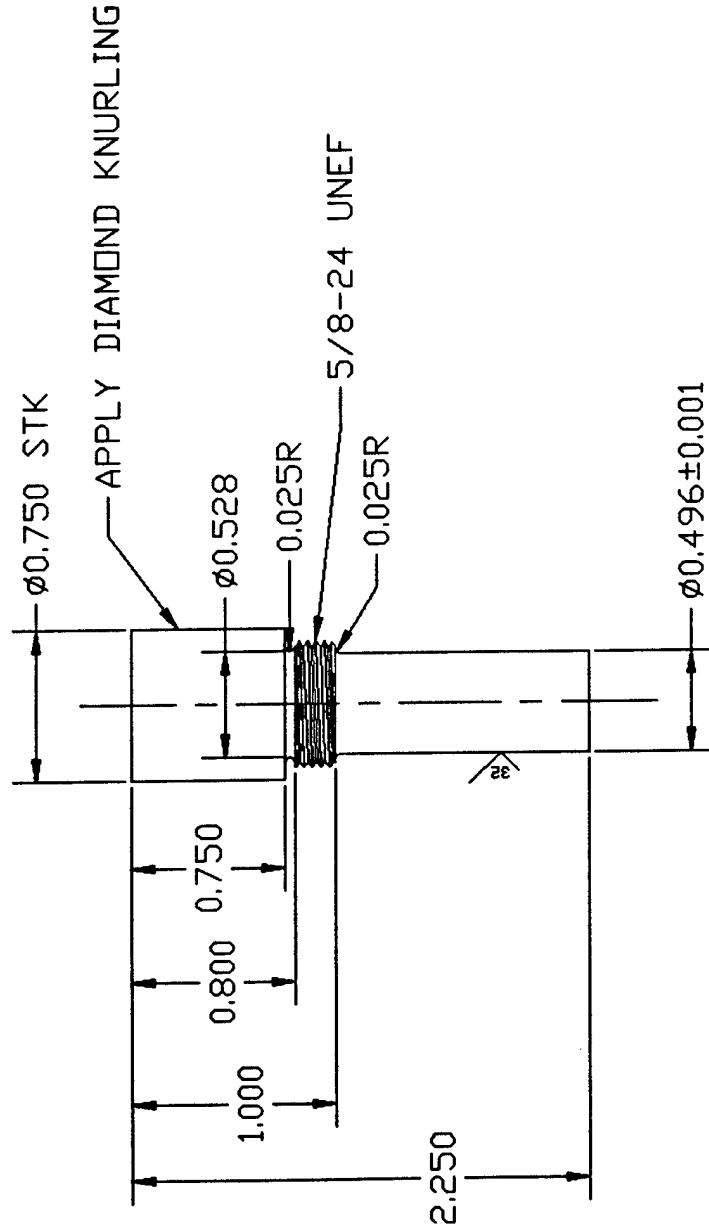
OF 4

-1 BASIC INSERT



-2 PLUG

DESIGN ENGINEER	INSERTS		
JOEY LLOYD	dB CHAMBER 1		
404-657-0445			
4 DEC 97			
SCALE 1 / 1	SIZE A	E25A541378	PAGE 2
DIMENSIONS ARE IN INCHES			
TOLERANCES			
X=±1			
XX=±03			
XXX=±005			
ANGLES 40°30'			
SURFACE ROUGHNESS 64			



-1 BASIC INSERT

-6	HYDROPHONE FEED	MAKE FROM -1	END ARTICLE	1
-5	BORE SCOPE FEED	MAKE FROM -2	END ARTICLE	1
-4	AIR FEED	MAKE FROM -2	END ARTICLE	4
-3	IV FEED	MAKE FROM -2	END ARTICLE	4
-2	PLUG	MAKE FROM -1	-3 -4, AND -5	15
-1	BASIC INSERT	3/4" 303 STAINLESS ROUND BAR	-2 AND -6	16
PART PAGE	DESCRIPTION	MATERIAL OR MAKE FROM	NEXT ASSY.	QTY

PARTS LIST

DESIGN ENGINEER

JOEY LLOYD
404-657-0445
4 DEC 97

SCALE 1 / 1

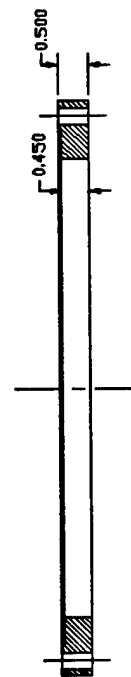
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TOLERANCES
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XX=±0.03
XXX=±0.005

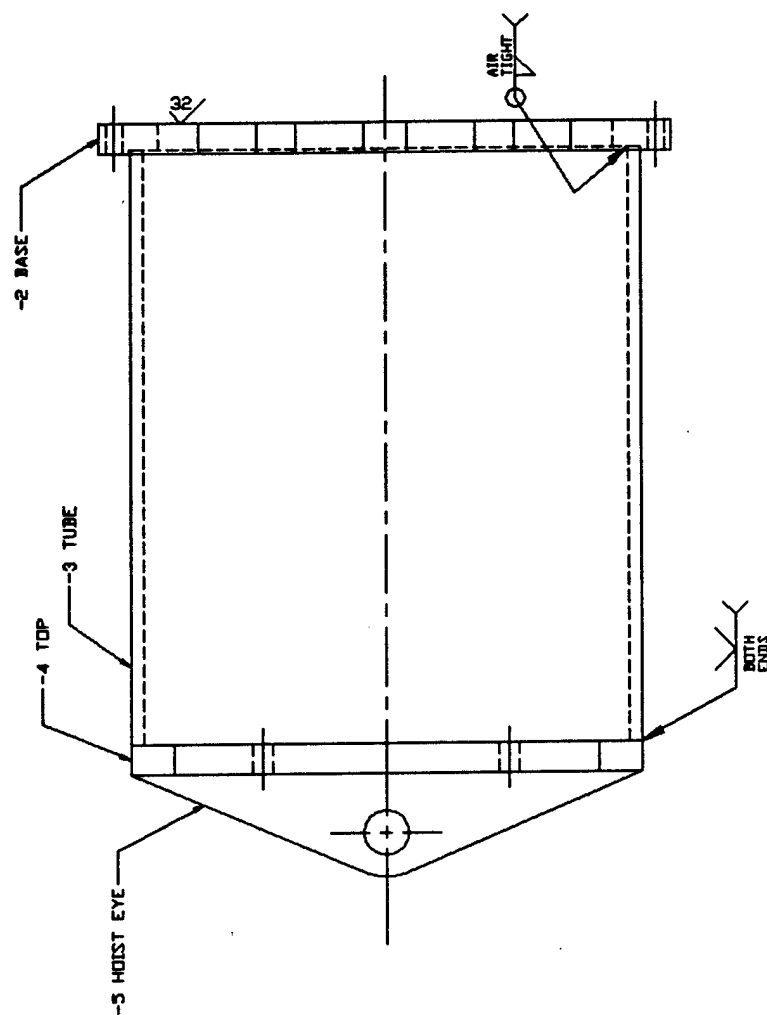
ANGLES 40°/30°

SURFACE ROUGHNESS 64

INSERTS
dB CHAMBER 1

SIZE	A	E25A541378	PAGE	1	OF	1
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-1 CASE ASSEMBLY

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DESIGN ENGINEER

JOEY LLOYD

404-637-0443
17 DEC 97

SCALE 1/1 3745

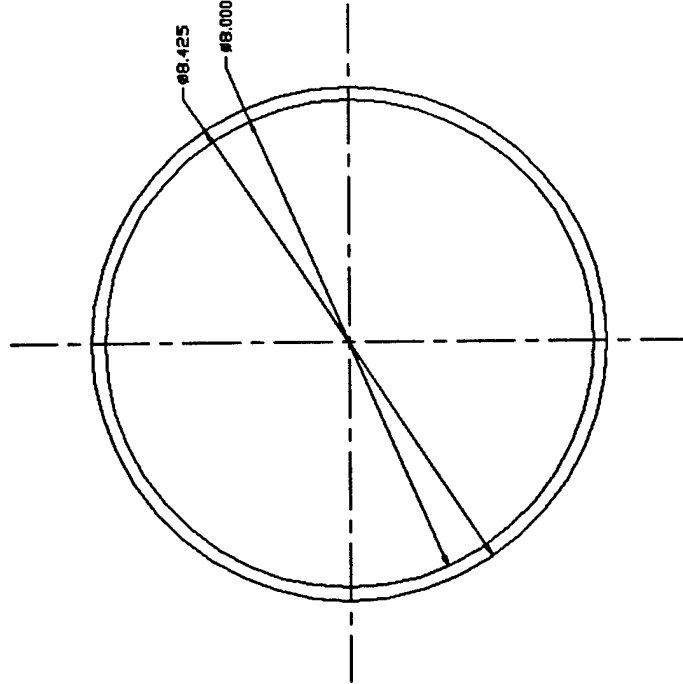
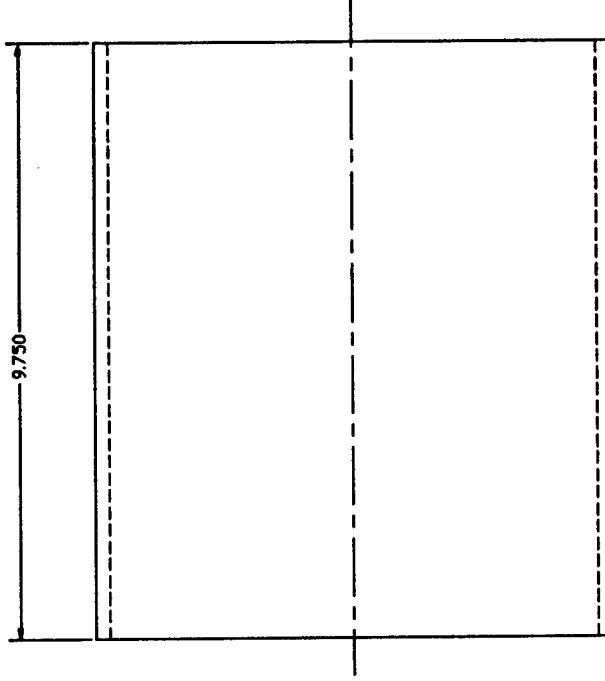
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ACOP 2270W
 BARBICOR
 2270W

RESEARCH TOWNSHIP

1

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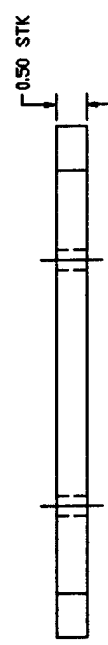
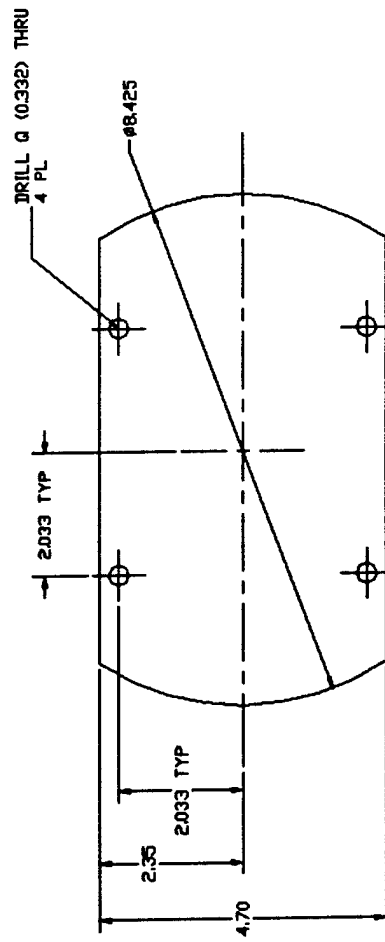


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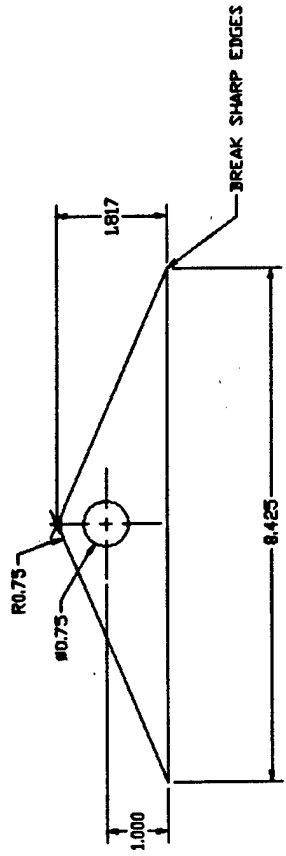
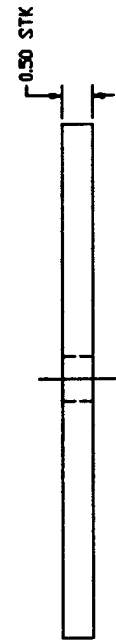
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JEE Y LLOYD	
404-657-4445	
17 DEC 97	
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FRACTIONS	
DECIMALS	
ANGLES	
HOLE LOCUS	
SURFACE FINISHES	

SHAKER CASE
QB CHAMBER 1

SIZE	D
PROJECT	E25T251379
PAGE	3
TOTAL	4

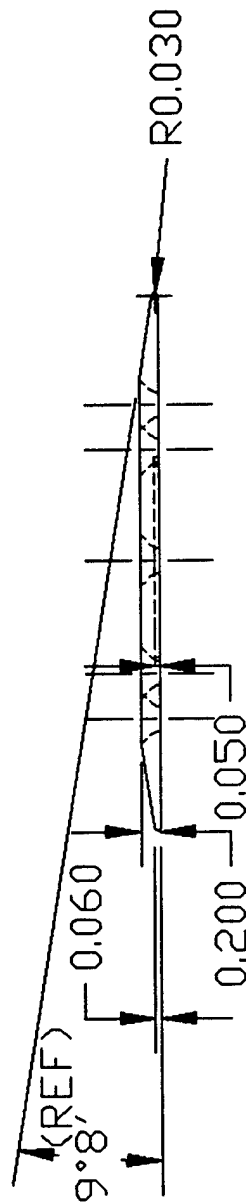
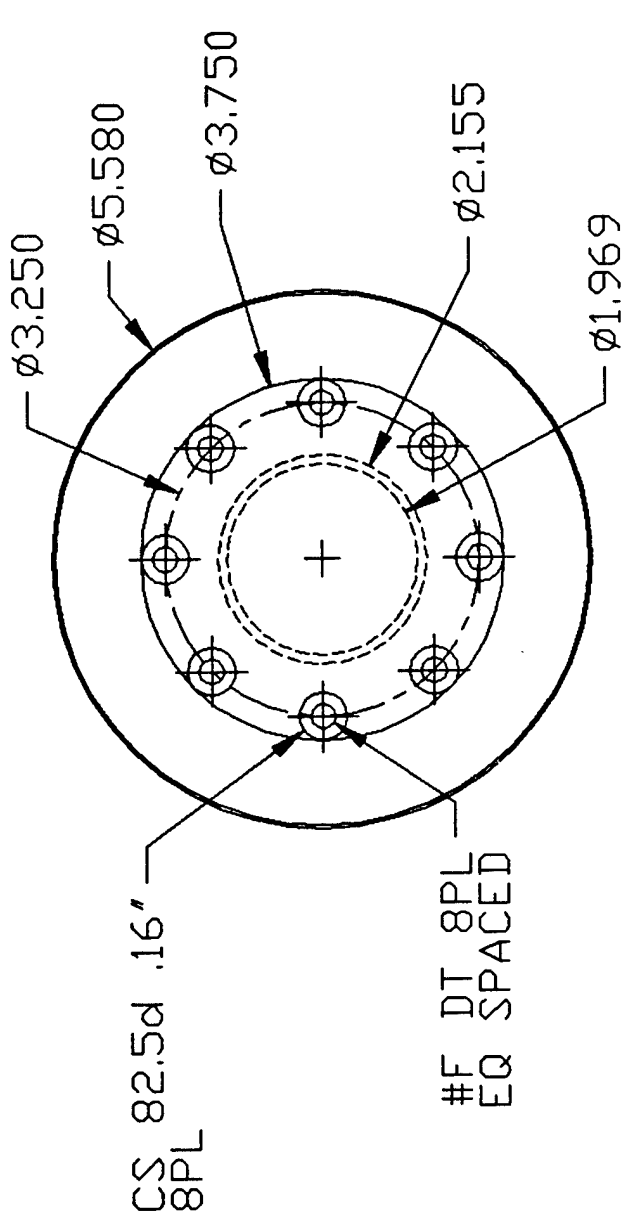


-4 TOP



-5 HOIST EYE

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DATE	17 DEC 97
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CHECKED BY	SEE LUTD
APPROVED BY	SEE LUTD
SHEET NUMBER	1
TOTAL SHEETS	1
PROJECT NUMBER	E25T251379
PROJECT NAME	SHAKER CASE QB CHAMBER 1



MATERIAL: ALUMINUM
QUANTITY REQUIRED: 2

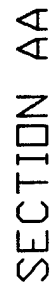
DESIGN ENGINEER	JAMES MARTIN
	894-6794
	3/16/98
SCALE	NTS
DIMENSIONS ARE IN INCHES	
TOLERANCES	
.X=±1	
.XX=±.03	
.XXX=±.005	
ANGLES 40°/30'	
SURFACE ROUGHNESS	125

GEORGIA INSTITUTE OF TECHNOLOGY
MECHANICAL ENGINEERING


RATABRATOR

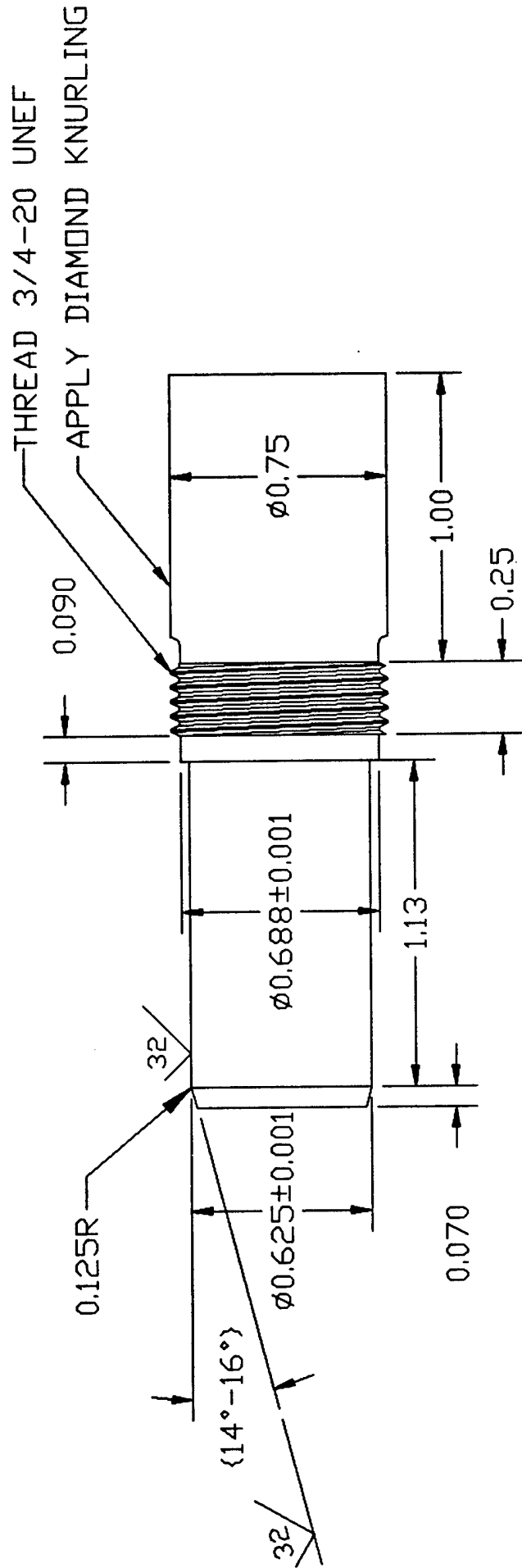
RATABRATOR PISTON
MK II, FRONT PLATE

SIZE	A	E25A541406	PAGE	2
OF				2



MATERIAL: ALUMINUM
QUANTITY REQUIRED: 2

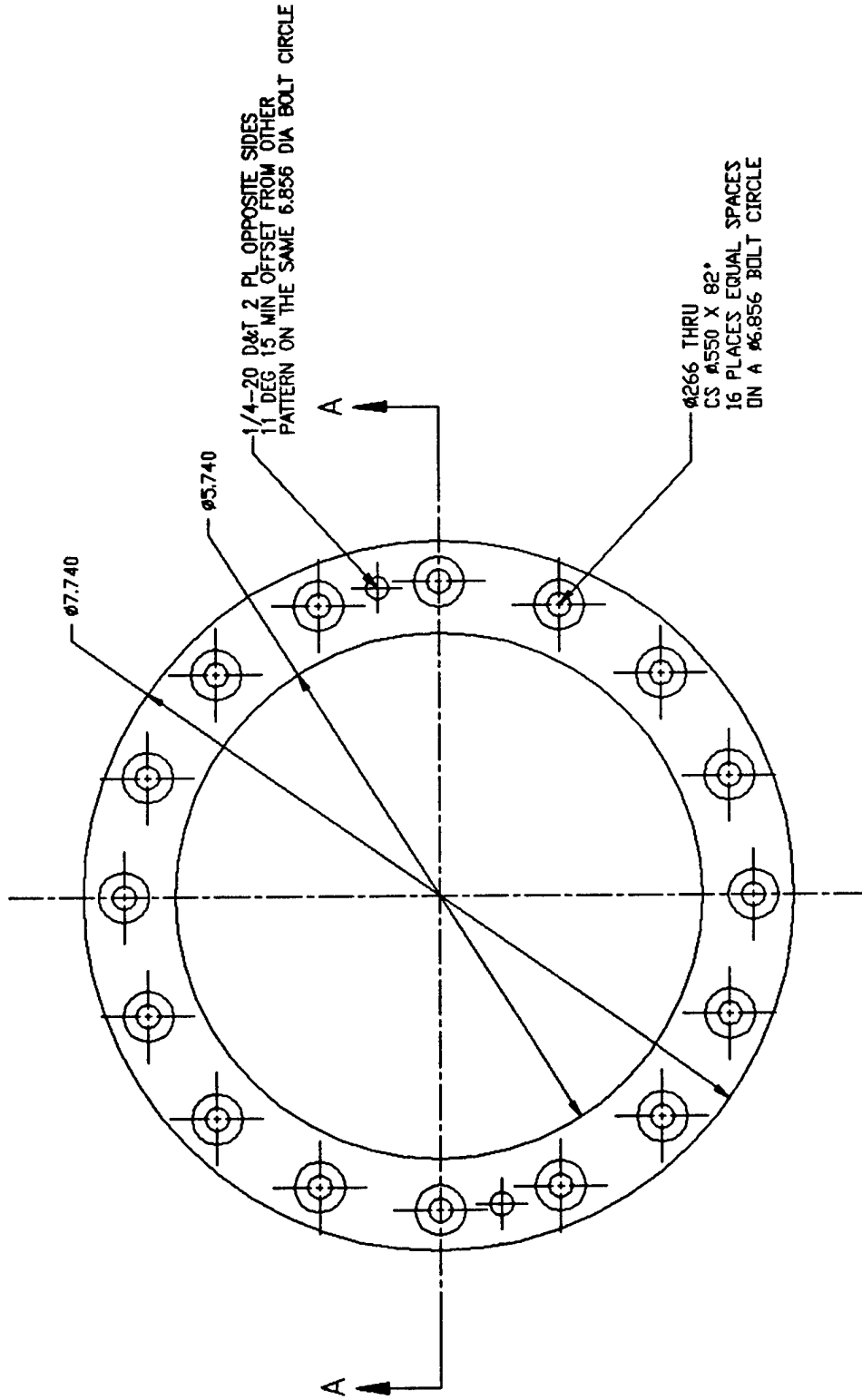
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JAMES MARTIN		
894-6794	RATABRATOR	
3/16/98	RATABRATOR PISTON MK II, BACK PLATE	
SCALE NTS	SIZE	PAGE OF
DIMENSIONS ARE IN INCHES	A	1 2
TOLERANCES	E25A541406	
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$.XX \pm .03$		
$.XXX \pm .005$		
ANGLES $40^{\circ}30'$		
SURFACE ROUGHNESS	125/	



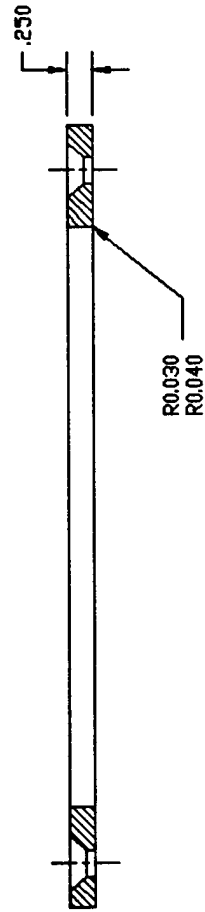
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DESIGN ENGINEER					
JAMES MARTIN					
894-6794					
31 MAR 98					
SCALE NTS					
DIMENSIONS ARE IN INCHES					
TOLERANCES					
XX±.03					
.XX±.005					
ANGLES ±0°30'					
SURFACE ROUGHNESS					
64					
GEORGIA INSTITUTE OF TECHNOLOGY					
MECHANICAL ENGINEERING					
TRANSDUCER PLUG					
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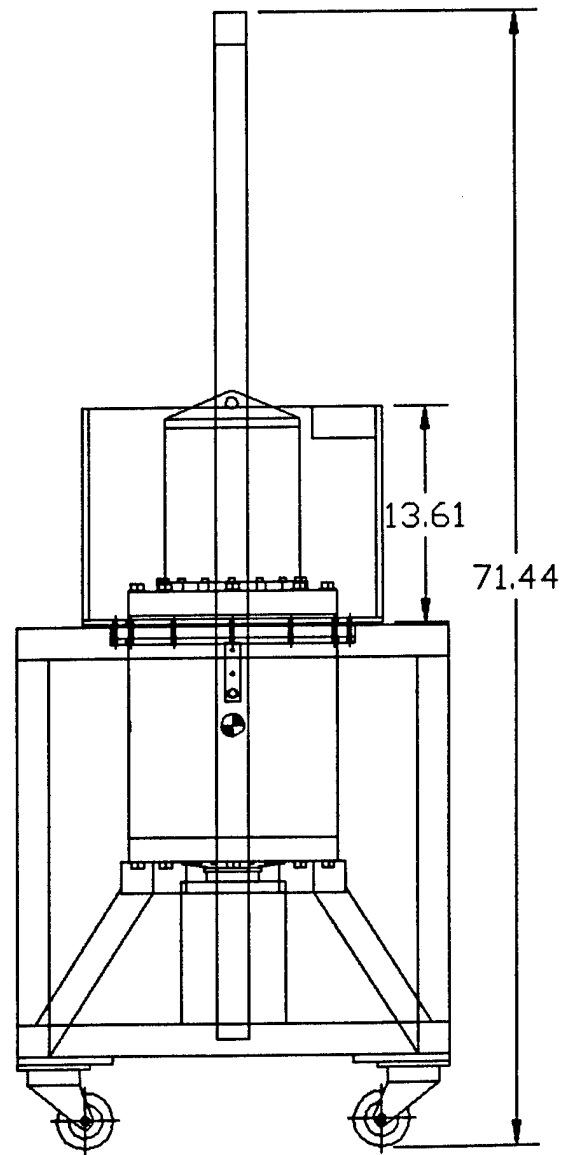
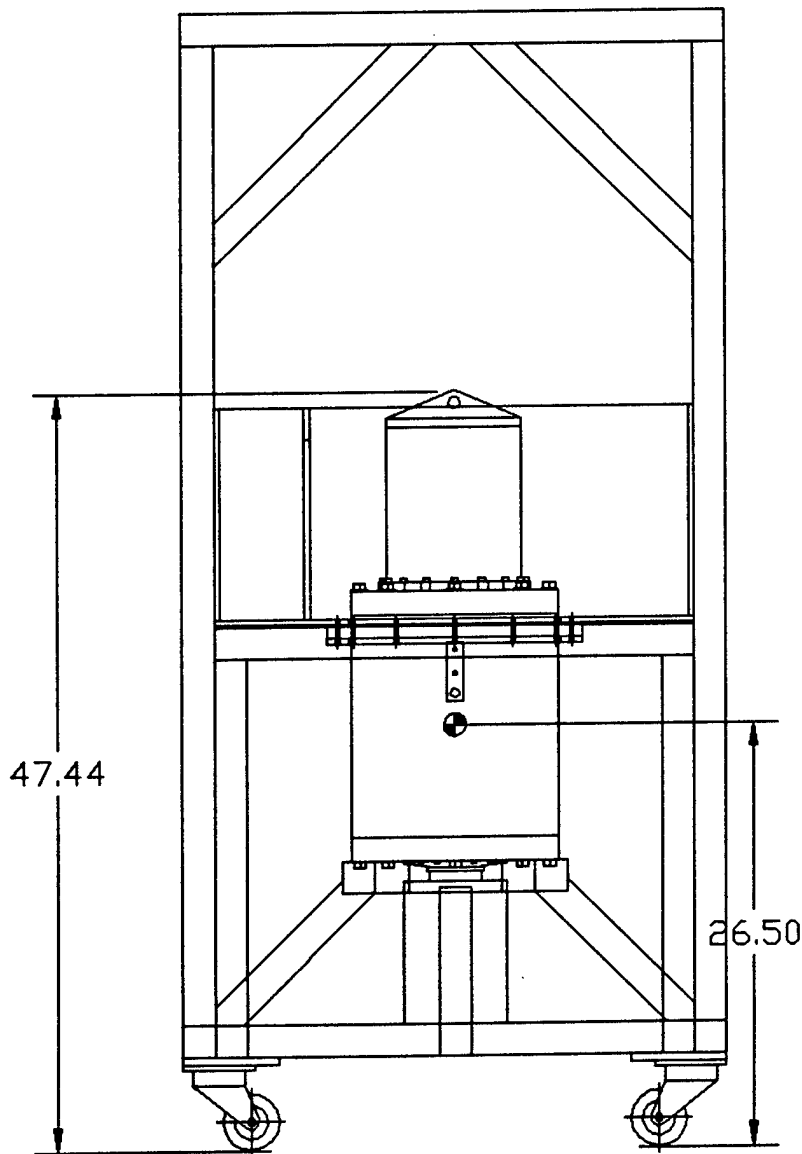
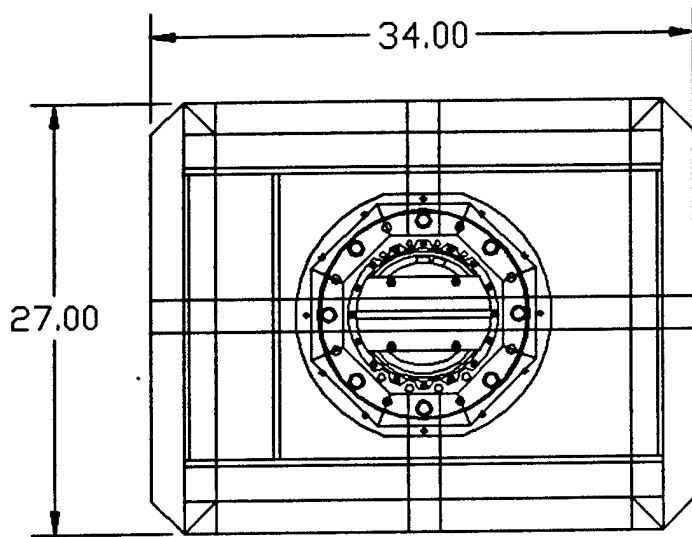
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-1 RETAINING RING



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PARTS LIST					
DESIGN		J. MARTIN	24 MAR 98	GEORGIA INSTITUTE OF TECHNOLOGY	
DRAWN		J. LLOYD	24 MAR 98	MECHANICAL ENGINEERING	
RETAINING RING RATABRATOR					
SCALE		NTS			
DIMENSIONS ARE IN INCHES					
TOLERANCES:					
.X=±.1					
.XX=±.03					
.XXX=±.005					
ANGLES 30°-90°					
SURFACE ROUGHNESS 63					
SIZE		D E25A541408			PAGE DF
					1 1



DESIGN ENGINEER

JAMES MARTIN

894-6794

27 FEB 98

SCALE: NTS

DIMENSIONS ARE IN INCHES

TOLERANCES:

.X=±.1

.XX=±.03

.XXX=±.005

ANGLES 40°/30°

SURFACE ROUGHNESS .125

GEORGIA INSTITUTE OF TECHNOLOGY

RATABRATOR

RATABRATOR BUGGY
COMPLETE ASSEMBLY

SIZE

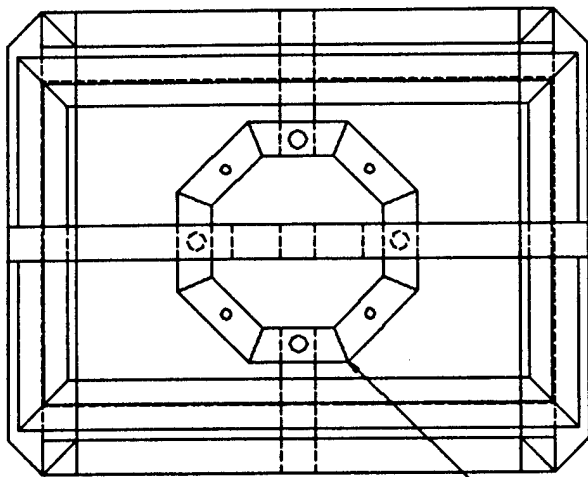
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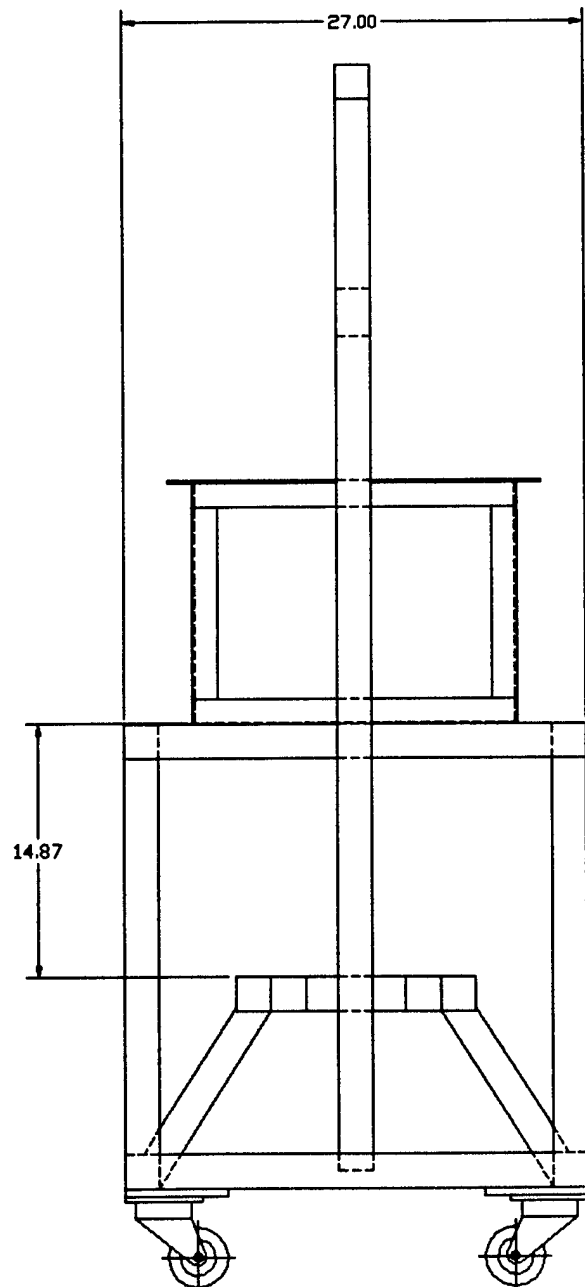
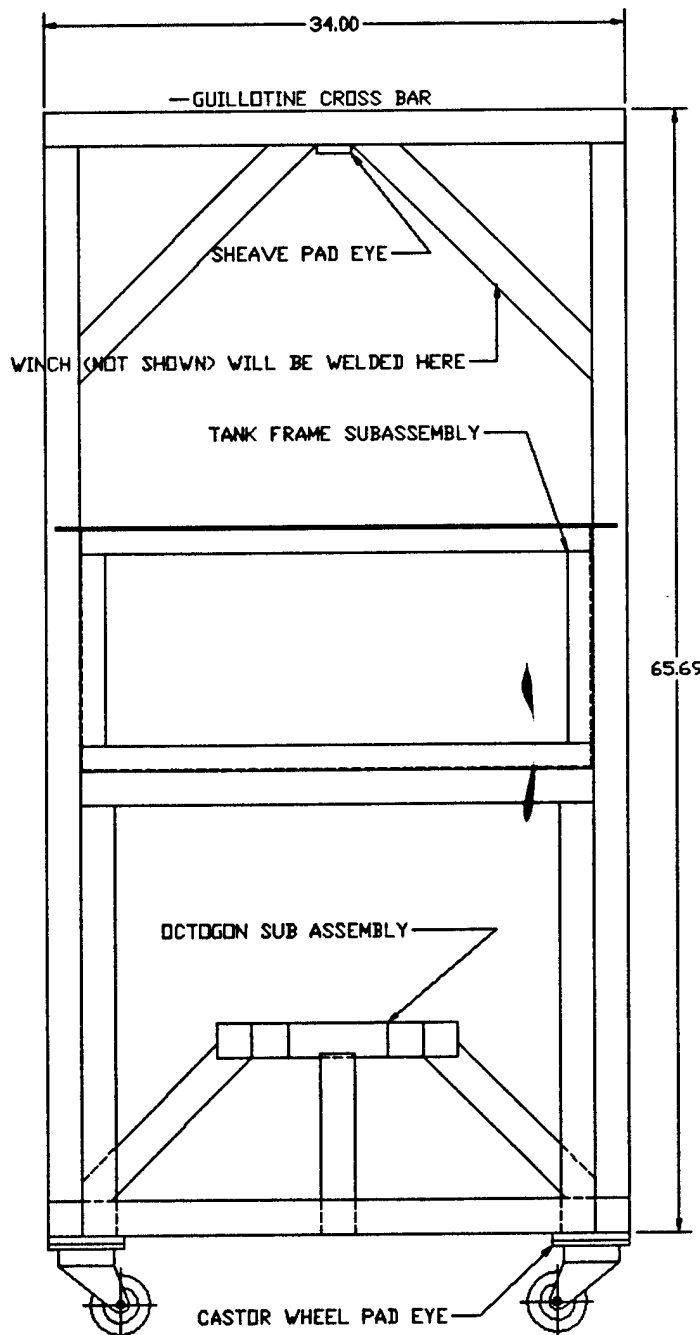
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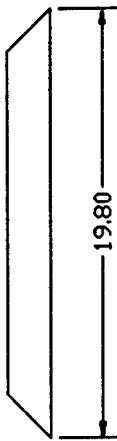
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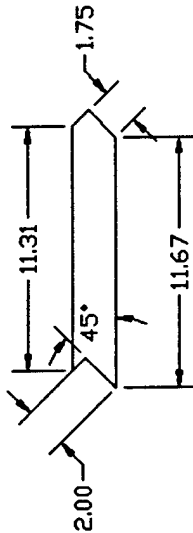
OCTOGON SHOULD BE CENTERED ON FRAME



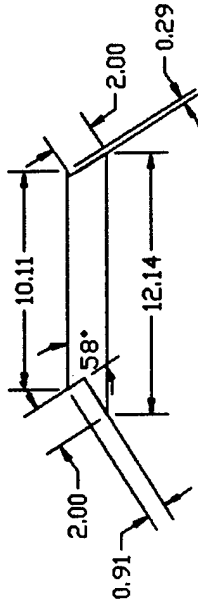
GUILLOTINE BRACE
2 PEICES PER ASSEMBLY



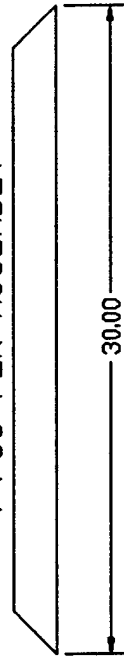
LONG SIDE OCTOGON LEG
2 PEICES PER ASSEMBLY



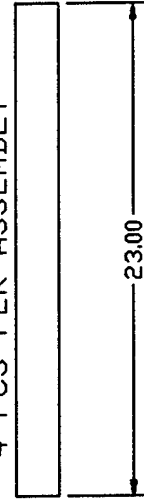
SHORT SIDE OCTOGON LEG
2 PEICES PER ASSEMBLY



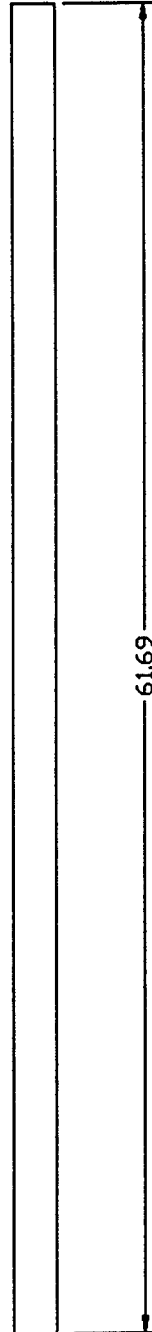
LOWER BOX LONG SIDE
4 PCS PER ASSEMBLY



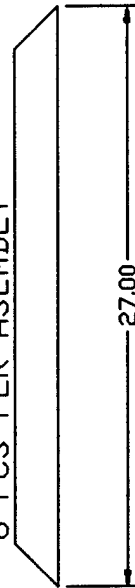
LOWER BOX VERTICAL LEG
4 PCS PER ASSEMBLY



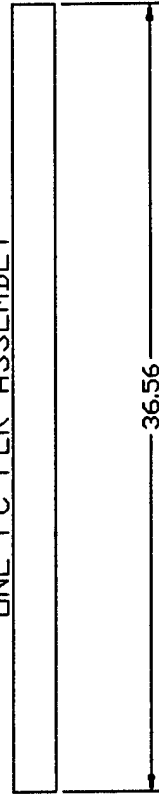
VERTICAL GUILLOTINE SUPPORT
TWO PCS PER ASSEMBLY



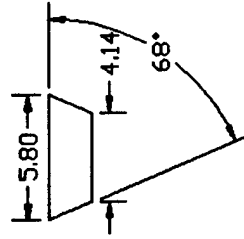
LOWER BOX SHORT SIDE
6 PCS PER ASSEMBLY



GUILLOTINE CROSS BAR
ONE PC PER ASSEMBLY



OCTOGON SIDE
8 PEICES PER ASSEMBLY



GEORGIA INSTITUTE OF TECHNOLOGY

DESIGN ENGINEER

JAMES MARTIN
894-6794
27 FEB 98

RATABRATOR

RATABRATOR BUGGY
PARTS DETAILS

SCALE: NTS

DIMENSIONS ARE IN INCHES

TOLERANCES:

.X=±.1

.XX=±.03

.XXX=±.005

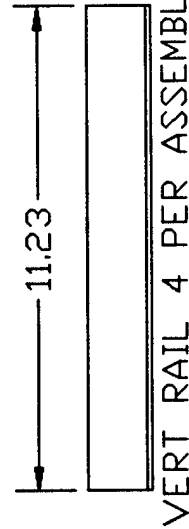
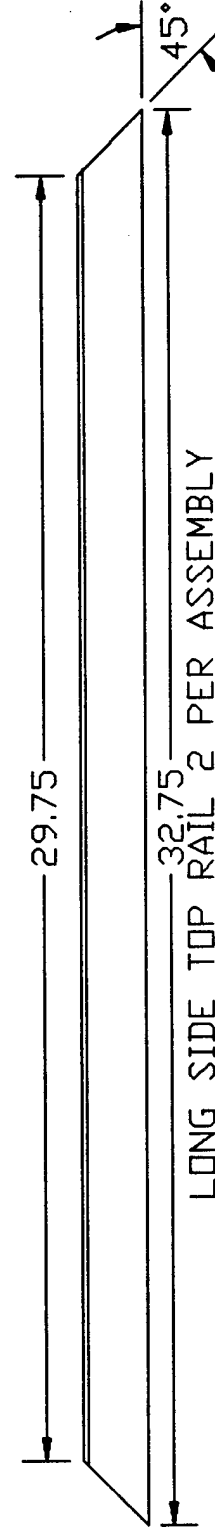
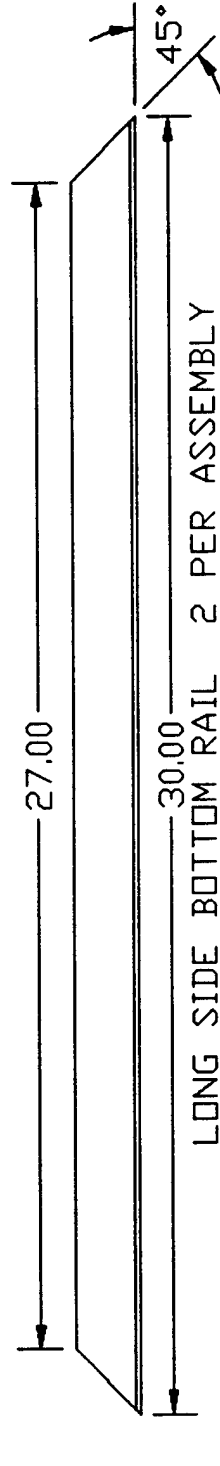
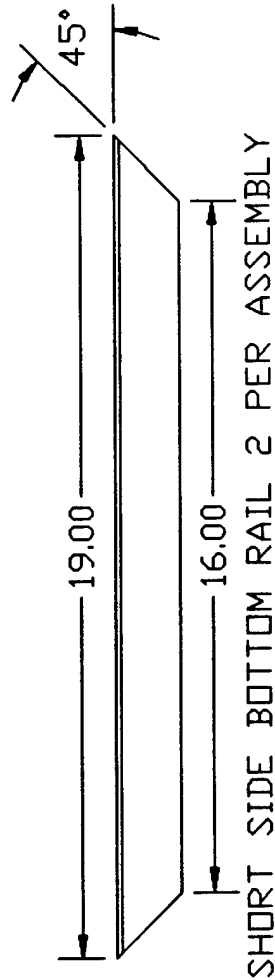
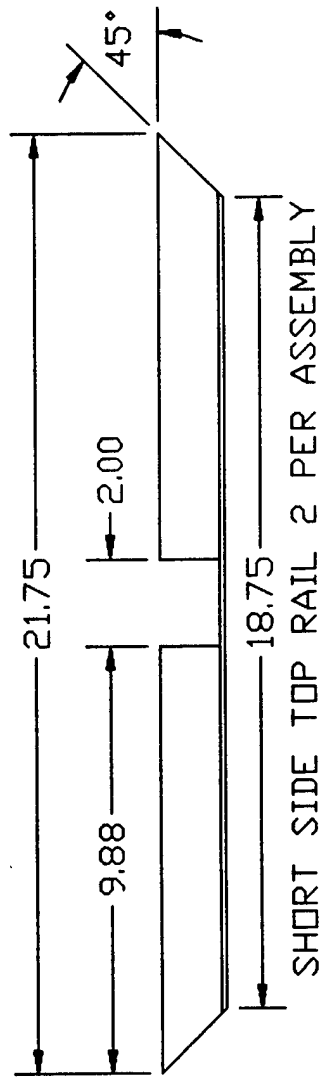
ANGLES ±0°30'

SURFACE ROUGHNESS

125

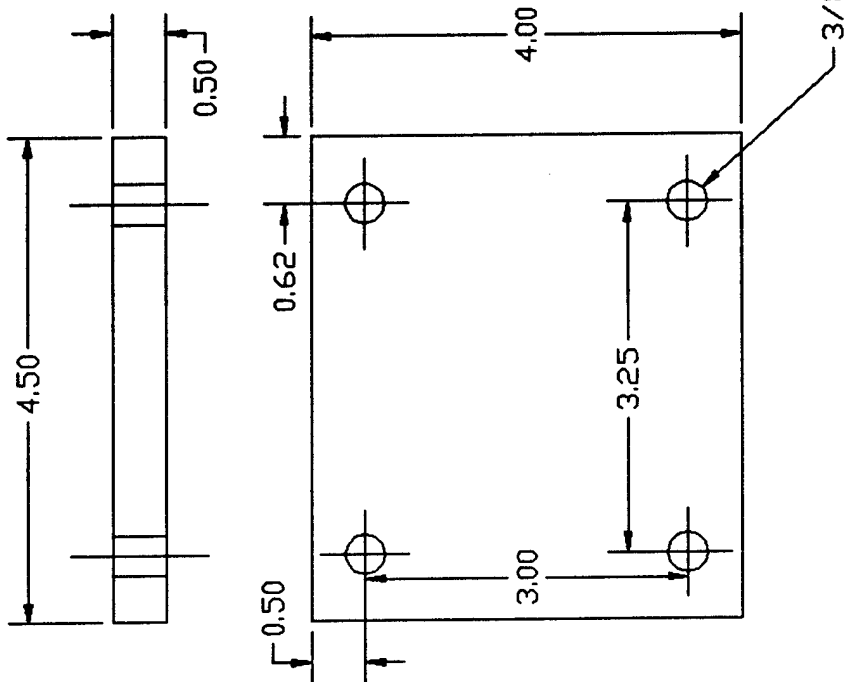
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PAGE 2 OF 6

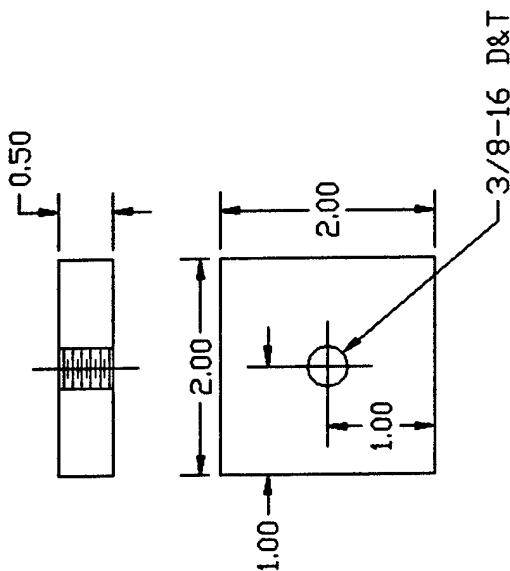


DESIGN ENGINEER JAMES MARTIN 894-6794 27 FEB 98	GEORGIA INSTITUTE OF TECHNOLOGY						
SCALE: NTS DIMENSIONS ARE IN INCHES TOLERANCES: .X=±.1 .XX=±.03 .XXX=±.005 ANGLES ±0°30' SURFACE ROUGHNESS 125	<div data-bbox="1274 126 1364 609"> <h1>RATABRATOR</h1> </div> <div data-bbox="1372 126 1461 609"> <h2>RATABRATOR BUGGY PARTS DETAILS</h2> </div> <div data-bbox="1469 31 1542 619"> <table border="1"> <tr> <td>SIZE</td> <td>A</td> </tr> <tr> <td>PAGE</td> <td>3</td> </tr> <tr> <td>OF</td> <td>6</td> </tr> </table> </div>	SIZE	A	PAGE	3	OF	6
SIZE	A						
PAGE	3						
OF	6						

CASTOR WHEEL PAD EYE 4 PER ASSEMBLY



SHEAVE PAD EYE 1 PER ASSEMBLY



DESIGN ENGINEER

JAMES MARTIN
894-6794
27 FEB 98

SCALE: NTS

DIMENSIONS ARE IN INCHES
TOLERANCES:
.X=±.1
.XX=±.03
.XXX=±.005

ANGLES ±0°30'
SURFACE ROUGHNESS 125

GEORGIA INSTITUTE OF TECHNOLOGY

RATABRATOR

RATABRATOR BUGGY
PARTS DETAILS

SIZE

A

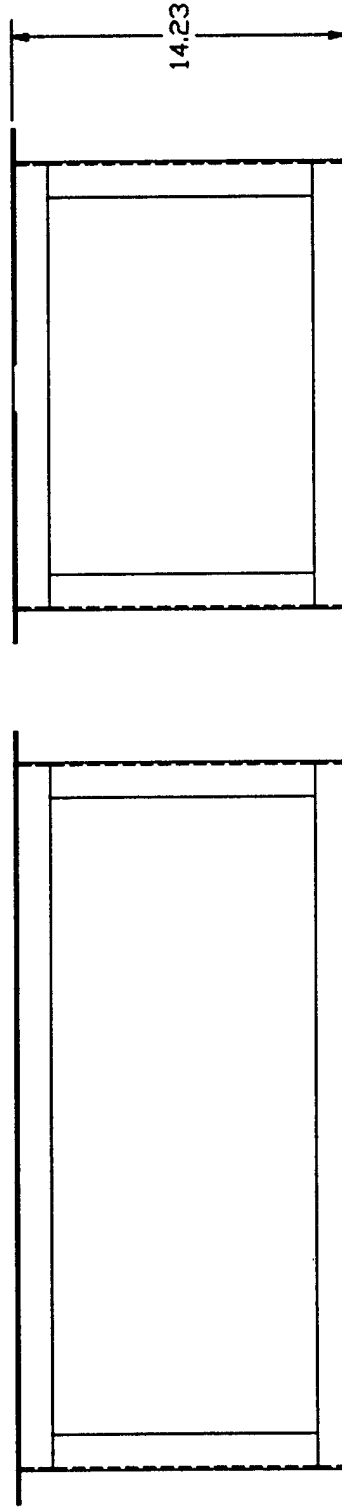
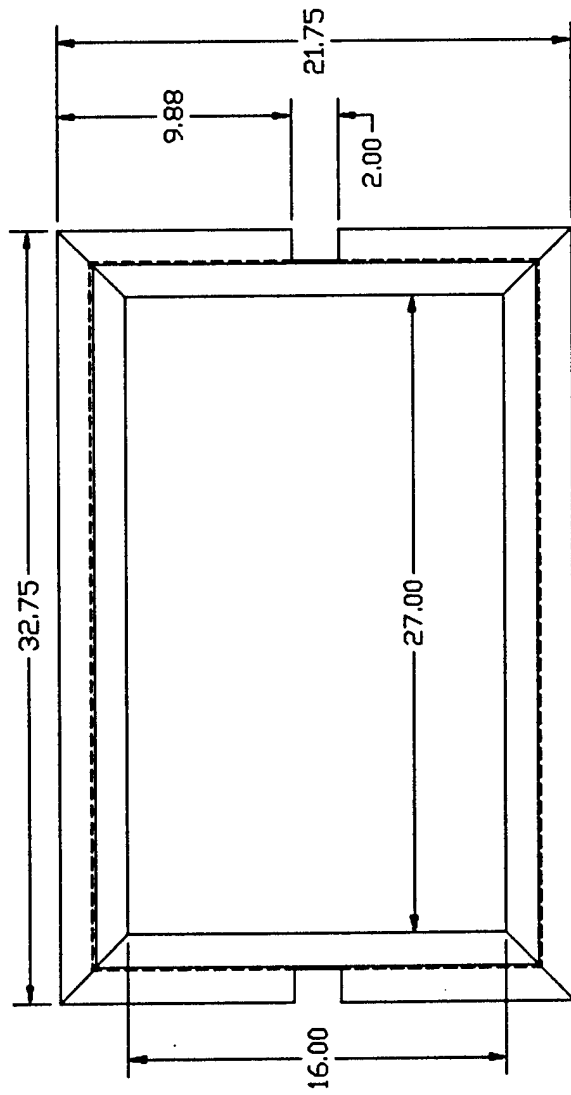
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PAGE

4

OF

6



DESIGN ENGINEER

JAMES MARTIN
894-6794
27 FEB 98

GEORGIA INSTITUTE OF TECHNOLOGY

RATABRATOR

RATABRATOR BUGGY
TANK FRAME SUBASSEMBLY

SCALE: NTS

DIMENSIONS ARE IN INCHES

TOLERANCES:

.X=±.1

.XX=±.03

.XXX=±.005

ANGLES ±0°30'

SURFACE ROUGHNESS

125

SIZE

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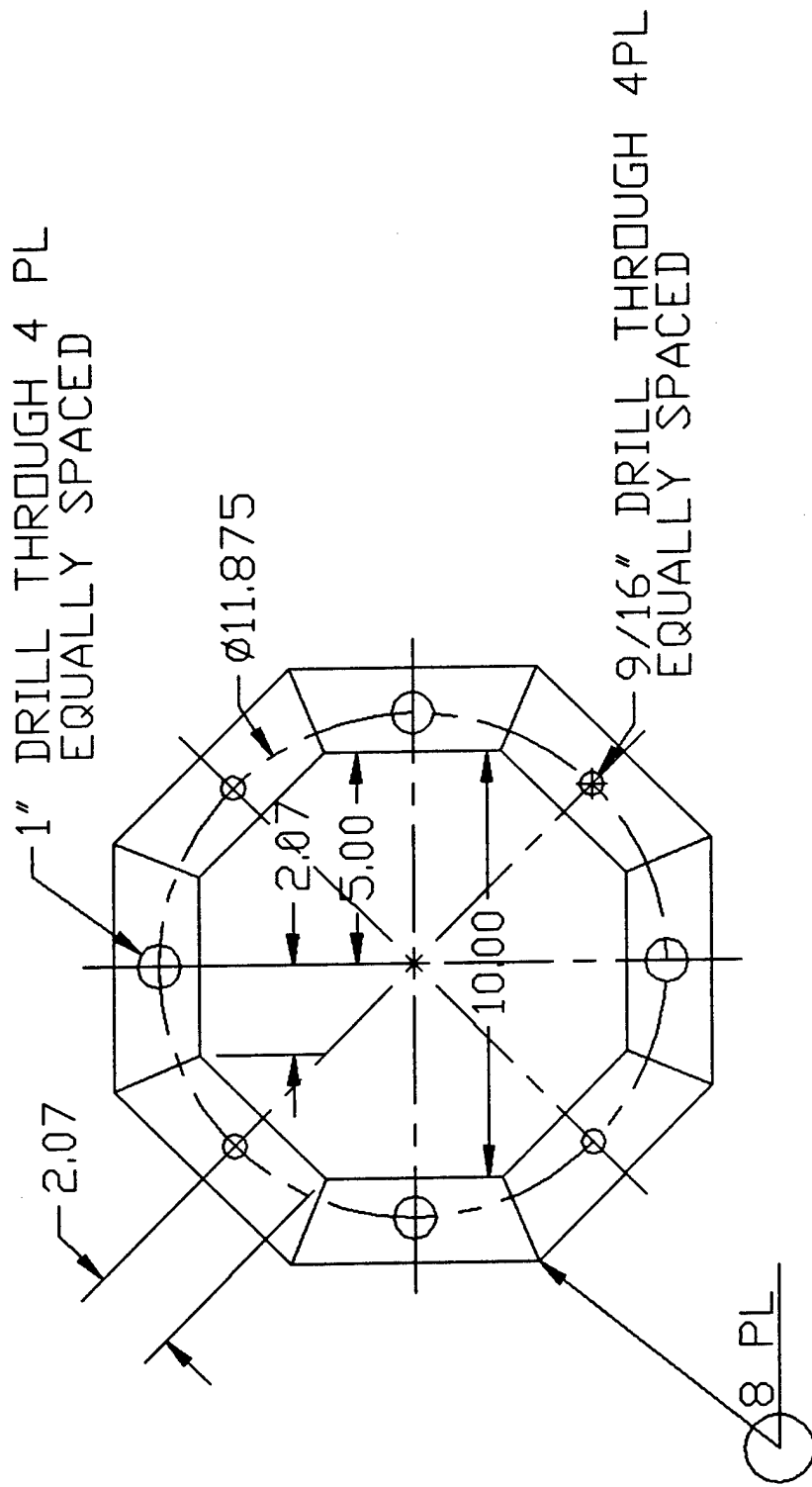
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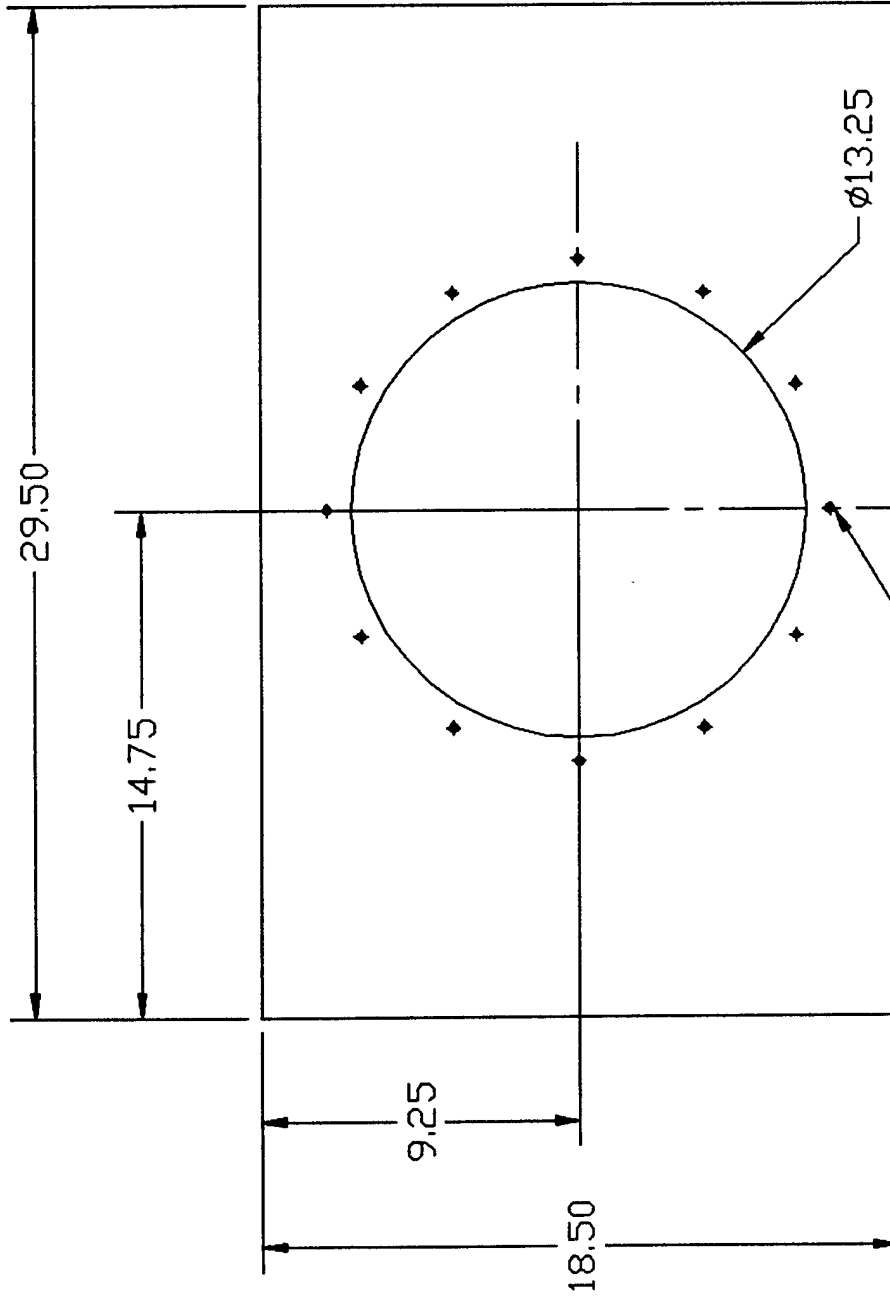
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6



WELD OCTOGON SIDES TOGETHER AS SHOWN
 GRIND WELDS FLAT ON ONE FACE AND DRILL
 8 EQUALLY SPACED HOLES ON THE BOLT CIRCLE SHOWN.
 FACE WITH GROUND WELDS SHOULD BE UP IN FINAL ASSEMBLY.

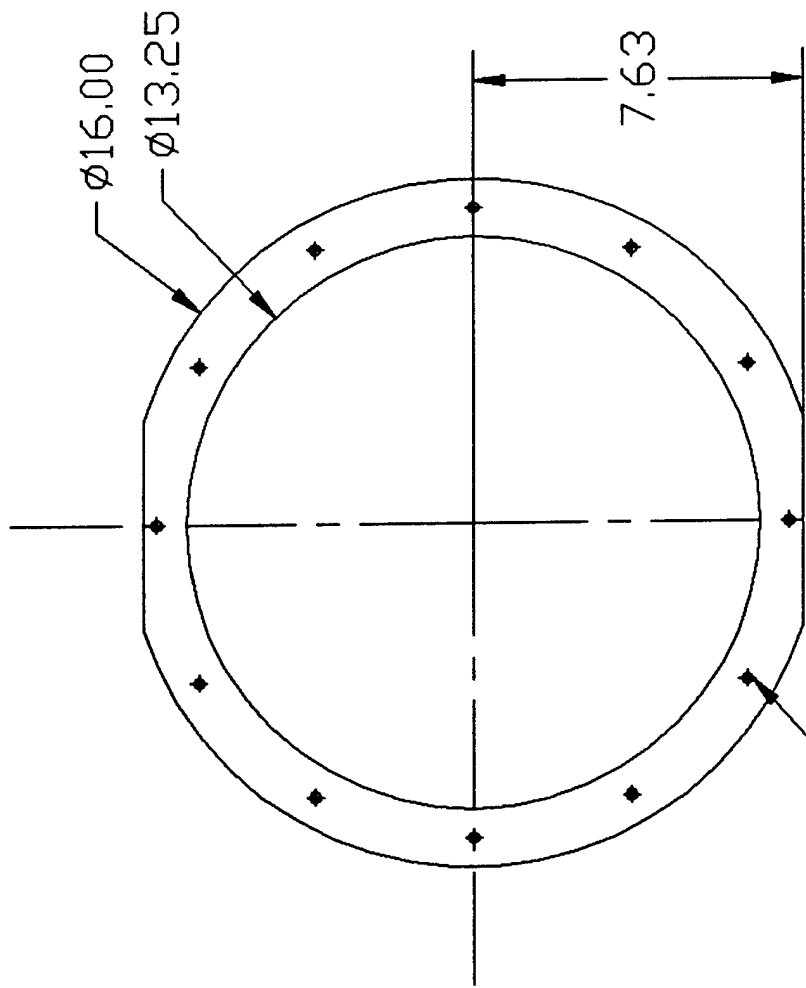
DESIGN ENGINEER	GEORGIA INSTITUTE OF TECHNOLOGY		
JAMES MARTIN 894-6794 27 FEB 98	RATABRATOR		
SCALE: NTS	RATABRATOR BUGGY		
DIMENSIONS ARE IN INCHES	OCTOGON SUBASSEMBLY		
TOLERANCES: .X=±.1 .XX=±.03 .XXX=±.005	SIZE	A	E25A541404
ANGLES ±0°30'	PAGE	6	6
SURFACE ROUGHNESS 125	DF		



#F DRILL THROUGH 12 PLACES EQ. SPACED
ON A 14.63" CIRCLE AS SHOWN

MATERIAL: 3/8" LEXAN (PROVIDED)
QUANTITY REQUIRED: 2

DESIGN ENGINEER	GEORGIA INSTITUTE OF TECHNOLOGY
JAMES MARTIN 894-6794 28 MAY 98	RATABRATOR
SCALE: NTS	RATABRATOR TANK FLOOR
DIMENSIONS ARE IN INCHES	SIZE
TOLERANCES: .X=±.1 .XX=±.03 .XXX=±.005	A E25A541416
ANGLES ±0°30'	PAGE
SURFACE ROUGHNESS 125	OF 11



12 PLACES EQ. SPACED
ON A 14.63" CIRCLE, MATCHED TO TANK FLOOR

MATERIAL: 1/4" LEXAN (PROVIDED)
QUANTITY REQUIRED: 2

DESIGN ENGINEER	GEORGIA INSTITUTE OF TECHNOLOGY		
JAMES MARTIN 894-6794 28 MAY 98	RATABRATOR		
SCALE: NTS	RATABRATOR GASKET RETAINING RING		
DIMENSIONS ARE IN INCHES TOLERANCES: .X=±.1 .XX=±.03 .XXX=±.005 ANGLES: 30°/30°	SIZE	PAGE	DF
SURFACE ROUGHNESS 125	A	E25A541417	11

Appendix C:

Human Subjects Protocol:

**Measurement of Lung Vibration from Low Frequency
Underwater Sound in Divers**

I. COVER PAGE

1. Protocol Number: N/A NSMRL, 1998, DoD
2. Title: Measurement of Lung Vibration From Low Frequency Underwater Sound in Divers
3. Date of Submission: 7 July, 1998
Date of Study: 1 October, 1998- 30 October, 1998
4. Measurement of Lung Vibration From Low Frequency Underwater Sound in Divers:
5. Principal Investigator:
P. H. Rogers, Neely Prof., School of Mechanical Engineering, Georgia Institute of Technology, Atlanta, GA.
6. Co-Investigator:
E. A. Cudahy, Ph.D., Naval Submarine Medical Research Laboratory, Naval Submarine Base, Groton, CT.
7. Medical Monitor:
E.L. Hanson, LT, MC, USNR, Naval Submarine Medical Research Laboratory, Naval Submarine Base, Groton, CT.
8. Primary Performing Institution:
Georgia Institute of Technology, School of Mechanical Engineering, Atlanta, GA, 30332-0405
9. Collaborating Institutions:
Naval Submarine Medical Research Laboratory, Box 900, Naval Submarine Base, Groton, CT 06349-5900.
10. Subjects: 10 active duty, qualified Military Divers, (male and female), 0 civilians
11. CRDA (Y/N)

II. SIGNATURE PAGE

1. _____
P. Rogers, Ph.D., Prof., GA Tech, Date (DD/MM/YY)
Principal Investigator
2. _____
E. Cudahy, Ph.D. Date (DD/MM/YY)
Co-Investigator
3. _____
E. Hanson, LT, MC, USNR Date (DD/MM/YY)
Medical Monitor
4. _____
J. Martin, REII, GA Tech, Date (DD/MM/YY)
Key Support Personnel
5. _____
T. Buell, Ph.D., Date (DD/MM/YY)
Auditory Department Head
6. _____
J. Dearie Date (DD/MM/YY)
Command Diving Officer
6. _____
T. Anderson Ph.D., Date (DD/MM/YY)
Technical Director
7. _____
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Commanding Officer, NSMRL

III RECORD OF CHANGES TO THE PROTOCOL

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V. SCIENTIFIC BACKGROUND AND OBJECTIVES

1. Background

Introduction

Underwater Low Frequency Sound (ULFS) is being increasingly used for submarine detection. A recently declassified low frequency sonar SURTASS LFA (SURveillance Towed Array Sonar System Low Frequency Active) offers advantages over more conventional higher frequency sonar for detection in littoral areas. The long distances that waterborne low frequency sound can travel, along with the shift toward use in coastal waters, increases the likelihood of inadvertent diver exposure.

Recent research and experience suggest that divers and marine mammals may suffer adverse auditory and non-auditory effects from exposure to intense, low-frequency (<1250 Hz) underwater sound (Montague and Strickland, 1961; Molvaer and Gjestland, 1981; Smith, 1988; Steevens et al., 1994A, 1994B; Steevens and Smith, 1994C). Moreover, one unplanned exposure and two experimental exposures have resulted in transient neurological symptoms (Steevens et al., 1994D, 1996). No confirmed mechanisms exist to account for these symptoms and threshold parameters for most low frequency effects remain undefined.

The Navy has expressed interest in determining such parameters for both marine life and humans. Defining damage risk thresholds for a variety of organ systems will help the Navy draft an upcoming environmental impact statement for the SURTASS LFA system required by the Environmental Protection Agency. Currently, the Navy is funding a large multi-center research effort involving over a dozen University and DOD laboratories. Work involves the use of humans, marine mammals and small land mammals to help determine safe exposure limits.

We are planning to measure the displacement frequency response of divers' lungs during a low frequency sound exposure. This information will be useful to the overall research effort. It will provide a baseline for the correlation of data taken on

divers in the tank facility with data from the open ocean. It will also provide the needed scaling laws for the comparison of data from the animal studies with diver experiments.

It is likely that the lungs have at least one resonance close to the band of interest. At this frequency the lungs may be the organs most susceptible to damage and thus define the threshold. It is also possible that excessive pressures and velocities produced by scattering from the lungs causes a lowering of thresholds dictated by other damage mechanisms at or near lung resonance frequencies.

Current Guidance

The Navy currently provides guidance to military divers for 160-320 Hz, 3-6kHz and >30kHz. The low frequency region between 160 - 320 Hz is covered by NAVSUBMEDRSCHLAB (1995), ltr 3900 Ser 01/1016 of 4 Oct 95. NAVSEAINST 3150.2 "Safe Diving Distances from Transmitting Sonar" covers the 3- 6kHz and >30kHz frequency region. For the 3-6 kHz range, this guidance is based primarily on results of underwater hearing experiments, and gives little consideration to non-auditory effects (Smith et al., 1970; Smith, 1984). For exposures above 30 kHz, the guidance stems largely from the extensive literature pertaining to the bioeffects of ultrasound (NCRP, 1983; 1992). A model based on a similar theoretical knowledge base for exposure to low frequency (<2.5 kHz) sonar does not exist. A further limitation to understanding the bioeffects of low frequency waterborne sound is the narrow frequency range (160-320 Hz) covered by the NAVSUBMEDRSCHLAB guidance.

Human Studies in Water

The results of human studies, in general, reveal that non-impulse, water borne sound within the narrow frequency range of 160-320 Hz, limited to 100 second pulses, a 50% duty cycle (sound on for 50% of the time in a given period), and 160 dB SPL (all sound pressure levels (SPL) are given in dB referenced to 1 μ Pascal), can be expected to be well tolerated and not result in

significant harm to an exposed diver (Rogers et al., 1994; Verrillo et al., 1994; Steevens et al., 1994A; 1994B; 1995; Russell and Knafelc, 1995; Smith et al., 1994). Human studies using sound beyond these parameters, however, are few and very limited in scope (Nedwell and Parvin, 1994; 1995; Steevens and Smith, 1994C; Smith et al., 1994). Furthermore, isolated reports from these latter studies indicate that significant diver compromise may result when exposures exceed the above parameters.

Specifically, during two prolonged continuous exposures (15 minutes), one using a 240 ± 80 Hz warble tone at 160 dB SPL (Steevens and Smith, 1994C), and the other using a 1000 ± 50 Hz warble tone at 181 dB SPL (Smith et al., 1994), the divers being exposed exhibited symptoms which could be considered compromising to their health. In both cases the symptomatology was consistent with sound induced central nervous system and/or vestibular system effects.

The first case involved a healthy 32 year old diver who reported light-headedness, dizziness, lethargy, vibration in the extremities and blurring of vision. He also reported a sensation of being pulled toward the sound source and was described by the investigators as being incoherent while experiencing these symptoms. Months after the exposure he continued to complain of irritability, memory impairment and insomnia. Sixteen months post exposure he presented to an emergency department with symptoms consistent with a complex partial seizure and is currently receiving anti-seizure medications.

The second case involved a 39 year old diver who completed his exposure without apparent incident, but seemed agitated during the post-dive interview. Upon questioning, he reported the sensation of vibration ("brain and teeth") and weeks later continued to report sensitivity to noise, increased irritability and inability to concentrate on tasks (Steevens et al., 1996).

Lung Vibration and Low Frequency Sound

Previous studies (Parvin, 1994) have sought to characterize the motion of lungs in response to low frequency underwater

sound. In these studies, strong indications were found that the lung resonates below 100 Hz and also in the range of 100 Hz to 200 Hz. The higher of these two resonances was observed most strongly with divers whose heads were not submerged. The former has not been measured directly. Even off resonance the displacements of lung tissue were found to be at least an order of magnitude higher than particle displacements in the surrounding fluid.

In the simplest analysis, the lungs may be considered to be a single compliant object whose stiffness is governed by the fixed volume of air contained within them. They are driven by the oscillating pressure of the low frequency acoustic stimulus and their motion is mediated by the radiation loading of the surrounding fluid (radiation mass and radiation resistance). If one imposes the additional simplification of assuming a virtually spherical geometry then the first and only lung resonance would be expected to occur between 50 and 100 Hz and to be predicted by the equation:

$$f_n = \frac{1}{d_{lung}} \sqrt{\frac{3\gamma_{air} P_{ambient}}{\pi^2 \rho_{water}}}$$

Where γ_{air} is the ratio of specific heats for the entrained gas in the lungs (about 1.4 for air), $P_{ambient}$ is the ambient static pressure, ρ is the density of the subscripted quantity, and d_{lung} is the lung diameter.

In this analysis the lung response is identical to that of a single degree of freedom harmonic oscillator with mass, stiffness, and damping as follows:

$$M_{rad} = 3\rho_{water} V_{lung}$$

The radiation mass load on a spherical lung:

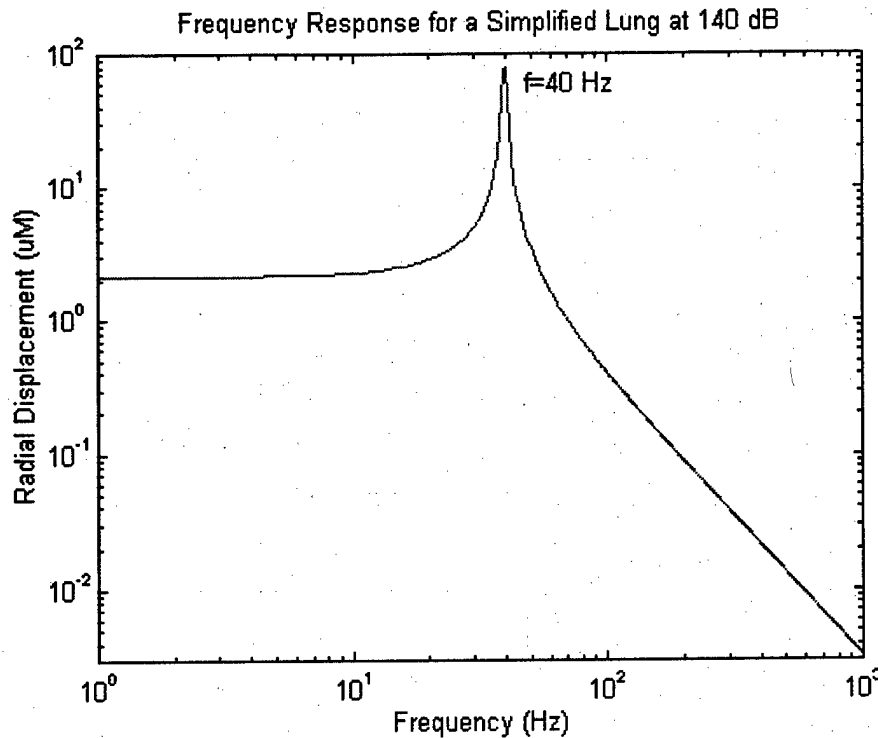
$$K_{lung} = \rho_{air} c_{air}^2 \frac{A_{lung}^2}{V_{lung}}$$

The stiffness of confined gas in a lung of any shape undergoing small uniform oscillation is:

$$R_{rad} = \frac{\pi \rho_{water} f^2 A_{lung}^2}{c_{water}}$$

The equivalent resistance of the radiated acoustic energy for a lung which is much smaller than a wavelength in the surrounding medium. Where A_{lung} and V_{lung} are the surface area and volume of the lung, ρ is the density of the subscripted medium, and c is the adiabatic speed of sound of the subscripted quantity. The resonance frequency of this system is determined from the square root of the ratio of K/M which gives the same result shown in the previous equation. The specific heat ratio is related to the sound speed and the gas density relates to the ambient pressure. The relative magnitude or sharpness (defined as Q) of the resonance is inversely related to R .

For a lung that could be described by these simplified assumptions, the frequency response curve shows a single resonance, a flat displacement response below resonance, and a 12 dB/octave rolloff (flat acceleration) above resonance. The predicted frequency response for such a spherical lung exposed at a sound pressure level of 140 dB is shown below:



This approximation is a reasonable baseline for the design of this experiment and is very loosely in agreement with the data which currently exists. Unfortunately, the reality of lung motion is considerably more complicated and less well understood than this. The actual lungs are two coupled systems each with many degrees of freedom. The stiffness of the lungs is considerably less than that assumed because of their non-spherical geometry. It is, however, probably increased by the presence of the chest wall and ribs. The radiation damping is augmented by losses in body tissues and air, and blood flow in peripheral structures. It is uncertain which mechanism provides the dominant mode of damping for lung vibration. The radiation mass is highly shape dependent and cannot be accurately predicted for a complicated geometry like a lung. It could easily vary by a factor of 2 or more from that predicted by an assumption of sphericity. This would be the case if the lungs were well constrained by the rib cage and moving in a piston like manner toward the abdomen. To date, an analytical model which accurately accounts for these factors has not been developed.

Since an accurate analytical model is not available, it is necessary to perform direct measurements on human lungs to determine their response to ULFS. Data obtained from these measurements should be useful in determining the requisite complexity for a predictive model as well as providing a base of input data.

Perceptual Responses to ULFS

Previous studies [Parvin 1994] have been concerned with the sensations experienced by divers exposed to ULFS. Since the intent of the current study is the determination of a specific physical characteristic of the lungs (their displacement frequency response) no perceptual data will be recorded. Sound exposures will be of sufficiently small amplitudes and short duration (<140 dB SPL, <2 Sec, <10% duty cycle) that subjects may feel no sensation at all and should not experience any discomfort, although they will hear the sound. Any unusual reports of sensation will be recorded and investigated.

Animal Studies

Non-human studies offer the advantage of being able to determine damage thresholds directly without having to rely on extrapolation. Unfortunately, animal studies to determine damage risk thresholds of key organ systems are only now getting underway.

Published data involving ULFS and animals are limited to two small studies on immersed pigs (Percy and Duykers reported in Smith and Hunter, 1979; Lehner, 1994). In both efforts only a narrow band of low frequency sound was used (40-70 Hz and 100-400 Hz), and sound pressure levels were limited by the capacity of their transducers (no exposures above 177 dB SPL). In addition, neither study incorporated adequate controls so that effects observed could be attributed with any degree of certainty to the sound exposures.

Current studies involve the use of rodent models. Extrapolation of data from these studies requires a clear

understanding of the relevant scaling factors. Lung response is certainly one of these factors and may well be the most significant. Thus, although animal data which would be relevant to the planning of this experiment is not currently available, the proposed experiment will have considerable relevance for the planning of future animal research and for the interpretation of animal data for human threshold estimation.

Currently the only damage attributable to ULFS which has been produced in rodents (lung hemorrhage) required continuous exposure levels in excess of 180 dB SPL near resonance for several minutes [Dalecki, 1998 ongoing]. The present experiment will involve exposure levels which are 40 dB (a factor of 100) below this and an exposure duration of less than 1 second.

Summary of Current Understanding

To summarize, very little data exists to predict the neurological, psychological and physiological response of the scuba diver to underwater low frequency sound. Evidence exists, however, that significant diver compromise may result from inadvertent exposure. The proposed protocol will help validate our theory that lung response is a significant factor in the determination of tolerance thresholds.

2. Objectives

a. Hypotheses to be tested:

i) Low frequency waterborne sound, over the intensity range of 130-140 dB SPL, will generate measurable displacements in the lungs of divers, in the frequency range of 10-1250 Hz.

ii) Measurable lung resonances exist in the frequency range of 10-1250 Hz.

iii) The frequency response of the lungs will undergo a measurable change with changes in ambient pressure.

b. Specific Objectives:

Objective 1: Determine the displacement frequency response of a point on the lung in the presence of ULFS.

Objective 2: Measure the displacement response from at least 3 different aspects to qualify the modes of lung vibration.

Objective 3: Measure the displacement response at three different ambient pressures.

VI. EXPERIMENTAL METHODS

1. Experimental Procedures and Rationale

Human Subjects

Ten currently qualified military divers will be recruited from the estimated 40 - 50 divers at the Groton Submarine Base. Additional divers from commands in the northeast could be recruited if required. All divers will be given a detailed pre and post dive neurological exam, and pre and post-audiogram testing.

Overview of Experimental Design

In order to simulate open water low frequency sound exposures at multiple depths, a controlled environment is desirable for optimal safety of participants. To accurately define control exposure variables and record effects, the following are necessary:

1. Non-resonant test tank of adequate volume with variable depth capabilities and signal generation capabilities.
2. An organized, efficient approach to sound delivery to accurately and quickly identify resonant frequencies and thoroughly span the frequency range of interest.
3. A simultaneous measure of exposure pressure and surface displacement from which lung compliance can be computed.
4. A quasi-real time data viewing capability that will allow

quick verification of the function of the measurement system.

Test Tank, Apparatus, and Required Sound Equipment

The experimental testing will be done in an 1,100 gallon test pool assembled inside the Genesis hyperbaric chamber at NSMRL. A four-sided aluminum pool with no parallel walls has been constructed to fit in the chamber. The walls, floor and mounting brackets are acoustically dampened with rubber and/or foam padding to reduce reflection of incident waves. These design specifications are necessary to simulate, as close as possible, free field conditions (i.e. open water) in a controlled setting. The dimensions are such that the pool is less than $1/2$ the signal wavelength at frequencies below 500 Hz. Acoustic testing across the frequencies of interest reveal a flat frequency response from 50-1250 Hz with the exception of a tank resonance at 950 Hz. Data taken at frequencies near 950 Hz will probably be invalid as a consequence of this. Interpolation will be used to cover this frequency range. No lung resonances are expected to occur close to 950 Hz.

It is difficult to invoke the desired measurements in a tank of this size. In addition to the potential for structural resonance, the standing wave field in the tank will introduce an inappropriate pressure-velocity relationship in the acoustic field and will alter the radiation loading from the free field condition. Construction of a larger tank is not practical. Basic assumptions regarding the physics of the situation can be used to translate the frequency response measured in the tank into an actual free field frequency response. If the lungs behave quite nearly as a one degree of freedom system then this should work well. The method is, however, contingent on the complexity of the vibration which is observed.

The test apparatus will consist of signal generation equipment (an Analogic 2020 waveform synthesizer and an Instruments Inc L6 power amplifier), two sound projectors (both USRD type J-11 transducers), two monitoring hydrophones connected to a data acquisition system and a waterproof display box fitted

with an oscilloscope screen. Similar equipment has been used in previous studies conducted by NSMRL personnel including the underwater display. The transducers will be suspended from opposite ends of the pool and face toward the diver. The diver will be located midway between the two transducers which will be 18 inches from the surface of the divers chest at the depth of his sternum. The transducers will incorporate a safety cutout at 151 dB SPL (a hydrophone located in front of one transducer will serve as the monitor). Drive signals for the two transducers will be chosen based on the results of experiments on inanimate objects for the closest possible approximation of free field conditions at the divers lung location.

The diver will sit on a chair made entirely of nylon webbing, hung from the chamber ceiling by ropes. The chair will be fixed into position via ropes and weight such that no direct contact will exist between the chair and either the walls or the floor of the tank.

The diver will use a weight belt placed over his lap in order to overcome buoyancy and rest on the chair. The diver will not be physically attached to the chair and can simply stand up to remove his head from the water (the pool is 5 feet deep).

Sound Delivery Approach

Since all of the planned measurements are objective measurements of a linear transfer function (the displacement response of the lungs), it is not necessary that the incident sound be presented in any particular order or with any particular pulse shape. Provided that it contains sufficient energy over the entire band of interest a single pulse should be sufficient for all measurements and is likely to be the least time consuming way in which to present the stimulus. This pulse will be designed experimentally in the test tank. Ring down time in the tank, sensitivity of the measurement system, and length of the available data record will be used to determine signal shape. A 0.5-1.0 second windowed frequency modulated chirp will be used. If a single chirp does not have sufficient energy over the entire

band two or three similar signals within that 0.5- 1.0 second time frame (each with different spectral content) will be used.

Vibration Recording Strategy

The demodulated NIVAMS signal and the outputs of the two chest hydrophones will be recorded digitally for later analysis. All data records will be triggered simultaneously off of the signal source and last for at least -20 dB of ring down in the coupled diver-tank system. When the digital demodulation scheme is employed for the NIVAMS system then the data record will contain the carrier signal. When the analog scheme is employed then periodic measurements of the carrier signal will be made manually and recorded for system calibration purposes (see section on Demodulation scheme below for clarification).

All data files will be tagged with the time and date at which they were recorded and this information will later be cross referenced with written notes to determine subject, aspect, and ambient conditions.

The following depths will be used: surface head in (chest at 3FSW), 3ATM (chest at 66 FSW) and 5 ATM (chest at 132 FSW). Three lung position measurements will be made: right (between ribs 6 and 7, mid axillary line), middle (just right of sternal angle) and left (between ribs 6 and 7, mid axillary line). Three trials at each depth and each position will take place per diver. These range of depths will necessitate two types of dives. The first will consist of right, middle and left measurements at the surface then chamber travel to 66 FSW for repetition of measures. The second will measure right, middle and left measurements at 132 FSW only. Therefore 2 dive types x 3 trials = 6 total dives per diver x 10 divers for 60 total dives under this protocol. The total number of measurements will be 3 positions x 3 depths x 3 trials for 27 measurements per diver x 10 divers for 270 measurements.

Each measurement will take up to 5 minutes to adequately position NIVAMS so that the lung surface is targeted, and up to 1 minute to get the reading. The first dive type (surface + 66

FSW) will take approximately (3 positions x 2 depths x 6 minutes) + 2 minutes of travel time = 38 minutes and will therefore not require decompression time. The second dive type will take approximately (3 positions x 6 minutes) + 3 minutes of travel for 21 minutes. This dive will require decompression which will be conducted IAW Standard Air Table, US Navy Diving Manual.

The first 2 days of the study will involve NIVAMS training for all subjects. This will consist of each diver standing (head out) in the tank and practicing placement of the NIVAMS device at the three locations. The subjects will be trained to recognize the signal (from a handheld waterproof oscilloscope screen) that indicates targeting of the lung surface by the transmitting and receiving transducers. In past studies conducted by the principal investigator using NIVAMS, all divers were able to learn this process fairly rapidly. Having the subjects view the signal underwater and make the adjustments resulted in considerably less time wasted acquiring the signal. Topside investigators will also view the signal on another oscilloscope to verify placement.

Dive specifics are located in the attached dive protocol (see appendix E) including a step by step outline of a typical experimental dive proposed in this protocol.

Description of Vibration Measuring Device and Its Use

NIVAMS uses ultrasound to measure, in vivo, the vibration of tissues and organs induced by low frequency underwater sound (Cox and Rogers, 1987). NIVAMS is non-invasive (no surgery is required to make the measurement) and it is non-intrusive (i.e. the vibrational response is unaltered by the measurement process). This technique has been previously used to characterize the vibrational response of the swimbladders of fish (Lewis and Rogers, 1996), and the lungs of a large animal model and human subjects (Rogers et al., 1996).

NIVAMS consists of two subsystems: the ultrasonic transmitter and receiver, and low frequency source (in this case

the J-11s). The low frequency source drives the motion of the organ or structure of interest. The Transmitter ensonifies this surface with a 1 to 20 MHz CW (carrier wave) ultrasound signal. Frequency selection is a function of specific application requirements such as the range, the loss in transmission, and the size of the target. A transmit frequency of 1 MHz is likely to be the most effective for this experiment. The receiver transduces the reflected ultrasonic signal. Its output can be viewed on a spectrum analyzer, on an oscilloscope, or fed into a demodulator and viewed as displacement on an oscilloscope. Both the transmitter and receiver are held in a fixture such that their beams cross 1- 3 inches away from the transducers. This distance is adjusted depending on the depth within the subject of the target of interest. Both transducers are supported on a manual positioner so the focal region may be adjusted to coincide with the vibrating surface.

The low frequency motion of the vibrating surface causes a phase modulation in the reflected ultrasound signal. This shifts energy into side bands at the carrier frequency \pm the low frequency stimulus i.e. if the transmitted ultrasound signal is 1 MHz, and the ULFS source is vibrating the lung at 100 Hz, then the receiver will read alternating side band signals of 999,900 Hz and 1,000,100 Hz at the vibrating lung surface. The displacement of the vibrating surface is directly related to the side band amplitude relative to the carrier. Demodulation of the reflected signal provides a real time measure of the surface displacement. In other words, a computer will automatically convert these signals into something immediately recognizable such as displacement as a function of time graphs.

The system can also be operated in pulse mode and the received signal viewed directly. This is done to classify the source of the reflection from the time delay and inversion (in the case of a compliant scatterer such as a lung) associated with the received signal. It provides the operator the ability to maximize the content of the reflected signal which is contributed from the surface of interest. Since the lung constitutes a

strong reflector this will not be a difficult task.

Signal demodulation

In past experiments NIVAMS data was recorded directly from a spectrum analyzer. A problem with this scheme was that it permitted only a sparse sampling within the excitation frequency domain and required substantial time, both during and between measurements, during which the measured quantity could change. A typical sequence required 30 seconds to sample an excitation frequency and 30 additional seconds to record that sampling. Two real time demodulation schemes will be used to overcome these limitations in the current experiment. One of these is an analog scheme involving a 100 KHz phase locked loop (PLL) and a 1-0.9 MHz mixer. The other is a digital demodulation scheme involving a PC with a 250 MHz Gage A to D card. Both schemes will be employed in this experiment due to unique advantages of each. The majority of the data will be taken using the PLL because it is a less memory intensive system. The digital scheme will be used primarily as a backup and as a calibration check because it is an inherently self-calibrating system.

Rationale/Research Transition Plan

An immediate application of this research is to modify or expand the current interim protocol regarding low-frequency sound. Past work has involved close cooperation with NAVSEA 00C32 regarding guidance for diver safety in the presence of sonar. The recent revisions and addition of the interim low-frequency guidance to NAVSEAINST 3150.2, were done by the Co-Principal Investigator in collaboration with NAVSEA. This cooperation will insure that any guidance modifications will be quickly transmitted to the appropriate operational units.

It is anticipated that this study will also serve as the basis for defining additional research in this area. The additional research will be required in order to develop the kind of model needed by the Navy to provide a much more broad based guidance for operation of low-frequency sonar and to meet

environmental concerns regarding civilian and marine mammal exposure to sonar. There are several potential areas to follow on research. One of these would be the development of a realistic predictive model for lung response which accounts for individual parameters such as body mass, gender, age, and lung volume. Another is the determination of the frequency response of other air filled cavities such as the sinuses and the G.I. system. A less straight forward task is the measurement of non-damaging transient effects on mechanisms like mucus clearing and oxygen absorption in the lungs which could impair divers' work performance during prolonged exposures.

2. Sample Size Determination with Statistical Power Calculation

Because of logistical and time constraints, the maximum workable number of subjects is 10. Each subject will act as his or her own control in a repeated measures experimental design. Since multiple physical measurements will be obtained under conditions where normal variability within individual subjects is not known, statistical power calculations are difficult to make. One could take several approaches to such a calculation.

If a level of certainty were required for the causal link between the excitation signal and the resultant motion then this could be made almost arbitrarily large by an increase in the drive signal and a repetition of measurements on any single individual. A measure of the signal to noise ratio is a more appropriate representation of this sort of statistical certainty. It is completely independent of the number of subjects chosen.

If a level of certainty is required for the existence of resonance then it will be a function of the number of measurements made and the Q of the resonance studied rather than of the number of subjects. A very low Q resonance might be difficult to find but is of very little interest for the purposes of this study. There is no way for such a resonance to have a substantial impact on a subject's tolerance threshold.

A particular resonance such as the fundamental (or breathing

mode) is certain to shift in frequency based on the physical parameters of the subjects being studied. The extent of these shifts is one of the parameters of interest. The group under study will certainly exhibit a narrower range of resonances than a random sampling of 10 from the overall population because factors like advanced age, ill health, and obesity will be screened from the test group. Any apparent link between the frequency of a resonance and a particular parameter (such as body mass or age) of a subject will need to be determined in a later study where a test group that covers a wider range of the parameter of interest can be chosen.

The only portion of this experiment for which a statistical significance test is relevant, and can reasonably be performed, is the depth dependence of lung resonance study. The question being addressed here is: Does the fundamental lung resonance frequency change as a function of depth? The model proposed earlier would suggest that it does, but this model has not been validated experimentally. There is a competing model (one in which the lung behaves as a Helmholtz resonator) which asserts that there is no depth dependence.

To estimate the smallest change of concern we can look at the span of estimates for the fundamental frequency. These range from around 30 to 40 Hz as represented by the earlier simplified calculation to subjective observations of roughly 70 Hz (Parvin, 1994). If the worst case is assumed, then the difference between these two numbers can be attributed entirely to the added stiffness of the chest wall. If the added stiffness triples the resonance frequency, compared to a sphere with the same volume, then 89% of the lung stiffness is introduced by the chest wall and 11% is introduced by the air inside the lung. This is because the resonance frequency relates to the square root of the stiffness. The contributions of the chest wall should be depth independent since the diver is breathing at ambient pressure. The contribution of the air should go up directly as the pressure (or density) as discussed earlier. Thus, the air spring stiffness will increase by a factor of 3 as the subject is

pressurized to the immediate depth (66 FSW) this would correspond to a 22% change in the overall lung stiffness and a 10% up shift in the resonance frequency.

The person to person variability of lung resonance is likely to be dominated by the variability of lung size. This is not a random variable and can be measured and accounted for. There are, however, several random variables such as transducer alignment, degree of inspiration at the time of measurement, and ambient noise, which must be taken into account. For comparative purposes, the most relevant data is that taken by Lewis (1994) of the resonances of the swim bladders of fish (Oscars) using NIVAMS. When his data is normalized by the cube root of the fish's mass (a linear scaling), there is a 9.5% standard deviation which accounts for both fish to fish variability and the noise and misalignment susceptibility of NIVAMS. This might be indicative of the random person to person variability, which will be observed in the proposed experiment.

Applying these assumptions to the one sided significance criteria following Woolson (1987) for a resonance frequency determination within the desired 10% ($M=0.1$), with a predicted standard deviation of 9.5% ($\sigma = 0.095$) a significance level and statistical power of 9.5% ($=1.644$) can be achieved with 10 subjects as shown below:

$$n = \frac{\sigma^2 (Z_s + Z_p)^2}{M^2}$$

$$n = \frac{0.095^2 (1.644 + 1.644)^2}{0.10^2} = 10 \text{ (approximately)}$$

3. Justification for Exclusion of Specific Groups

Test subjects will consist of healthy male and female, qualified military divers between the ages of 18 and 45. A maximum age of 45 was chosen because it is the maximum age for qualifying as a Navy Diver without a medical waiver. 'Military Diver' is specified because we do not want to exclude recruitment

of potential subjects from other branches of service. We are excluding civilians for the following reasons: ease of recruitment, and our primary variable of interest (lung vibration) should not be influenced by level of training.

4. Required Equipment and Supplies

The following equipment will be used for sound generation and data recording:

2 USRD type J-11 Transducers, 2 Instruments Inc. type L6 Amplifiers, Gage data card, Pentium PC, 3 hydrophones, 3 color video cameras, VCR for documentation, 2 panametrics type A303 Ultrasound transducers, one waterproof box with embedded oscilloscope display

VII. ORGANIZATION OF RESEARCH EFFORT

1. Duties and Responsibilities

A. Investigators/Duties

1. Peter H. Rogers Ph.D., Neely Professor - Georgia Institute of Technology, School of Mechanical Engineering, Atlanta GA., Principal Investigator
-Assist in preparation of Protocol, Supervise experiment, Prepare reports.
2. Edward A. Cudahy - Naval Submarine Medical Research Laboratory, Naval Submarine Base, Groton, CT., Co-Investigator
-Assist in writing protocol, coordination of study and preparing reports.
3. James S. Martin, REII, - Georgia Institute of Technology, School of Mechanical Engineering, Atlanta GA., Key Support Personnel
-Write protocol, setup and operate NIVAMS system during

experiment, Assist in data analysis and preparation of reports.

4. LT Eric L. Hanson, MC, USNR - Naval Submarine Medical Research Laboratory, Naval Submarine Base, Groton, CT., Medical Monitor

-Assist in preparation of protocol, coordinate the medical support for the experiment.

2. Chain of Command

Conduct of the study will be the primary responsibility of Peter Rogers, GA. Tech., Ed Cudahy will help facilitate this protocol as Co-Investigator. His Department Head is Dr. Thomas N. Buell, Ph.D. and his Commanding Officer is CAPT M. Wooster, MSC, USN. The Technical Director of NSMRL is T. Amerson, Ph.D. Mr. Sylvester and Mr. Schwaller will provide acoustic technical support. The Medical Monitor for these experiments will be LT Eric L. Hanson, MC, USNR, from the Naval Submarine Medical Research Laboratory.

VIII. RISKS AND DISCOMFORTS TO RESEARCH VOLUNTEERS

1. Risk to the Volunteer and Means of Mitigation

Diver safety will be the primary concern at all times during the course of this experiment. Although participation in this study is considered to not be of great risk beyond those normally associated with diving and chamber use, if any injury occurs as a result of participation, medical treatment will be readily available through the existing military health care system. Under no circumstances will medical treatment be withheld for any reason because of participation in this study.

a. Risks Related to Underwater Sound and Means of Mitigation (non-Auditory)

The result of human studies, in general, reveal that non-impulse water borne sound within the narrow frequency range of 160-320 Hz, limited to 100 second pulses, a 50% duty cycle, and 160 dB SPL can be expected to be well tolerated and not result in significant harm to an exposed diver (Rogers et al., 1994; Verrillo et al., 1994; Steevens et al., 1994A; 1994B; 1995; Russell and Knafelc, 1995; Smith et al., 1994). Human studies outside of these parameters, however, are few and very limited in scope (Nedwell and Parvin, 1994; 1995; Steevens and Smith, 1994C; Smith et al., 1994). Furthermore, isolated reports from these latter studies indicate that significant diver compromise may result when exposures exceed the above parameters. Specifically, during two prolonged continuous exposures (15 minutes), one using a 240 +/- 80 Hz warble tone at 160 dB SPL (Steevens and Smith, 1994C), and the other using a 1000 +/- 50 Hz warble tone at 181 dB SPL (Smith et al., 1994), the divers exhibited symptoms which could be considered compromising to health and safety in an operational setting. In both cases, the symptoms were consistent with sound induced central nervous system and/or vestibular system effects. A recent study (Russell, Knafelc, 1995) using exposure frequencies from 160 to 320 Hz and intensity levels up to 160 dB SPL, reported no events during the series that compromised a diver's health or safety. Of the 156 manned dives however, 5 were terminated prematurely because the divers felt the sound was too loud or irritating.

By design, our study will include exposure SPLs up to 140 dB only. Of reported episodes where a diver's safety was questioned and the sound characteristics were known (see above), both had intensity levels significantly above 140 dB. In addition, one diver in the open sea reported numbness for 2 hours after an unknown exposure. All three of these subjects recovered without any measurable persistent abnormalities. Previous experiments involving water-borne sound exposure at the frequency range and intensity levels being proposed indicate:

- exposures totaling over 90 dives (15 subjects x 6 dives each) nearly identical to those proposed resulted in no adverse

consequences (FY97 work done by investigators Hanson and Cudahy, unpublished)

- that four minute exposures to continuous warble tones at 250 Hz (+/- 25 Hz) produced no effects on hearing for exposure levels up to 161 dB (Smith et al., 1994)

- that exposures to LFA at frequency range from 15-1000 Hz up to 160 dB re 1 μ Pa for up to 30 minute durations resulted in no reported significant diver discomfort (Nedwell and Parvin, 1993)

- that divers (n=22) whose torsos were intermittently exposed to 250 Hz (+/- 25 Hz) warble tones for a total of 15 minutes at levels up to 160 dB experienced no significant measurable effects on performance or vital organ function (Stevens, 1994A)

- that although subjects felt vibrations at 130 dB and higher, they were tolerable and no after effects were noted (experiments at NEDU, n=18, Roosevelt Roads n=19 and NSMRL, n=22) (Steevens, et al. 1994A) (Steevens, et al. 1994B)

To minimize the risk due to sound exposure while maintaining the objectives of the study, continuous exposure duration to any given frequency will not be used. No exposure will last longer than 5 seconds with at least 60 seconds of no noise in between exposures.

At a maximum of 140 dB SPL, all exposures will be significantly below those found to be problematic in previous studies. In addition, visual and verbal contact will be maintained with the diver at all times to detect and prevent harm as early as possible. Any evidence that the diver is compromised will lead to immediate termination of the sound exposure and recovery of the diver. The subject may also signal termination of the sound exposure, and abort a dive at any time.

b. Risks Related to Underwater Sound and Means of Mitigation (Auditory)

Standards exist for limitation of exposure to underwater sound to avoid damage to the auditory system (Smith, 1983). This study can be done at levels 20 dB below current promulgated

guidance because the derived measure is the displacement frequency response of the lung and this system should be linear for the exposure levels of interest.

To ensure that delivered sound does not exceed desired levels, the transducer is supplied with a Supplemental Fail-Safe Cutoff (SFC). Placed between the Auto-Level Controller's (ALC) output and the power amplifier's input jack, the purpose of the SFC is to reduce the power amplifier's input to zero and sound an audible alarm if an excessive SPL is detected. Thus two systems exist (the ALC and SFC) to ensure our divers are not exposed to greater than 151 dB SPL. In the extremely unlikely event that 151 dB is exceeded, sound exposure will be terminated, the diver recovered, and an audiogram will be performed. Any temporary threshold shifts (TTS) will be resolved before the subject is allowed to continue.

c. Risks Related to ultrasound exposure and Means of Mitigation

Ultrasound exposures are required for the NIVAMS system which will be used in this experiment. The signals to which subjects will be exposed will be continuous wave 1 MHz signals with peak pressure levels below 20 KPa (206 dB). In this frequency range, tissue damage which has been reported in the literature occurs as a result of cavitation (Child 1990). This phenomenon cannot occur at peak acoustic levels of less than 220 dB SPL. Past NIVAMS work on animals showed no lung damage resulting from the ultrasound exposure. In past NIVAMS work on human subjects there were no reports of discomfort or perceptible sensations as a result of the ultrasound exposure. The accepted standard for safe energy density exposure to diagnostic biomedical ultrasound at 1 MHz is 100 mW/cm² (AIUM/NEMA 1983). Therapeutic ultrasound exposures can be much higher. For this experiment the exposures will be less than 27 mW/cm². If subjects report discomfort due to the ultrasound exposure, the exposure will be discontinued. Inadvertent exposure to levels

significantly higher than those intended is precluded by the physical limitations of the ultrasonic transducers which will be used. A detailed pre and post dive neurological exam will be given.

d. Risks Related to Diving and Chamber Operations and Means of Mitigation

The risks of this research include those risks of diving and chamber operations known to the diver-subjects secondary to their certification and experience as professional military divers. These risks include:

- There may be damage to the ears, sinuses, lungs or any enclosed air-filled space in the body during compression or decompression.

- During ascent to the surface there may be tissue damage with the passage of bubbles into the circulation (arterial gas embolism) that can cause damage to any organ, including the brain.

- Decompression sickness, as manifested in joint or lymph node pain, skin marbling, or neurological symptoms may follow any ascent from a deeper to a shallower depth.

- Other known risks include the risk of contamination of the breathing gas, failure of life support systems, risk of hypercapnia, oxygen toxicity, hypoxia, mechanical injuries from equipment, and finally the risk of drowning.

All procedures related to diving and dive operations will follow the USN Diving Manual (NAVSEA 0994-LP-001-9010 and 0994-LP-001-9020 revision 3) and are explained in detail in Appendix E (Dive Protocol).

The chamber was chosen as the test site because of the advantages of working in a controlled environment. These advantages include ability to better specify the exact signal delivered to the test subject, excellent control of pressurization, and better monitoring of the subject. Furthermore, key staff and equipment can be maintained on site,

which reduces travel costs, provides continuous monitoring of the experiment and quick turnaround on any experimental issues that may arise.

A Diving Medical Officer will be on site at all times during exposures to assist in the evaluation and treatment of subjects as a result of any untoward events or injuries. Emergency procedures will be conducted in accordance with the USN Diving Manual. All dive support personnel will have been trained in these procedures. Review of the emergency procedures will be conducted by the diving supervisor on site prior to initiation of diving. The chamber in use for this study will also serve as a treatment chamber should the need arise for HBO therapy. Naval Ambulatory Care Center is located within 5 minutes of the chamber. Medevac and/or ambulance service are available and will be instituted according to local emergency medical procedures.

The risks associated with diving will be further minimized by using only fully qualified military divers as subjects, tenders and safety divers.

e. Risk of Electrical Shock and Means of Mitigation

The risk of electrical shock from sound transducer and associated equipment is minimal since the diver is not directly in the current's path. Even in the unlikely event that a cable is cut, the circuit is protected with a ground fault interrupt to automatically shut off the current. Additionally, all 110 volt power sources are located outside the chamber; the maximum power in the chamber is in the transducers at 1 amp and 20 volts. The hand held oscilloscope display will carry a maximum of 1 amp at 12 Volts. These concepts will be explained in greater detail under the Safety Precautions section.

f. Risk of exciting resonances in the tank or the coupled diver-tank system

A serious issue for testing at low frequencies in an enclosed space is possibility of exciting cavity resonances and

generating excessive pressure levels at the subject. It is possible, under a resonant condition and excessive sound levels, for very high pressures to exist in regions close to relatively low pressures (i.e. nodes and antinodes). Therefore, a subject could be exposed to excessive sound pressure levels while the hydrophones record acceptable levels. Since the equivalent exposure of the lung is not represented by the pressure at the lung because the lung unloads the surrounding pressure field, it is not possible to select a hydrophone location that would permit one to monitor an exposure accurately under such a resonant condition. Moreover, since the tank is relatively small and the diver constitutes a significant disturbance in the tank as well as the dominant compliance in the coupled diver-tank system, resonances may exist with the diver present that can not be predicted from the field measure in the diver's absence. One strategy for dealing with this is to use a pulse with a relatively short duration. Thus the energy transferred to any resonant oscillations will be spread out in time rather than build to a large, and potentially dangerous, amplitude. A good analogy for this would be to consider the impulse response of an undamped oscillator. This system will move perpetually at its resonance frequency with a finite amplitude and no damage to itself. The same system, if it were excited continuously at resonance, would undergo unbounded oscillations and fail. The other strategy is to use low intensities of sound (140 dB SPL). Both strategies are being employed here.

g. Risk of Chamber Fire and Means of Mitigation

As with any chamber operation, the risk of a spark causing a fire exists and increases with depth assuming a hyperbaric chamber pressed with air (21%O₂/79%N₂). Minimal combustible materials will be introduced into the chamber. Virtually all testing materials to be used inside Genesis are constructed of non-flammable metals. The diver, the dive gear and the acoustic dampening panels will be totally immersed in approximately five feet of water and will therefore pose no fire hazard. The tender

will wear only chamber approved static free clothing.

2. Special Risks to Pregnant or Potentially Pregnant Women Volunteers

All women divers receive frequent counseling (NAVMEDCOMINST 6200.2) regarding the potential health hazards of diving to developing fetuses. Accordingly, if signs of pregnancy exist, they are required to present themselves to medical personnel and refrain from diving. Since our study also involves sound exposure, we will add the following additional precautions to ensure no fetal or embryo exposure occurs: a urine pregnancy test will be administered on day one prior to testing, and female subjects will again receive counseling as specified in the above instruction. Positive tests result in exclusion.

3. Safety Precautions and Emergency Procedures

The following electrical safety features will be maintained to protect subject participants:

- Power sources for the J-11 transducers, NIVAMS measuring devices, and the hydrophones will be located outside the chamber. The current carried through any in-water cables will be in the milliamp range. Specifically, NIVAMS carries a maximum current of 16 milliamps and a power of 60 milliwatts in the cable supplying the signal to the transmitter. The electrical signal generated by the receiver is at least an order of magnitude less. Maximum current for the chamber will be in the transducer circuit at 1 Amp at 20 Volts. To place this in perspective, divers routinely use 300-400 Amp underwater welders.

- All circuits will be connected to ground fault interrupts. These sense the difference between the wire carrying electricity and the ground wire; if a difference of 5 milliamps or more is detected then the circuit is shut off automatically. In the unlikely event that a wire is cut (there will be no sharp edges on the tank or diver apparatus), the ground fault interrupt

shuts off the current.

-All equipment in contact with the water is designed to be water proof and has been used safely in previous aquatic experiments.

-All electrical wiring installed in the chamber will comply with the requirements of NFPA 70, National Electrical Code, Article 500, Class 1 Division 1. In other words, it will be approved for use in Class 1, Group C atmospheres at the maximum proposed pressure and oxygen concentrations in our experiment.

All chamber diving operations are done in accordance with existing diving practice as described in the attached dive protocol (appendix E) and the USN Diving Manual. For more discussion on safety precautions, see previous section 'Risks and Discomforts to Research Volunteers.'

4. Assessment of Sufficiency of Plans to Deal With Untoward Events or Injuries.

The diving operations will take place inside a fully manned recompression chamber. Should the need arise for HBO therapy, the diver (and a qualified tender) are where they need to be. A backup chamber is located on site at NSMRL and another within a quarter mile at The Escape Trainer, SUBSCOL, Naval Submarine Base. A qualified Diving Medical Officer will be chamber-side during all diving procedures. The Naval Ambulatory Care Center is located within 1 mile by ambulance should the need arise for non-hyperbaric medical care.

5. Qualification of Medical Monitor and Medical Support Personnel

The medical monitor for these experiments will be NSMRL's LT Eric Hanson, MC, USNR. LT Hanson is a qualified Diving Medical Officer. He will serve as an independent medical consultant available to help subjects with any questions or problems arising during testing.

IXa. DESCRIPTION OF THE SYSTEM FOR MAINTENANCE OF RECORDS

1. Experimental Data:

The following data will be obtained: NIVAMS measurements of lung displacement as time histories taken at several locations under a variety of conditions. Study data will be coded and stored at the Naval Submarine Medical Research Laboratory and at Georgia Tech. It is available only to the researchers involved in this work unit and other official purposes at the discretion of C.O., NSMRL.

2. Research Protocol, Consent Forms, and Related Documents for Protection of Human Research Volunteers:

The confidentiality of all records that pertain to an individual subject will be maintained, including the research protocol, consent forms, and related documents for protection of human research volunteers. Specifically, the experimental data will be stored on computer and hard copy files, and will not be available to the subjects or their commands directly. None of this data will be entered into the subjects medical records. These records are maintained by the Principal Investigator and Co-Investigator.

3. Individual Medical Records:

Individual medical records will be maintained by the medical monitor during the course of the study. They will be available at the test site during actual testing. Health record entries will be made for each subject and include a brief description of the experiment, dates of exposure, any medical treatment provided, and the status of the subject upon completion of the study. Medical records will be returned to the subjects at the conclusion of their participation.

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APPENDICES

A. Sample of Consent Document and Privacy Act Statement Used

Measurement of Lung Vibration From Low Frequency Underwater Sound in Divers

VOLUNTARY CONSENT TO PARTICIPATE

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1. DESCRIPTION OF PROCEDURES:

You are being asked to volunteer in a research study at the Naval Submarine Medical Research Laboratory entitled ~~Measurement of Lung Vibration From Low Frequency Underwater Sound in Divers~~. The purpose of this study is to characterize the physical behavior of the human lung during exposure to underwater low frequency sound. You will be asked to participate in the study for a period of up to 12 working days. During your participation in this study, you will be involved in the following procedures or tests: a comprehensive history with emphasis on diving related illnesses and injuries, a detailed pre and post dive neurological exam, diving and chamber operations consistent with wet-pot evolutions performed by all subjects during dive training, exposure to a wide range of frequencies and intensities of low frequency underwater sound, focused pre and post dive evaluations, and women subjects will receive a urine pregnancy test on day one prior to testing. Of these procedures, the history, neurological exam, wet-pot diving operations, urine pregnancy test, and pre/post dive evaluations are considered routine. Only the exposure to low frequency sound is considered experimental. Exposure will be SPLs up to 140 dB only.

Military Divers may be exposed to low-frequency active sonar transmissions. To provide safe exposure limits, it is

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important to conduct controlled laboratory experiments to determine their effects on the diver. This study is designed to test how the lung vibrates. We will be using an ultrasound base vibration measuring device to detect and measure lung vibration. The system is called NIVAMS (Non-Invasive Vibration Amplitude Measuring System). It uses the same principles as a diagnostic medical ultrasound. You will neither hear nor feel this type of sound. The principal investigator has used this system underwater with divers in the past. You will be trained as part of this protocol to identify on an oscilloscope screen when the device is in the proper position.

During each exposure you will be assisted by a dive and/or chamber qualified tender who will maintain visual contact with you at all times and who can assist you immediately in the unlikely event that a problem should arise. We will also maintain visual and verbal contact with you via a video camera situated over the tank and a scuba communication device.

The following represents a typical dive:

- a) You will enter the GENESIS chamber's inside lock and don a chest harness which you will adjust to be snug fitting and comfortable.
- b) You will step into the test tank and snap a flexible arm supporting two small NIVAMS ultrasound transducers onto the chest harness. (see diagram)
- c) You will don a facemask and a scuba regulator with an ANU scuba communications device.
- d) You will submerge and sit on nylon webbing in the center of the pool between two large acoustic sources (J11s).
- e) A round robin communication check will commence (dive supervisor, tender, and diver).
- f) Your position will be adjusted so that your chest is at the midpoint between the two J11s. When this is completed

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you will be given a verbal 'OK'.

g) You will adjust the position of the NIVAMS transducers on your chest to maximize a signal that will be shown to you on a small display (you will receive instruction and hands on training for this as part of the study). This signal is the NIVAMS output in pulse echo mode. Once the transducers are properly adjusted and confirmed by the investigators, you will be given a verbal 'OK'.

h) You will be asked to hold your breath (for no more than 10 seconds) and give a visual queue that it is held (thumbs up).

i) A brief (< 1 second), audible chirp will be emitted from the J11s and the data will be acquired. The breath hold and measurement together will take no more than 10 seconds.

j) You will be given a verbal queue ('OK') to breathe freely again when the measurement is done or at 10 seconds, whichever comes first. You may breathe freely at any time during that breath hold should you need to; that measurement will just be repeated.

k) At this time you will be asked to move the flexible NIVAMS device to a different portion of your chest. G-J will be repeated at two more locations on your chest for a total of 3 locations per depth (right, left and center).

l) Two dive profiles will be used during this protocol. The first will consist of right, middle and left measurements at the surface then chamber travel to 66 FSW for repetition of measures. The second will measure right, middle, and left measurements at 132 FSW only. Each subject will complete 3 trials of each dive type. Therefore 2 dive types x 3 trials = 6 total dives per diver.

m) Upon completion of the dive, you will remain at the chamber facility for the appropriate clean period.

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The first dive will not require decompression, the second dive will be decompressed according to the Standard Air Decompression Tables, US Navy Dive Manual. You may be asked to complete up to two dives per day under this protocol, one of each profile. You will not have more than one decompression dive per day. All dives will be conducted in accordance with the US Navy Diving Tables.

3. RISKS AND DISCOMFORTS:

The investigators believe that most of the risks and discomforts to you are those consistent with any diving or chamber operation and include:

- Potential damage to the ears, sinuses, lungs or any enclosed air-filled space in the body during compression and decompression.

- During ascent to the surface there may be tissue damage with the passage of bubbles into the circulation (arterial gas embolism) that can cause damage to any organ, including the brain.

- Decompression sickness, as manifested in joint or lymph node pain, skin marbling, or neurological symptoms may follow any ascent from a deeper to a shallower depth.

- Other known risks include the risk of contamination of the breathing gas, failure of life support systems, risk of hypercapnia, oxygen toxicity, hypoxia, mechanical injuries from equipment, and finally the risk of drowning.

Other risks and discomforts unique to underwater sound experiments include:

- Risk of electrical shock from sound transducer and associated equipment. The risk is minimal since the diver is not directly in the current's path. Even in the unlikely event that

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a cable is cut, the circuit is protected with a ground fault interrupt to automatically shut off the current. Additionally, all 110 volt power sources are located outside the chamber; the maximum voltage in the chamber is 1 amp at 20 volts. Divers routinely work with 300-400 amp underwater welders without any harmful effects. In addition all equipment setup and supervision will be reviewed by an electrical engineer with safety the first priority.

-While you can expect to hear and feel some of the sound transmissions used in these experiments, they are not expected to be harmful to you. During underwater low frequency sound studies conducted in the past using much higher sound levels and longer exposures, significant diver injury occurred. Two subjects reported symptoms, both short term and persistent, consistent with neurological injury. One developed a seizure disorder 16 months later. The mechanism of injury is presently unknown. However, the underwater sound that you will be exposed to is $1/6^{\text{th}}$ as intense as those associated with injury. The Navy has conducted hundreds of exposures with the same sound levels without diver incident.

Experimental dives have been voluntarily terminated secondary to annoyance but in all cases the sound levels (loudness) were significantly higher than those you will be exposed to.

-Special Risks to Pregnant or Potentially Pregnant Women
Volunteers:

All women divers receive frequent counseling (NAVMEDCOMINST 6200.2) regarding the potential health hazards of diving to developing fetuses. Accordingly, if signs of pregnancy exist, you are normally required to present yourself to medical personnel and refrain from diving. Since our study also involves sound exposure, we will add the following additional precautions

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to ensure that no fetal or embryo exposure occurs: a urine pregnancy test will be administered to you on day one prior to testing, and you will again receive counseling as specified in the above instruction. A positive test will result in exclusion.

Participation in this study may involve risks to you which cannot be predicted at this time.

3. BENEFITS:

There are no direct benefits to you as a result of your participation in this study. However, the benefits of this research may extend to all Military and recreational divers.

4. ALTERNATIVE PROCEDURES:

If you decide not to participate in this study there are no alternative methods for obtaining the desired information, i.e. the biophysical effects of low frequency sound on divers.

5. CONFIDENTIALITY OF RECORDS

Your confidentiality during the study will be ensured by restricting medical and study information to the study investigators. The confidentiality of the information related to your participation in this study will be assured by not using names or social security numbers in association with study data (i.e. it will be coded).

6. POINT OF CONTACT:

If you have questions about this study you should contact the following individuals: for questions about research or science aspects of the study contact the technical supervisor,

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Mr. JS Martin, REII, at GA Tech 404-894-6794; for questions about medical aspects, injury, or any health or safety questions you have about your or any other volunteer's participation, contact the Medical Monitor, LT EL Hanson, MC, USNR, at NSMRL 860-694-2510; for questions about the ethical aspects of this study, your rights as a volunteer, or any problem related to protection of research volunteers, contact LT R. Jackman, Chair, Naval Submarine Medical Research Laboratory, Committee to Protect Human Subjects at 860-694-2514.

7. VOLUNTARY PARTICIPATION AND DE-VOLUNTEERING

Your participation in this study is completely voluntary. If you do not want to participate, there will be no penalty and you will not lose any benefit to which you are otherwise entitled. You may discontinue your participation in this study at any time you choose. If you do stop, there will be no penalty and you will not lose any benefit to which you are otherwise entitled.

8. MEDICAL TREATMENT

The procedure may involve risks to you that are presently unforeseeable. If injury occurs as a result of your participation as a volunteer in this research project, medical treatment will be available to you. Medical care available to you is through the existing military health care system. You may obtain further information about these issues from LT Jackman, MC, USNR.

9. COMPENSATION

There will be no direct compensation, monetary or otherwise,

for participation in this study.

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10. TERMINATION OF PARTICIPATION

Your participation in this study may be stopped by the researchers or the medical monitor without your consent. At this point, there are no anticipated circumstances that would necessitate termination of a subject's participation in this study without regard to the subject's written consent. If it becomes necessary that you must be removed from this study for any reason, you will be notified by the investigators.

11. ADDITIONAL COSTS TO THE SUBJECT

There are no additional costs to you resulting from your participation in this research.

12. CONSEQUENCES OF VOLUNTARY WITHDRAWAL

If you decide to withdraw from further participation in this study, there will be no harmful penalties to you and withdrawal will be without prejudice. In order to ensure your safe and orderly withdrawal from the study, we ask that you notify the principal investigator as soon as possible. Again, we would like to tell you that you may discontinue your participation in this study at any time you choose and without penalty.

13. MAJOR NEW FINDINGS

Major new findings developed during the course of the research, which may relate to your willingness to continue participation, will be provided to you.

14. OFFICIAL GOVERNMENT AGENCIES

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Official government agencies, such as the Environmental Protection Agency may have a need to inspect the research records from this study, including yours, in order to fulfill their Privacy Act.

15. PRIVACY ACT STATEMENT

You have received a statement informing you about the provisions of the Privacy Act.

16. STORAGE OF RECORDS

You have been informed that the Commanding Officer, Naval Submarine Medical Research Laboratory (NSMRL) is responsible for storage of your consent form and the research records related to your participation in this study. These records are stored at NSMRL, Naval Submarine Base, Groton, CT 06349-5900.

17. QUESTIONS REGARDING RESEARCH .

You have asked the questions on the attached paper entitled 'Subject's Inquiries', and the written answers provided by the researcher(s) are understandable and are satisfactory. You understand what has been explained in this consent form about your participation in this study. You (do/do not) need further information to make your decision whether or not you want to volunteer to participate. By your signature below, you give voluntary informed consent to participate in the research as it has been explained to you, and acknowledge receipt of a copy of this form for your own personal records.

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Privacy Act Statement

18. Authority: 5 U.S.C. 301

19. Purpose: Medical research information will be collected in an experimental research protocol entitled ~~Measurement of Lung Vibration From Low Frequency Underwater Sound in Divers~~ to enhance basic medical knowledge, or to develop tests, procedures and equipment to improve the diagnosis, treatment or prevention of illness or injury, or improve performance.

20. Routine Uses: Medical research information will be used for analysis and reports by the Departments of the Navy and Defense, and other US Government agencies, provided this use is compatible with the purpose for which the information was collected. Use of the information may be granted to non-government agencies or individuals by the Commanding Officer, Naval Medical Research and Development Command in accordance with the provision of the Freedom of Information Act.

21. Voluntary Disclosure: You understand that all information contained in this Consent Statement or derived from the experiment described herein will be retained permanently at the Naval Submarine Medical Research Laboratory. You voluntarily agree to it's disclosure to agencies or individuals identified in the preceding paragraph and have been informed that failure to agree to such disclosure may negate the purpose for which the experiment was conducted.

Volunteer

Date (DD/MM/YY)

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Witness

Date (DD/MM/YY)

Investigator

Date (DD/MM/YY)

SUBJECTS INQUIRIES AND RESPONSES

Name of Subject: _____

SSN: _____

Rank/ or Rate: _____

Title Of Study: Measurement of Lung Vibration From Low Frequency
Underwater Sound in Divers

Date of Inquiries: _____

Place Inquiries Made: _____

Name and Title of Person Responding to Inquiries: _____

Substance of Inquiries and Associated Response to These
Inquiries: _____

B. Investigator Assurance Agreement

I, the principal investigator, cited as responsible for performing and monitoring the research under the protocol entitled, "Biophysical Effects of Low Frequency Sound on Divers," have read and understand the provisions of Title 32 Code of Federal Regulations Part 219 (Protection of Human Subjects), Department of Defense (DOD) Directive 3216.2 (Protection of Human Subjects if DOD supported Research), Secretary of the Navy Instruction (SECNAVINST) 3900.39B (Protection of Human Subjects), Naval Medical Command Instruction (NAVMEDCOMINST) 6710.4 ("Use Of Investigational Agents In Human Beings"- if applicable), and Naval Medical Research and Development Command Instruction (NMRDCCINST) 3900.2 (Protection of Human Research Volunteers from Research Risks), SECNAVINST 5370.2H (Standards of Conduct) (and local instructions, as applicable). I will abide by all applicable laws and regulations, and agree that in all cases, the most restrictive regulation related to a given aspect of research involving protection of human research volunteers will be followed. In the event that I have a question regarding my obligations during the conduct of this Navy sponsored project, I have ready access to each of these regulations, as either my personal copy or available on file from the Chairperson, Committee for the Protection of Human Subjects. I understand that my immediate resource for clarification of any issues related to the protection of research volunteers is the Chairperson, Committee for the Protection of Human Subjects.

Signatures and dates: Date (DD/MM/YY)

Dr. Thomas N. Buell, Ph.D.
Department Head

Date (DD/MM/YY)

Peter Rogers, Ph.D.
Principal Investigator

Date (DD/MM/YY)

E. Cudahy Ph.D.
Co-Investigator

Date (DD/MM/YY)

C. Review for Protection of Human Research Volunteers from research risks.

To be provided by CPHS

D. POST APPROVAL DOCUMENTATION

To be provided by CPHS

E. Dive Protocol

Measurement of Lung Vibration From Low Frequency Underwater Sound
in Divers

7 August, 1998

Prepared By:

Reviewed By:

Approved By:

Peter Rogers, Ph.D.
Principal
Investigator

Eric L. Hanson
Diving Medical
Officer

M. Wooster
Commanding
Officer

J. Dearie
Command Diving
Officer

Record of Changes

Changes affecting dive policy or test objectives will be made only by authority of the Commanding Officer, NSMRL. Minor Changes altering daily program, as necessary to maintain dive continuity, may be made by the Command Diving Officer, or in his absence, the Dive Supervisor.

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Dive Protocol

Development of a model of lung vibration in the presence of low frequency underwater sound.

Operations: Determination of the vibration characteristics of the human lung

1. Objective. The purpose of the experiment is to determine the vibrational characteristics of the human lung in the presence of low frequency underwater sound. The goal is to form the basis for the first steps in developing a model of human bioeffects in the presence of low frequency sound.

2. Medical Examinations: All divers will receive standard air conduction and bone conduction audiograms before and after the experiment, subjects should have generally equivalent (within 10 dB) sensitivities for both air and bone conduction hearing. The standard clinical audiograms are used to document any changes at any frequency for either ear that may have occurred as a result of participation in this experiment. No changes are anticipated. All subjects will receive a thorough neurological exam with emphasis on vibrotactile perception prior to exposure to document any preexisting neurological deficits that might impair perceptual measurements. Also this will serve as a baseline neurological exam in the unlikely event of diver injury.

All Diver/subjects will be required to have an up to date SF 88 that indicates ☒ Qualified for Dive Duty☒ and their most recent audiogram. The audiograms will be sent to NSMRL for review prior to the arrival of the Diver/subjects for the protocol. Further physical examination and/or diagnostic tests (e.g. chest X-Ray etc.) will be at the discretion of the medical monitor. A general physical exam is not required since stressful or exceptional diving evolutions are not used. Final subject determination is made by the Medical Monitor based on the above review process.

Once subjects are chosen, they will be questioned both pre and post dive by the principal investigator to determine if any

discomforts exist, willingness to continue testing etc. Any physical examinations will be guided by the subjects' responses.

3. Watch Section Duties and Training:

Command Diving Officer: Approves this protocol and ensures that adequate staffing is provided for all diving operations. Appoints the Dive Supervisor, and reports to the Head, Department of Operational Medicine for all diving operations (per direction, CO, NSMRL).

Dive Supervisor: Directly responsible for the Diver/subjects safety, minute to minute supervision of diving evolutions and chamber operations. He will run the scheduling and ensure the Command Diving Officer is kept informed as to the conduct of the dive.

Recorder: This function is to be performed by a diver-subject under control of the Dive Supervisor. The Dive Supervisor will maintain dive duty logs IAW US Navy Diving Manual Appendix (e).

Chamber Driver: The Dive Supervisor will appoint this position to either a qualified NSMRL staff member or a diver/subject as scheduling permits.

Surface Tender: Diver/subjects and NSMRL staff qualified for pressurization will serve in this role. The surface tender will communicate with the Diver/subject and the Dive Supervisor via round robin communications. He will have immediate direct access to the diver/subject and be able to enter the water in an effort to assist the Diver/subject in the event of an emergency. During dives to 66 and 132 FSW, the tender will be pressurized along with the subject.

Principal Investigator (PI): Peter Rogers, Ph.D., Neely Professor, Georgia Institute of Technology, School of Mechanical

engineering, has overall responsibility for the conduct of the experiment and to bring to the attention of the Dive Watch Supervisor any situation which may compromise Diver/subject safety. He will schedule all activities with the Dive Supervisor and the Dive Officer. The Principal Investigator will maintain all the experimental logs.

Co-Investigator: Edward Cudahy, Ph.D., Auditory Department, Naval Submarine Medical Research Laboratory, will help the PI with the conduct of the experiment and will provide expertise regarding stimulus selection, sound generation equipment, data collection and data analysis.

Dive Watch Medical Officer: LT J. Sims, MC, Operational Medicine Department, NSMRL. Responsible for the safety of the Diver/subjects and will consult with the PI and Dive Supervisor regarding medical aspects of the dives or the experiment. He is also responsible for prescribing treatments for dysbaric injury or any other medical conditions as they arise. Alternatives for this position are LT R. Jackman, MC, or the Bends Watch DMO.

Medical Monitor: LT E.L. Hanson, MC, Department of Operational Medicine, NSMRL, will be available (in house) during the entire waterborne testing and will consult with the PI and Dive Supervisor regarding any medical aspects of the dives or the experiment. He will be responsible for the overall well being of the subjects and perform duties as described in NMRDCINST 3900.2.

4. Diver/subjects: There will be 10 subjects. All 10 subjects will be volunteers and must be U.S. Military qualified divers.

5. Dive Records and Logs: A master dive log will be kept by the Dive Supervisor IAW the US Navy Diving Manual, Appendix (e). Experimental logs including data will be kept by the PI.

6. Compression / Decompression: All dives will be conducted IAW the US Navy Dive Manual (0994-LP-001-9010, revision 3). Descent rates will not exceed 60FPM, slower as dictated by the subject, to ensure that ear squeezes or the need for vigorous clearing are avoided. Decompression rates will not exceed 30FPM.

7. Depth Control: Divers will sit suspended on a flexible nylon harness at a depth of approximately 4 FSW (at the chest) during testing evolutions, and are limited by the depth of the acoustic tank to 5 and 1/2 FSW.

8. Excursion Procedures: None

9. Atmosphere and Water Temp Control: Chamber atmosphere, diver's gas and emergency BIBS gas will be monitored with gas analysis instrumentation per routine and interior chamber temperature and relative humidity will be maintained for tenders comfort and not exceed 90 ° F or be below 50%. Water temp will be between 84-91 ° F.

10. Primary and Emergency Breathing Gas: The primary breathing apparatus will consist of a standard scuba regulator fitted with an ANU approved scuba communication device. Emergency breathing gas for chamber occupants (including the subject) is compressed air and will be provided via the BIBS header.

11. Contaminated Gases: Any suspicion of a contaminated gas source will be handled IAW written emergency procedure (3.0 loss of atmosphere control) and the dive will be aborted IAW Standard US Navy Diving Manual Procedures for STD AIR DECOMPRESSION.

12. Termination Criteria: Each subject may terminate any dive for any reason. The Command Diving Officer, Dive Supervisor and Diving Watch Medical Officer may also terminate any dive.

13. Abort Procedures: Dives will be aborted IAW US Navy Diving

Manual procedures for STD AIR DECOMPRESSION.

14. Dive Profile: Up to 60 manned dives will be completed under this protocol. The method for refining each exposure is described in the CPHS methods section. What follows is the step by step run through of a typical dive.

- a) Diver will enter the GENESIS chamber's inside lock and don a chest harness. The diver will adjust harness to be snug fitting and comfortable.
- b) Diver will step into the pool and snap a flexible arm supporting NIVAMS ultrasound transmitting and receiving transducers onto the chest harness. (see diagram, appendix F)
- c) Diver will don a face mask and a standard scuba regulator with an ANU (authorized for Navy use) approved scuba communications device attached to the mouth piece.
- d) Diver will submerge and sit on nylon webbing in the center of the pool between the two acoustic sources (J11s).
- e) A round robin communication check will commence (dive supervisor, tender, and diver).
- f) Diver position will be adjusted so that the center of the chest is at the midpoint between the two J11s. When this is confirmed by the investigators, the diver will be given a verbal 'OK'. Once the 'OK' is received back from both the tender and the diver, chamber travel will commence at this time for dive profile #2 only (132 FSW), dive profile #1 starts with the chamber on the surface.
- g) Once travel is complete (if necessary), the diver will adjust the position of the NIVAMS transducers to maximize the signal on a small underwater display. This signal is the NIVAMS output in

pulse echo mode and will also be viewed by the investigators on a topside oscilloscope. Once the transducers are properly adjusted (confirmed by the investigators) the diver will be given a verbal 'OK'.

h) The diver will be asked to hold their breath and give a visual queue that it is held (thumbs up). The breath hold will last no longer than 10 seconds and is necessary to maintain a constant volume of air in the lungs.

i) NIVAMS will be switched to continuous wave (CW) mode. A brief, audible chirp (< 1 second) will be emitted from the J11s and the data will be acquired. The breath hold, chirp and data acquisition will take a total of 10 seconds or less. The diver may breathe at any time should the need arise during that 10 seconds. That measurement will simply be repeated.

j) The diver will be given a verbal queue ('OK') to breathe freely once the measurement is complete or at 10 seconds, whichever comes first.

k) The diver will then complete measurements at the other two lung positions described in the methods section.

l) Dive profile #1 will require travel to 66 FSW (measured at the diver's chest) at this time and the three lung position measurements will be repeated. Once complete, the diver will stand up in the tank to remove his head from the water, remove facemask and NIVAMS, and then chamber travel to the surface will commence.

Dive Profile #2 requires 3 measurements at 130 FSW only.

Therefore, once these measurements are made, the diver will stand up in the tank to remove their head from the water, remove NIVAMS and mask and Chamber travel will commence IAW Standard Air Decompression tables, US Navy Diving Manual for a 140 FSW dive.

m) Upon completion of the dive, the diver (and tender) will remain at the chamber facility with tenders for the appropriate clean period for each dive.

15. Decompression Sickness Diagnosis and Treatment: Any casualties will be evaluated by the Dive Watch Medical Officer and the Dive Supervisor and treated at the NSMRL recompression chamber or Naval Ambulatory Care Center as needed.

16. Diver Dress/ Equipment: Diver dress will consist of UDT shorts and bikini type top for females. The divers will breathe a standard scuba regulator fitted with an ANU approved communications device and will wear a standard facemask. All dives will require the subjects to wear the nylon chest harness outfitted with NIVAMS transducers. The harness will pass around the abdomen and over both shoulders and fasten near the sternum.

19. Dive Team Members, Duties and Qualifications

Command Diving Officer: Mr. J. Dearie

Dive Supervisors: BMC Von Borstel
EN2 Lenormand

Topside support: diver-subjects as designated by the dive supervisor.

Recorder: diver-subjects as designated by the dive supervisor

Surface Tender/Communicator: diver-subjects as designated by the dive supervisor

Dive Watch Medical Officer: LT J. Sims, MC, (alternatives are LT R. Jackman, MC, or Bends Watch DMO)

Diver subjects: up to 10 volunteer USN divers

Principal Investigator: P. H. Rogers Ph.D.

Co-Investigator: E. Cudahy Ph.D.

Medical Monitor: LT E. L. Hanson MC

20. Master Schedule of Dates

Approximate dates	1 October 1998	31 October 1998
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F. Diagram of NIVAMS and Harness

