

Sample



Tel. (303) 682- 5871
Fax (303) 682- 5915

www.4sonora.com

Mailing:
2021 Miller Drive
Longmont, CO 80501

Sonora Medical Systems, Inc.
Sonic Technologies Laboratory Services

**REPORT ON ACOUSTICAL MEASUREMENTS
CONDUCTED FOR**

Sensortechnos, Inc.

Kasumi Building 3-24-17 Nishiazabu
Minatoku, Tokyo 106-0013 Japan

IEC60601-2-37

REPORT NUMBER: 565

PREPARED BY:
James M. Gessert
Mark E Schafer, Ph.D.

PREPARED ON: iDateî

Table of Content

<i>Section</i>	<i>Description</i>	<i>Page</i>
TEST METHODOLOGY		3
1.0 TEST METHODOLOGY REPORTING		4
1.1 MEASUREMENT INSTRUMENTATION		4
1.1.1 Calibration Procedures for Measuring Instruments		4
2.0 MEASUREMENT SETUP		5
3.0 MEASUREMENT PROCEDURES		7
3.1 General Procedure.....		7
3.2 System Specific Procedure.....		7
3.3 System Setup.....		8
3.4 Trigger Signal		8
3.5 Protocol for Global Maximum.....		8
3.6 Consistency Checks		9
3.7 Procedure used to correct spatial averaging.....		10
3.8 TI Calculation Method.....		10
3.8.1 Non-Scanning Mode		10
4.0 ERROR SOURCES AND ASSESSMENT OF UNCERTAINTIES.....		11
5.0 RESULTS		12
6.0 REFERENCES		15
APPENDIX A:.....		16
APPENDIX B: HYDROPHONE CALIBRATION INFORMATION		21

TEST METHODOLOGY

The following is the test methodology information required by IEC Standard 60601-2-37 [1]. The test methodology used to measure the model XXX probes for the “Company Name” ultrasound system is explained in the following sections.

All measurements were conducted in accordance with IEC Standard 60601-2-37 (International Electrotechnical Commission “Requirements for the Declaration of the Acoustic Output of Medical Diagnostic Ultrasonic Equipment”) [1], and the relevant measurement procedures of the NEMA Publications “Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment,” UD-2 [2] and “Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment,” UD-3 [3].

This report is not to be construed as either an actual or implicit endorsement of the device measured or as an indication of the suitability or safety of the device.

James M .Gessert

Mark E. Schafer, Ph.D.

1.0 TEST METHODOLOGY REPORTING

1.1 MEASUREMENT INSTRUMENTATION

The measurement instrumentation was comprised of calibrated PVDF hydrophone probes (described below), a Tektronix Digital Oscilloscope, a water tank (22°C deionized, degassed water), a stepper motor driven X-Y-Z micromanipulating system and a Pentium III computer. The system has been described in detail in Reference 4, although it has been updated since the time of that publication.

Two PVDF bilaminar shielded membrane hydrophones manufactured by Perceptron were used. One hydrophone (S/N S5-152) had an active element of diameter 0.4mm in combination with a submersible pre-amplifier and 50 Ω 'inline' shunt. This was the primary measurement hydrophone. The other (S/N S4-159) had an active element of diameter 0.6mm, but no pre-amplifier. This hydrophone was used to cross check the results of the primary hydrophone. The effective hydrophone diameter for S/N S4-159 was 0.800 ± 0.017 mm and for S/N S5-152 was 0.503 ± 0.014 mm.

Both hydrophones had calibrations traceable to the National Physical Laboratory. The sensitivities used and calibration certificates for these hydrophones are included with this report. The frequency response is smooth and flat, and is in compliance with international measurement standards. The ± 3 dB frequency response for the hydrophone S5-152 is from 1 to 40MHz and for the hydrophone S/N S4-159 is 1 to 20 MHz.

1.1.1 Calibration Procedures for Measuring Instruments

The Digital Oscilloscope is calibrated annually to verify performance using standards traceable to the National Institute of Standards and Technology. Certification records are on file showing that the instrument meets the measurement specification.

Internal reference hydrophones are calibrated at least bi-annually at National Physical Laboratory. They were cross-calibrated using the Time Delay Spectrometry method; the

calibration agreed to within ± 1.0 dB over the frequency range considered. This calibration technique is discussed further in References 6 and 7. The working hydrophone is spot checked at least monthly.

The hydrophone sensitivity data was corrected for the input impedance characteristics of the oscilloscope (13 pF in parallel with $1M\Omega$). For the membrane hydrophone without a preamplifier, the calibration information included the measured complex impedance as a function of frequency. The effective sensitivity M_L of the membrane was calculated using the following equation:

$$M_L = M_C \left[\frac{\text{Re}(Z_L)^2 + \text{Im}(Z_L)^2}{[\text{Re}(Z_L) + \text{Re}(Z)]^2 + [\text{Im}(Z_L) + \text{Im}(Z)]^2} \right]^{\frac{1}{2}}$$

where Z_L is the spectrum analyzer input impedance, Z is the hydrophone impedance, and M_C is the reported open circuit sensitivity of the hydrophone. Hydrophone SS-152 uses an integral preamplifier and the output has been corrected for the 50Ω oscilloscope load.

From the impedance corrected pressure sensitivity of the hydrophone, the hydrophone intensity response was calculated according to Section 3.31 of the NEMA Standard [2]. The transducer report includes plots and analyses of the measured waveforms using hydrophone S5-152 and beam distribution using hydrophone S/N S4-159.

2.0 MEASUREMENT SETUP

The measurement system used was comprised of calibrated PVDF hydrophone probes (described below), a PC compatible computer, a Tektronix Digital Oscilloscope, a water tank (22°C deionized, degassed water), and a stepper motor driven X-Y-Z micromanipulating system (see Figure 1). The positioning resolution and repeatability was 0.03175 mm in the X and Y directions (lateral with respect to the acoustic axis) and 0.05 mm in the Z direction (axial with respect to the acoustic axis). The positioning system allows the probe to be manually angled $\pm 10^\circ$ about its face, in order to align the probe for

maximum signal. The system has been described in detail in Reference 4. The oscilloscope and stepper motor controller were interfaced to the PC computer via an IEEE-488 bus for capture and storage of the hydrophone signals, and for automated positioning of the hydrophone.

A measurement program has been written in the LabView™ programming language. This language has built-in features for instrument control, data display, and data analysis. The measurement program included routines for automatic setting of the oscilloscope sensitivity, waveform capture, frequency analysis, and calculation of in-water pressure and intensity parameters. For Imaging (B or M) and Pulsed Wave Doppler (PW) modes, the routines for finding the intensity parameters work by squaring the waveform and forming the Pulse Intensity Integral (P_{II}). The final value of the P_{II} , denoted E_{sp} , is a measure of the total energy in the pulse. The pulse duration was determined by find the time for which the P_{II} was between 10 and 90 percent of its final value. This time was multiplied by 1.25 as called for in the NEMA Standard [2]. With the P_{II} , the pulse duration, and the pulse repetition frequency (the PRF is an operator-entered value), the pulse average and time average intensities can be calculated.

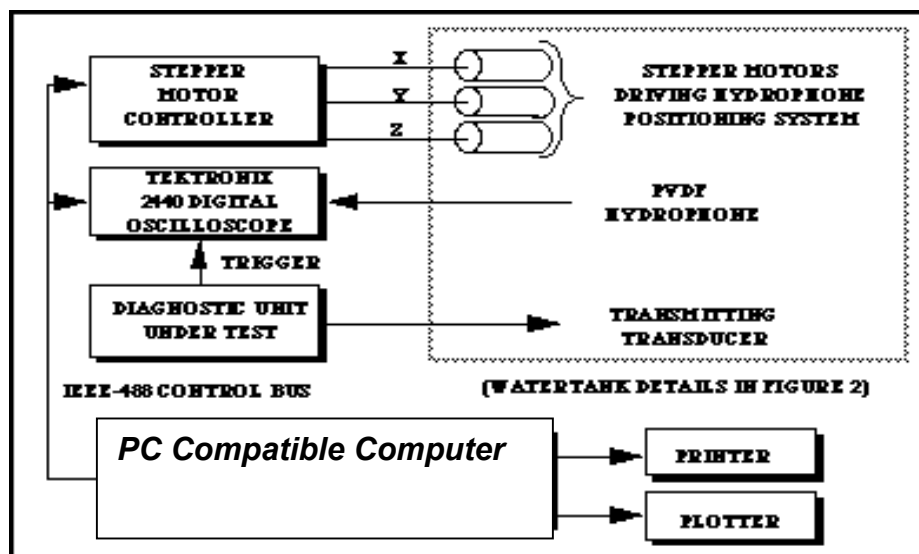


Figure 1: Overall System Arrangement

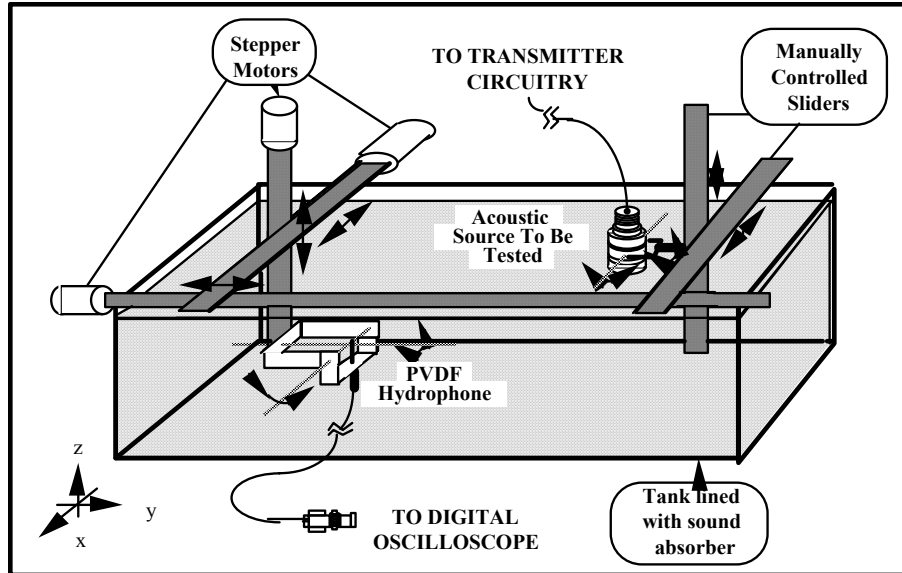


Figure 2: Measurement Tank Arrangement

3.0 MEASUREMENT PROCEDURES

3.1 General Procedure

The transducer under test was placed in the adjustable mounting fixture with the acoustic beam oriented downwards (see Figure 2), and the hydrophone was scanned laterally to find the true acoustic axis. At this point, the pressure-time waveform was captured and Fourier Transformed to find the center frequency (arithmetic mean of the upper and lower half power frequencies). The center frequency was used to find the hydrophone sensitivity from the appropriate calibration chart, corrected for the oscilloscope input impedance. At regular intervals, both the hydrophone and the transmitter were flushed with a stream of water from a small syringe. This removed any air bubbles that formed during the measurement process.

3.2 System Specific Procedure

This section details the specific measurement conditions and procedures used with the “Company Name” Model XXX ultrasound system and transducers, and describes the approach used for finding the worst case intensity levels.

3.3 System Setup

The ultrasound system used for the testing consisted of the “Company Name” Model XXX ultrasound system (s/n yyyyy) connected to either a Model A or Model B handheld transducer. Three Model A transducers and three Model B transducers were tested. The serial numbers of the probes are listed in table 1 below.

Probe No.	S/N	Model
1	00001	Model A
2	00002	Model A
3	00003	Model A
1	00001	Model B
2	00002	Model B
3	00003	Model B

Table 1: Serial number of tested probes.

3.4 Trigger Signal

The triggering signal was taken from an internal test point, so that the signal was synchronous with the transducer excitation.

3.5 Protocol for Global Maximum

After the initial alignment to get the actual acoustic axis, the hydrophone was scanned axially along the acoustic axis in the recommended scan range from z_{\min} to z_{\max} , where z_{\max} is 1.5 times the nominal focal depth of the probe in a given setting [2]. The initial scanning was done in steps of 0.5cm and then repeated with smaller steps of 0.1cm around the focal region identified by the scanning. At each axial position, the pressure-time waveform was captured and analyzed using the computer routines described above. The distance from the source to the hydrophone and the center frequency were then used to find the “derated” intensity values as a function of depth. In general, the derated intensity maxima occur at a shorter axial range than the in-water.

Once the axial location that produced the highest derated intensity was determined, the hydrophone was returned to the location of the derated maximum. At this location, the intensity values, MI, the peak rarefactional pressure at the focal location and other relevant parameters were calculated. To get the beam characteristics cross axis scans were

conducted. To measure and calculate the total power W_0 , the transducer was placed at a depth of z_{\min} to minimize distortion due to non-linear propagation. The spatial peak at this depth was located and a time waveform was captured. Then cross axis and raster scans were conducted. Since the W_0 at z_{\min} was the same as that determined at the point of derated spatial maximum intensity, the TI values were calculated based on this data.

Two separate spatial integration techniques were used to find the total power. The first involved integrating the beam intensity profile along two perpendicular directions, out to the -26 dB level. The hydrophone was first moved laterally away from the spatial peak location to the -26 dB point. The hydrophone was then scanned back through the beam, in past the peak, to the -26 dB point on the other side of the beam axis. This scanning procedure eliminated any backlash in the positioning system. The data was taken at intervals corresponding to one-half the acoustic wavelength in water. At each point, the oscilloscope gain was automatically adjusted to the proper setting. The signal was averaged to improve the signal-to-noise ratio, and the pressure-time waveform was captured and transferred to the computer. The waveform was analyzed as described before, and the average intensity value was used to measure the beam intensity as a function of position. The averaging both eliminated the effects of non-linear distortion on the beam pattern [8], and further improved the signal-to-noise-ratio. After the scan, the hydrophone was moved back to the spatial peak location, and the process was repeated in the perpendicular direction. The plots of the beam intensity profiles were included with the report.

The second integration technique involved a full two-dimensional integration of the field at z_{\min} . The hydrophone was scanned in a raster fashion, with a sufficient number of points taken to encompass the beam out to the -26 dB level, as found from the first scanning routine described above.

3.6 Consistency Checks

The measurements were performed in the following sequence: first, hydrophone S/N S4-159 was used to determine the axial distance to the maximum derated focal position in

focal zone. At the peak output depth in the focal zone producing maximum output conditions, a total power measurement using the cross-axis scanning and planar scanning method was then performed. The measurement process was then repeated with hydrophone S5-152.

3.7 Procedure used to correct spatial averaging

Because of the small beam width relative to the hydrophone spot size, the measured spatial peak intensities underestimate the true intensities due to spatial averaging effects [9]. In order to account for these effects, the correction factor for pulse pressure squared integrals (P_{II}) described in Reference 9 was used. This factor is stated as

$$C_{PII} = \frac{(3 - \sqrt{\beta_{PII}})^2}{4}$$

where β_{PII} is given by:

$$\beta_{PII} = \frac{\text{PII at one hydrophone radius}}{\text{PII on axis}}$$

This correction factor was examined and is reported for all probes tested. Intensity values (I_{spta} and I_{sppa}) are corrected by direct multiplication by the correction factor. Pressure values and MI are corrected by multiplication by the square root of the correction factor. The values shown in the plots in Appendix A are corrected.

3.8 TI Calculation Method

3.8.1 Non-Scanning Mode

The calculation of TI for this device involves selection of the appropriate calculation method, the following description is provided. Since the A-scan probes tested are a non-scanning devices and are used on the eye, only TIS for non-scanning modes is required. With an active aperture value, $A_{aprt} \leq 1.0 \text{ cm}^2$, for both probe models TIS is determined per Annex DD.4.1.3 [1].

$$P = I_{zpta} * PF * prr_{actual} / prr_{measured}$$

$$TIS = (P * f_{awf}) / C_{TIS1}$$

Where P is the Output Power in mW, pr_{actual} the actual pulse repetition rate in Hertz, $pr_{measured}$, the measurement pulse repetition rate in Hertz, PF the power factor in cm^2 , f_{awf} , the acoustic working frequency in MHz, $C_{TIS1} = 210$ mW MHz, and TIS the thermal index for soft tissue (Unitless).

3.8.1.1 Sample Calculation for Non-Scanning Probe

For probe Model A S/N 00001 on the “Company Name” Model YYY system:

$$P = 5.26 [mW/cm^2] * 0.024 [cm^2] * 5 [Hz] / 1000 [Hz] = 0.00063 \text{ mW}$$

$$TIS = 0.00063 [mW] * 10.8 [MHz] / 210 [mW/MHz] = 0.000032$$

4.0 ERROR SOURCES AND ASSESSMENT OF UNCERTAINTIES

The uncertainties in the measurements were predominantly systematic in origin; the random uncertainties were negligible in comparison. The overall systematic uncertainties were determined as follows:

1. **Hydrophone Sensitivity:** ± 16 percent for intensity, ± 8 percent for pressure.

Based on the substitution method of hydrophone calibration using an NPL calibrated reference hydrophone and the Time Delay Spectrometry Method. The principal source of this uncertainty is the stated uncertainty of the NPL calibration.

2. **Digitizer:** ± 4 percent for intensity ± 2 percent for pressure.

Based on the stated accuracy of the 8-bit resolution Tektronix Digital Oscilloscope and the signal to noise ratio of the measurements.

3. **Temperature:** ± 1 percent

Based on the temperature variation of the water bath of $\pm 1^\circ\text{C}$.

4. **Spatial Averaging:** ± 10 percent for intensity, ± 5 percent for pressure

See section 4.6.1.5 for full discussion.

5. **Non-linear Distortion:** ± 4 percent for intensity, ± 2 percent for pressure

The uncertainty of the intensity and (rarefactional) pressure are estimated from Ref. 9, and subsequent discussion with FDA personnel.

Since all the above error sources are independent, they may be added on an RMS basis, giving a total uncertainty of ± 19.7 percent for all intensity values reported, ± 9.9 percent for all the pressure values and ± 9.9 percent for the Mechanical Index.

Uncertainties for ultrasonic power and center frequency.

Since the total power is based on the intensity, the uncertainty for power is also ± 19.7 percent; the center frequency estimate is depended upon the digitizer, and is therefore given as ± 2 percent.

5.0 RESULTS

The results are given in Table 101 for the probes measured. Since the equipment meets the requirements of exemption clauses 51.2 aa) and 51.2 dd) of IEC60601-2-37 [1], providing this information in the operator's manual is not necessary. The values in the table are the average of the three samples measured. The supporting waveform data and beam plot data are given in Appendix A. These results include the pressure-time waveform, the Fourier transform, the pulse intensity integral and the waveform analysis taken at the derated spatial peak location ($z_{mjpII,3}$). Note that the hydrophone sensitivity appropriate to each measurement is included as part of the waveform analysis information. The sensitivity may be converted into a response factor using the equation given in the Guide [2]. These results are followed by the cross axis measurements taken at the derated maximum depth. This data consists of the pressure-time waveform, cross axis and two-dimensional planar scans. The results of the two-dimensional planar scans are shown on linear and logarithmic scales.

Acoustic Output Reporting Table

Transducer Model: A

Operating Mode: A-Mode

Index Label		MI	TIS			TIB	TIC
			Scan	Non-scan		Non-scan	
				$A_{aprt} \leq 1 \text{ cm}^2$	$A_{aprt} > 1 \text{ cm}^2$		
Maximum index value		0.12	-	0.00002	-	(b)	(a)
Associated acoustic parameter	$p_{r,a}$ (MPa)	0.40					
	P (mW)		-	0.0004		#	#
	min of $[P_{\alpha}(z_s), I_{ta,\alpha}(z_s)]$ (mW)				-		
	z_s (cm)				-		
	z_{bp} (cm)				-		
	z_b (cm)					#	
	z at max. $I_{pi,\alpha}$ (cm)	2.27					
	$d_{eq}(z_b)$ (cm)					#	
	f_{awf} (MHz)	10.5	-	10.5	-	#	#
	Dim of A_{aprt}	X (cm)		-	0.47	-	#
Y (cm)			-	0.47	-	#	#
Other Information	t_d (μsec)	0.10					
	prr (Hz)	5					
	p_r at max. I_{pi} (MPa)	0.92					
	d_{eq} at max. I_{pi} (cm)					#	
	$I_{pa,3}$ at max. MI (W/cm^2)	7.03					
Operating Control Conditions							
<p>Note 1: Information need not be provided for any formulation of TIS not yielding the maximum value of TIS for that mode.</p> <p>Note 2: Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.</p> <p>Note 3: Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2 aa) and 51.2 dd).</p> <p>Note 4 . Data shown represents the average of three probes measured.</p> <p>(a) Intended use does not include cephalic so TIC is not computed</p> <p>(b) Intended use is ophthalmic with no bone in the imaging field so TIB is not computed</p> <p># No data reported.</p>							

Acoustic Output Reporting Table

Transducer Model: B

Operating Mode: A-Mode

Index Label		MI	TIS			TIB	TIC
			Scan	Non-scan		Non-scan	
				$A_{aprt} \leq 1 \text{ cm}^2$	$A_{aprt} > 1 \text{ cm}^2$		
Maximum index value		0.14	-	0.000053	-	(b)	(a)
Associated acoustic parameter	$p_{r,a}$ (MPa)	0.46					
	P (mW)		-	0.001		#	#
	min of $[P_{\alpha}(z_s), I_{ta,\alpha}(z_s)]$ (mW)				-		
	Z_s (cm)				-		
	Z_{bp} (cm)				-		
	Z_b (cm)					#	
	z at max. $I_{pi,\alpha}$ (cm)	0.300					
	$d_{eq}(Z_b)$ (cm)					#	
	f_{awf} (MHz)	10.6	-	10.6	-	#	#
	Dim of A_{aprt}	X (cm)		-	0.20	-	#
Y (cm)			-	0.20	-	#	#
Other Information	t_d (μsec)	0.10					
	prr (Hz)	150					
	p_r at max. I_{pi} (MPa)	0.52					
	d_{eq} at max. I_{pi} (cm)					#	
	$I_{pa,3}$ at max. MI (W/cm^2)	5.96					
Operating Control Conditions							

Note 1: Information need not be provided for any formulation of *TIS* not yielding the maximum value of *TIS* for that mode.

Note 2: Information need not be provided regarding *TIC* for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Note 3: Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2 aa) and 51.2 dd).

Note 4 . Data shown represents the average of three probes measured.

(a) Intended use does not include cephalic so TIC is not computed

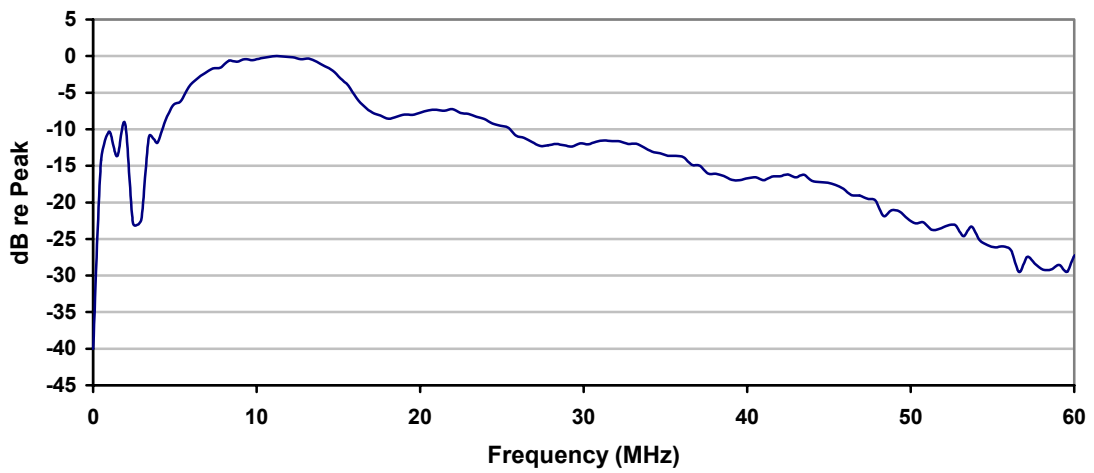
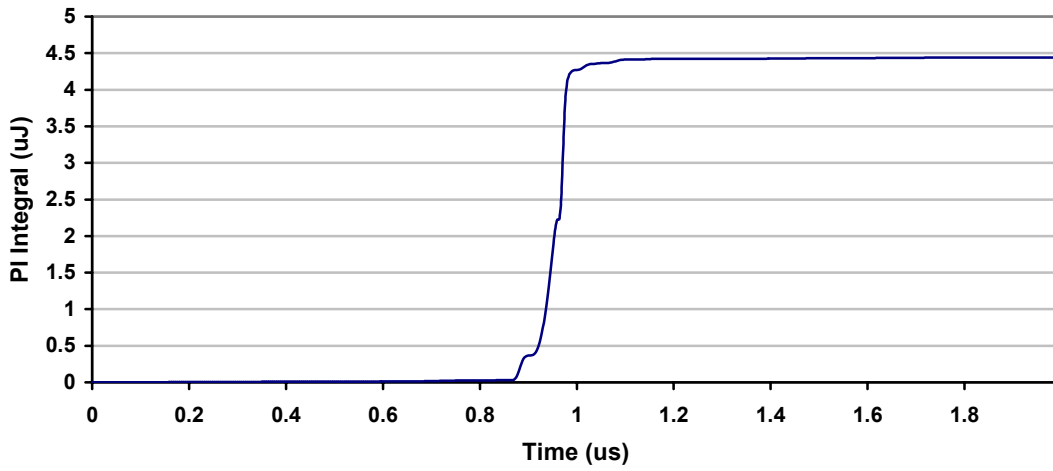
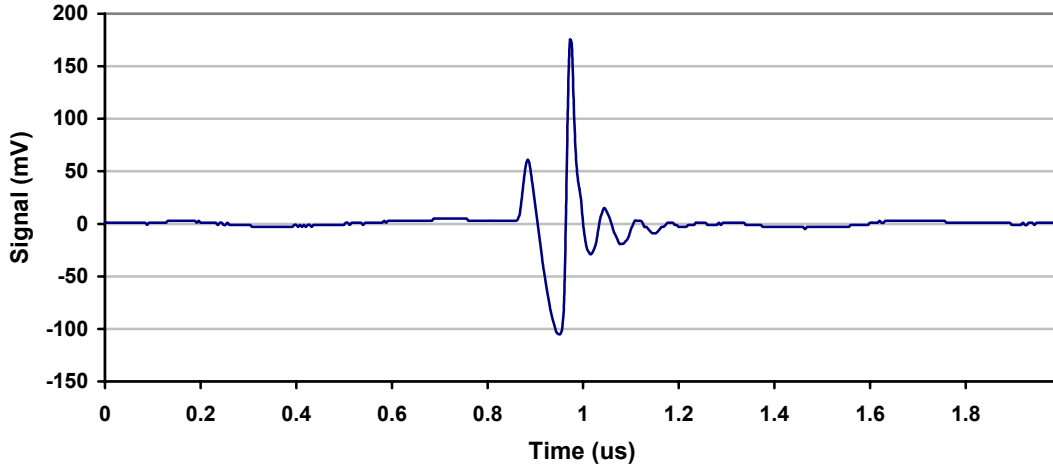
(b) Intended use is ophthalmic with no bone in the imaging field so TIB is not computed

No data reported.

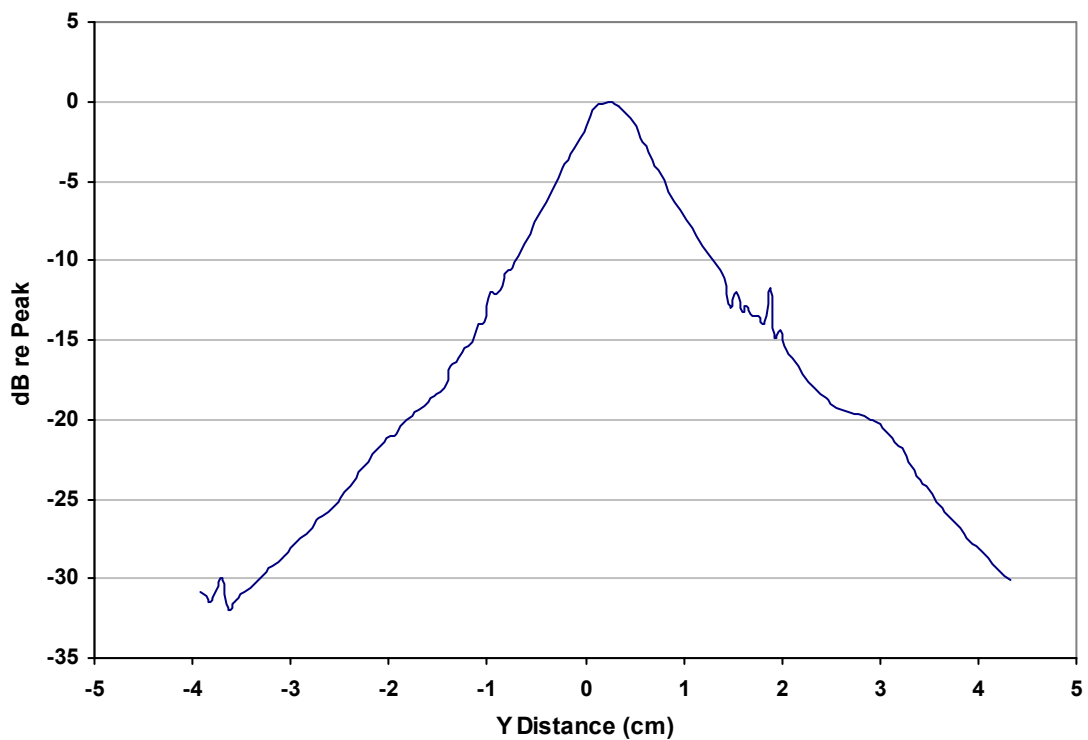
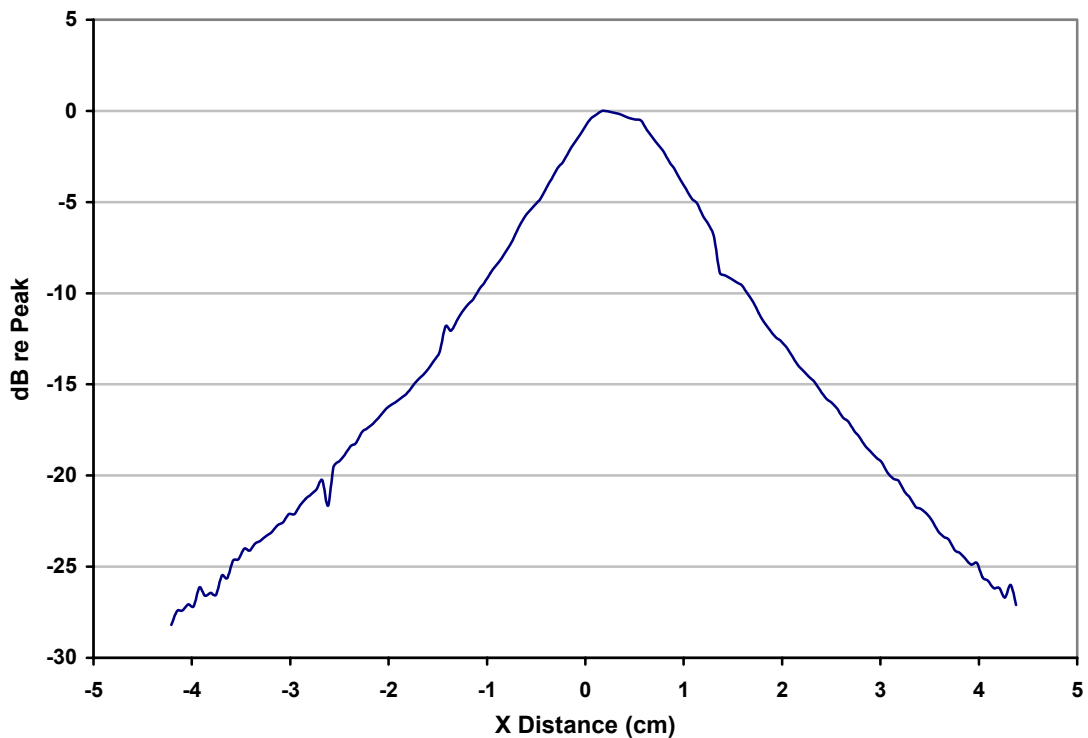
6.0 REFERENCES

1. "Medical electrical equipment-Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment", International Electrotechnical Commission (IEC) Reference number IEC 60601-2-37:2001(E).
2. "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment," NEMA Standard Publication UD 2-1998, National Electrical Manufacturers Association, 1998.
3. "Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment," NEMA Standard Publication UD 3-1998, National Electrical Manufacturers Association, 1998.
4. M.E. Schafer and P.A. Lewin, "A Computerized System for Measuring the Acoustic Output from Diagnostic Ultrasound Equipment," IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control, Vol. UFFC-35(2), pp. 102-109, 1988.
5. D.R. Bacon, "Characteristics of a PVDF Membrane Hydrophone for Use in the Range 1-100 MHz," IEEE Transactions on Sonics and Ultrasonics, Vol. SU-29 pp. 18-25, 1982.
6. P.C. Pedersen, P.A. Lewin, and L. Bjorno, "Application of Time Delay Spectrometry for Calibration of Ultrasonic Transducers," IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control, Vol. UFFC-35(2), pp. 185-206, 1988.
7. R.C. Preston, D.R. Bacon, S.S. Corbett III, G.R. Harris, P.A. Lewin, J.A. MacGregor, W.B. O'Brien, and T.L. Szabo, "Interlaboratory Comparison of Hydrophone Calibration," IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control, Vol. UFFC-35(2), pp. 206-213, 1988.
8. S.S. Corbett III, "The Influence of Non-Linear Fields on Miniature Hydrophone Calibrations Using the Planar Scanning Technique," IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control, Vol. UFFC-35(2), pp. 162-167, 1988.
9. R.C. Preston, D.R. Bacon, and R.A. Smith, "Calibration of Medical Ultrasound Equipment: Procedures and Accuracy Assessment," IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control, Vol. UFFC-35(2), pp. 110-121, 1988.

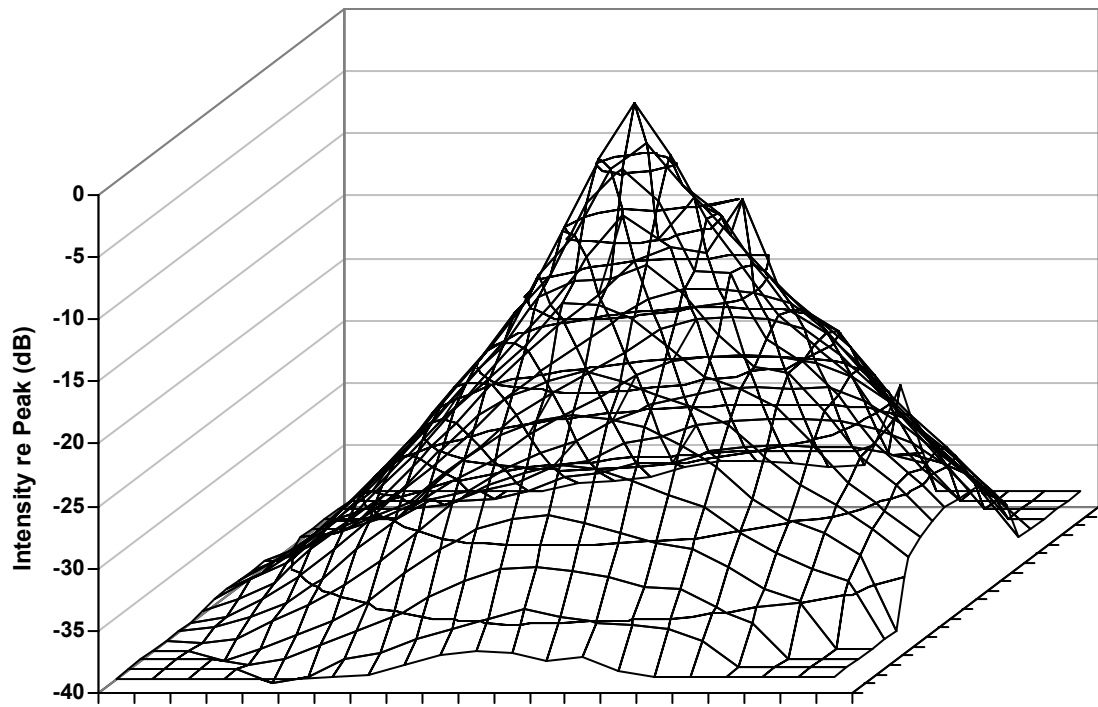
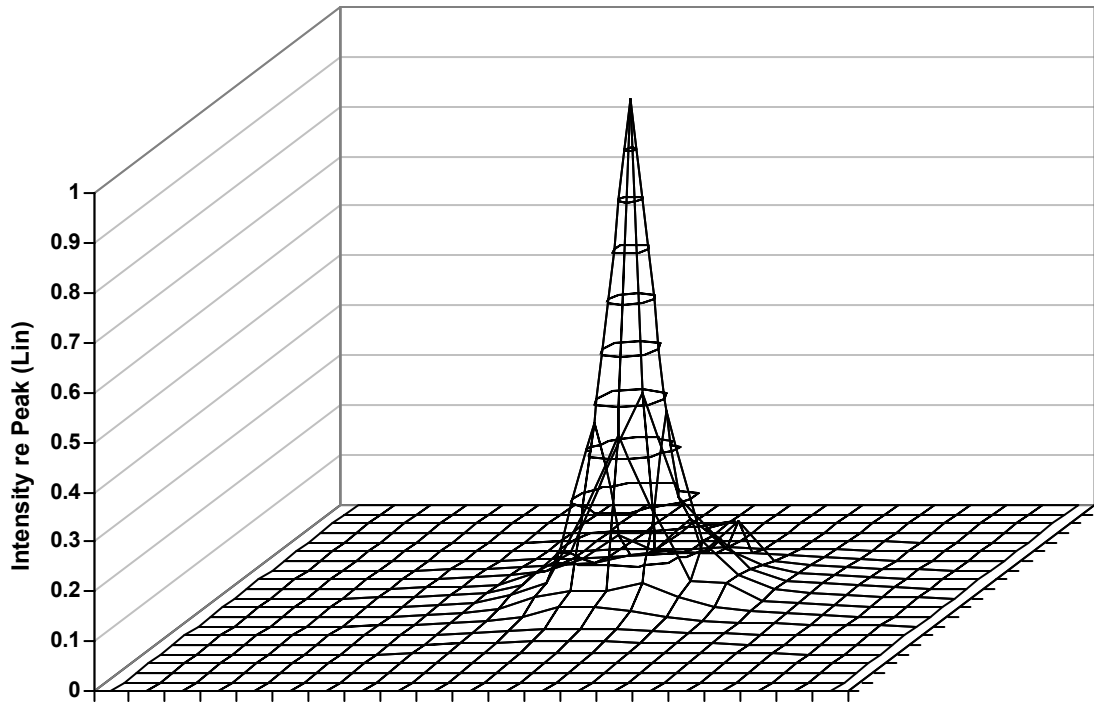
APPENDIX A:
WAVEFORM AND BEAMPLOT DATA



"Company Name" Model A	Probe S/N: 00001	Hydrophone S/N: S5-152
Center Freq (MHz): 10.821	Spatial Correction: 1.104	Hydro Sens (dB re 1 uV/Pa): -259.06
Pulse Length (us): 0.077	Derating: 0.167	PRF (kHz): 1
Z Depth (cm): 2.2	Isppa.0 (W/cm^2): 68.5	MI: 0.127
Ispta.0 (mW/cm^2): 5.262	Isppa.3 (W/cm^2): 11.41	Pr.0 (MPa): 1.03E+00
Ispta.3 (mW/cm^2): 0.877		Pr.3 (MPa): 0.419



"Company Name" Model A	Probe S/N: 00001	Hydrophone S/N: S4-159
-6dB Diam X (cm): 0.188	Z Depth (cm): 2.2	-6dB Diam Y (cm): 0.125
-6dB Area (cm^2): 0.01921		Cross PF: 0.017



"Company Name" Model A
Z Depth (cm): 2.2

Raster PF: 0.015

Probe S/N: 00001
Hydrophone S/N: S4-159

Plots for all probes tested are included.

APPENDIX B: HYDROPHONE CALIBRATION INFORMATION

NATIONAL PHYSICAL LABORATORY

Teddington Middlesex UK TW11 0LW Switchboard 020 8977 3222



Certificate of Calibration



SONORA MEDICAL SYSTEMS
PVDF ULTRASONIC HYDROPHONE
SERIAL NUMBER S5-152

FOR: Sonora Medical Systems
2021 Miller Drive
Longmont
Colorado 80501
USA

FOR THE ATTENTION OF GARY GREEN

DESCRIPTION: A PVDF membrane hydrophone manufactured by Sonora Medical Systems, with an active element of diameter 0.4 mm in combination with a submersible pre-amplifier and a 50 Ω 'in-line' shunt.

IDENTIFICATION: Hydrophone serial no. S5-152
Submersible pre-amplifier serial no. P-165

DATE OF CALIBRATION: 14 November 2003 to 17 November 2003

Calibration frequencies marked (*) in this certificate are not included in the UKAS accreditation schedule of our laboratory.

Reference: U1914

Page 1 of 6

Date of issue: 20 November 2003

Signed: 

(Authorised Signatory)

Checked by: 

Name: S. P. Dowson

for Managing Director

This certificate is issued in accordance with the laboratory accreditation requirements of the United Kingdom Accreditation Service. It provides traceability of measurement to recognised national standards, and to the units of measurement realised at the NPL or other recognised national standards laboratories. This certificate may not be reproduced other than in full, unless permission for the publication of an approved extract has been obtained in writing from the Managing Director. It does not of itself impute to the subject of the calibration any attributes beyond those shown by the data contained herein.

NATIONAL PHYSICAL LABORATORY
Continuation Sheet

MEASUREMENTS

The polyvinylidene fluoride (pvdf) membrane hydrophone and amplifier combination was calibrated using a multiple-frequency method by direct comparison with a secondary standard hydrophone of the membrane type. The calibration was performed in two distinct stages. Firstly, the measurements from 1 to 20 MHz (in 1 MHz steps), and lastly the high frequency calibration from 22 to 40 MHz (in 2 MHz steps).

The front face of the hydrophone is defined as the surface where the membrane is almost flush with the mounting ring. When calibrated this surface is presented to the transducer. The calibration is only valid for this orientation. During calibration, the hydrophone/preamplifier combination was terminated by an 'in-line' shunt of $50 \Omega \pm 1\%$. The results are only valid for this configuration.

All hydrophones were soaked in the water continuously during the measurements and for at least 1 hour before the first measurement. During the measurements the temperature of the water varied between 19.7°C and 20.2°C . The uncertainty of this temperature is $\pm 0.5^{\circ}\text{C}$.

1 MHz to 20 MHz

For the calibration in this range, the secondary standard hydrophone was placed at a point within the non-linear field of an ultrasonic transducer radiating into a tank containing freshly deionised and degassed water. The transducer was excited by a 1 MHz tone burst drive voltage and the hydrophone position was chosen such that the waveform was subject to finite-amplitude distortion and contained many harmonics of the fundamental frequency. Using a 40 MHz high-pass filter to isolate the high frequency component, the hydrophone was positioned and aligned for maximum signal in the plane perpendicular to the transducer axis. Following removal of the filter, the hydrophone output signal was measured over that region of the tone burst for which a voltage waveform of constant amplitude was observed.

Reference: U1914

Page 2 of 6

Checked by: NOL BZ

NATIONAL PHYSICAL LABORATORY
Continuation Sheet

After replacing the standard hydrophone with the test hydrophone/preamplifier combination, the orientation of the hydrophone was adjusted to maximise the high frequency component, isolated using a 40 MHz high-pass filter. After signal maximisation, the filter was removed and the output signal of the hydrophone/preamplifier combination was determined over the same region of the voltage waveform used for the secondary standard hydrophone.

22 MHz to 40 MHz

For the calibration from 22 to 40 MHz, the secondary standard hydrophone was placed at a point within the non-linear field of an ultrasonic transducer radiating into a tank containing freshly deionised and degassed water. The transducer was excited by a 2 MHz tone burst drive voltage and the hydrophone position was chosen such that the waveform was subject to finite-amplitude distortion and contained many harmonics of the fundamental frequency. Using an 80 MHz band-pass filter to isolate the high frequency component, the hydrophone was positioned and aligned for maximum signal in the plane perpendicular to the transducer axis. Following removal of the filter, the hydrophone output signal was measured over that region of the tone burst for which a voltage waveform of constant amplitude was observed.

After replacing the standard hydrophone with the test hydrophone/preamplifier combination, the orientation of the hydrophone was adjusted to maximise the high frequency component, isolated using a 60 MHz band-pass filter. After signal maximisation, the filter was removed and the output signal of the hydrophone/preamplifier combination was determined over the same region of the voltage waveform used for the secondary standard hydrophone.

Reference: U1914

Checked by: NOL AZ

NATIONAL PHYSICAL LABORATORY
Continuation Sheet

RESULTS

The sensitivity figures presented correspond to a calibration of the magnitude response of the hydrophone/preamplifier combination.

Frequency	End-of-cable loaded Sensitivity
$\overline{\text{MHz}}$	$\overline{\mu\text{V}/\text{Pa}}$
1	0.074
2	0.082
3	0.086
4	0.089
5	0.093
6	0.097
7	0.101
8	0.102
9	0.105
10	0.109
11	0.112
12	0.113
13	0.115
14	0.116
15	0.116
16	0.116
17	0.120
18	0.119
19	0.121
20	0.118

Reference: U1914

Checked by: NOL 62

Page 4 of 6

NATIONAL PHYSICAL LABORATORY
Continuation Sheet

RESULTS

Frequency	End-of-cable loaded Sensitivity
$\overline{\text{MHz}}$	$\overline{\mu\text{V/Pa}}$
22 (*)	0.119
24 (*)	0.122
26 (*)	0.126
28 (*)	0.125
30 (*)	0.123
32 (*)	0.125
34 (*)	0.124
36 (*)	0.124
38 (*)	0.123
40 (*)	0.120

For this hydrophone/preamplifier combination, a positive output voltage corresponds to a positive acoustic pressure.

(*) Calibration between 22 and 40 MHz falls outside the scope of UKAS accreditation.

The reported uncertainty is based on a standard uncertainty multiplied by a coverage factor, $k=2$, providing a level of confidence of approximately 95%. The uncertainty evaluation has been carried out in accordance with UKAS requirements.

Reference: U1914

Checked by: NOL BZ

Page 5 of 6

NATIONAL PHYSICAL LABORATORY
Continuation Sheet

UNCERTAINTIES

The uncertainties in the sensitivity values are determined from both type A (random) and type B (systematic) evaluations. One important type B uncertainty arises from the comparison between the test hydrophone and the secondary standard hydrophone; a second is the calibration of the secondary standard hydrophone, which is based on optical interferometry. Type A uncertainties are determined from at least four repeat measurements.

Expanded (overall) uncertainties have been calculated according to the method recommended in publication M 3003 (Edition 1) of the United Kingdom Accreditation Service entitled 'The Expression of Uncertainty and Confidence in Measurement'. For this calibration, the overall uncertainties are stated below.

1 to 4 MHz	± 8%
5 to 8 MHz	± 8%
9 to 12 MHz	± 8%
13 to 16 MHz	± 9%
17 to 20 MHz	± 12%
22 to 30 MHz	± 12%
32 to 40 MHz	± 12%

Reference: U1914

Checked by: NOL BZ

Page 6 of 6

Calibration Information is provided for all
hydrophones