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NEMA STANDARDS PUBLICATION

NEMA UD 2

Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 2

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NEMA Standards Publication UD 2-1998

Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
Revision 2

Published by:

American Institute of Ultrasound in Medicine
National Electrical Manufacturers Association

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Foreword

In 1996, the decision was made to break the measurement and labeling parts of the *Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment* (AIUM,1993) into two separate documents. The resulting measurements standard, the *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment*, is now fully harmonized with and identical to it's sister NEMA document, the *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment (UD-2), Revision 2.* The new labeling document, the *Acoustic Output Labeling Standard for Diagnostic Ultrasound Equipment* (AIUM 1998), has been substantially changed, with the original labeling requirements being replaced by the labeling specified in the FDA's 510(k) Guideline (FDA 1997) and, optionally, the labeling specified in IEC 1157 (IEC 1992a). As of this writing, the International Electrotechnical Commission, Technical Committee 87, is developing additional standards for ultrasonic output measurement, calibration, and labeling. Their efforts have been helpful in the development of this document. Relevant IEC standards should be consulted for further technical information as they become available.

User needs have been considered throughout the development of this publication. Proposed or recommended revisions should be submitted to:

Chairman, AIUM Technical Standards Committee
American Institute of Ultrasound in Medicine
14750 Sweitzer Lane, suite 100
Laurel MD 20707-5906

Revisions have been included which make the standard consistent with the NEMA UD-2 (as noted above) and *The AIUM/NEMA Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment,* (AIUM/NEMA, 1998).

A few improvements are reflected here which represent changes in all three of the documents. Members of the AIUM/NEMA Harmonization Task Group performing this revision were:

AIUM	NEMA
Paul L. Carson, Ph.D.	Charles Hottinger, Ph.D.
John G. Abbott, Ph.D.	Douglas Worth
Gerald R. Harris, Ph.D.	Kurt Sandstrom
Peter Lewin, Ph.D., Chairman	

The amended requirements supersede those of all previous revisions of the standard.

Foreword to the *Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment, 1993 revision 1:*

In July 1993, the *Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment* was amended. The primary purposes of the amendments are to (1) introduce harmonized requirements into both the AIUM publication *Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment* and the National Electrical Manufacturers Association's (NEMA) *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment* (UD-2), so that they are technically equivalent with regard to measurement procedures; (2) introduce those improved measurement practices developed for the *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment* (UD-3) (Output Display Standard) into

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this standard, so that it represents the latest thoughts on measurement practices; and (3) expand the coverage of the standard to the extent that generic measurement procedures necessary to support the Output Display Standard are included.

The amended requirements supersede those of the original edition.

The amendments were developed by a joint AIUM/NEMA Task Group, whose members were:

Peter Lewin, Ph.D., Chairperson
Charles Grossman
Charles Hottinger, Ph.D.
Ming Li
Kurt Sandstrom
Kai Thomenius, Ph.D.
Paul L. Carson, Ph.D.
Gerald R. Harris, Ph.D.
Seojoong Kwon
William O'Brien, Jr., Ph.D.
Mark Schafer, Ph.D.
Marvin Ziskin, M.D.

The encouragement of the past chairperson of the AIUM Standards Committee, Peter Edmonds, Ph.D., is acknowledged.

Foreword to the *Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment, 1992 version:*

This document has been prepared by a Task Force composed of members of the American Institute of Ultrasound in Medicine (AIUM) and members of the National Electronic Manufacturer's Association (NEMA). Initially the aim of this Task Force was to revise the 1981 document entitled, *The AIUM/NEMA Safety Standard for Diagnostic Ultrasound Equipment.* However, considerable progress has occurred in this field recently necessitating major rewriting to the point where the result is a truly new document. Furthermore, the discussion of safety considerations has been deleted because this is being pursued elsewhere by AIUM and the National Council on Radiation Protection and Measurements (NCRP).

AIUM and NEMA Task Group Members

AIUM	NEMA
Paul L. Carson, Ph.D.	John G. Abbott, Ph.D.
Gerald R. Harris, Ph.D.	Scott Corbitt, M.S.
Frank P. Leo, B.S., A.A.S.	John Dellinger, B.S.
Wesley L. Nyborg, Ph.D.	Charles Hottinger, Ph.D.
William D. O'Brien, Jr., Ph.D., Co-Chair	Thomas L. Szabo, M.S., Co-Chair
Marvin C. Ziskin, M.D.	

Appendices A, B, C, D, E, F, G, H, I, J, and K are for informational purposes only.

In this standard, the following print types are used:

- requirements and definitions: roman type
- NOTES: in smaller roman type
- terms used in this standard as defined in Section 1: **bold roman type**

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Purpose

The objective of this Standards Publication is to describe a set of measurement procedures for ultrasonic output parameters. This document implements this by setting forth precise definitions of quantities, primarily those relating to acoustic output levels, and specifying standard procedures for measuring the pertinent acoustic output parameters.

It is hoped that this standard will be found useful to individuals performing the indicated measurements.

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Scope

This standard covers all active ultrasound apparatus designed for medical diagnostic use, including ultrasonic echo ranging devices (both manual and automatically **scanned**), through-transmission devices, Doppler echo equipment, and combinations thereof.

This document establishes measurement standards for acoustic output quantities of ultrasonic diagnostic equipment.

Measurements of acoustic output quantities are to be performed in water. However, in order to provide values more typical of what might occur within tissue, derated values of output quantities will be required in addition to the in-water values. To provide an example, detailed derating procedures and requirements are discussed in this standard for a specific model; this is a 0.3 dB/cm-MHz uniform attenuation model, and will be notationally designated by the subscript ".3," i.e., $I_{SPPA.3}$.

It is anticipated that in the future, different **derating factors** will be necessary to better represent different applications. The standard provides for the implementation of different derating schemes by the manufacturer, provided that the implementation of that scheme is described.

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Road Map

In this document, requirements are set forth on information which manufacturers of ultrasound diagnostic equipment are to provide. This kind of information, which pertains to acoustic output levels, is to be made conveniently available to purchasers and users of diagnostic equipment. It can then be considered when making decisions on the appropriate instruments and procedures for various applications.

What to Read in this Document: (I) Engineers, physicists, technicians

The readers who will study this standard most intensively are engineers, physicists, and other technical people who are responsible for making the required measurements, or for testing the equipment.

Sections 3 to 5 contain information on how the measurements are to be made. For those planning to establish a facility for making these measurements, Section 3 is required reading. Here are lists of equipment, including hydrophones and force balances, required for measurements, as well as equipment needed for calibration and testing of the measurement-devices. Along with the lists are discussions of required characteristics for the devices (especially, the hydrophones) used in measurements and in calibration.

While calibrated hydrophones can be purchased, experience has shown that it is necessary for each measurement facility to have, at least, its own means of testing the calibration periodically. It is preferable to have also the capability of carrying out independent **hydrophone calibrations**. It is also necessary to have means for periodically testing the force balance calibration. Procedures for testing and calibration of hydrophones and force balances are described in Section 4.

The measurement procedures themselves are described in Section 5, as they would be applied to an **ultrasound system** intended for clinical diagnostic use. Determination of the required pressure quantity and of the two required **intensity** quantities are carried out with a hydrophone. The total acoustic **power** is measured with a force balance. A test for self-consistency between force balance and hydrophone measurements can be carried out by using a planar scanning technique.

The important analysis required in reporting 95 percent confidence levels is discussed in Appendix A. Other appendices give additional information on matters which require more detailed treatment than is appropriate in the main text.

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Section 1
DEFINITIONS

(Where used in this standard, the terms defined below are in **bold** type.)

The purpose of this section is to provide precise definitions for the pertinent technical terms used in this document.

acoustic pressure: The value of the total pressure minus the ambient pressure.

Symbol: p
Unit: Pascal, Pa

active aperture: The aperture defined by the **entrance beam dimensions** for **unscanned** cases or **entrance dimensions of the scan** for **scanned** cases. In cases with nonuniform excitation of the transducer elements in contact with the skin, the area (in cm^2) of the **active aperture** at the beam entrance shall be taken as the maximum dimensions at which the rms excitation voltage per unit transducer area, exceeds –12 dB relative to the spatial maximum excitation voltage per unit transducer area. This definition for nonuniform excitation is intended to cover phased arrays, linear and curved arrays in both **scanned** and **unscanned** modes. This definition is also applicable to annular array-based mechanical probes in both **scanned** and **unscanned** modes.

Symbol: A_{aprt}
Unit: centimeter squared, cm^2

amplitude modulated waveform: A **waveform** in which the **amplitude modulation factor** is greater than 5 percent.

amplitude modulation factor: The value of the expression $100 \times (|A| - |B|)/ |A|$ where |A| and |B| are the absolute maximum and absolute minimum values of the **envelope** of a modulated acoustical or electrical carrier (first order quantity), respectively, expressed as a percentage.

anechoic material: Acoustic absorbing material that exhibits no reflective properties.

autoscan (autoscanning): The electronic or mechanical steering of successive ultrasonic pulses or series of pulses, through at least two dimensions.

bandwidth: The difference between the most widely separated frequencies f_1 and f_2 at which the transmitted **acoustic pressure** spectrum is 71 percent (–3 dB) of its maximum value.

Symbol: BW
Unit: Hertz, Hz

beam axis: A straight line joining the points of maximum **pulse intensity integral** measured at several different distances in the **far field.** This line, calculated according to regression rules, is to be extended back to the **transducer assembly** surface.

beam cross-sectional area: The area on the surface of a plane perpendicular to the **beam axis** consisting of all points where the **pulse intensity integral** is greater than 25 percent of the maximum **pulse intensity integral** in that plane. For situations in which the relative **acoustic pressure waveform** does not change significantly across the **beam cross-sectional area**, the **beam cross-sectional area** may be approximated by measuring the area on the surface of a plane perpendicular to the **beam axis**

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consisting of all points where the **acoustic pressure** is greater than 50 percent of the maximum **acoustic pressure** in the plane.

Symbol: A
Unit: centimeter squared, cm^2

center frequency: Defined as $f_c = (f_1 + f_2)/2$

where:

f_1 and f_2 are frequencies defined in **bandwidth**.

Symbol: f_c
Unit: Hertz, Hz

centroid: Is the point of a surface whose coordinates are the mean values of the coordinates of a representative sample of all points on the surface.

combined mode (combined operating mode): Any combination of two or more of the **discrete operating modes** operating simultaneously.

continuous waveform: A **waveform** in which the **amplitude modulation factor** is less than or equal to 5 percent.

cw Doppler (continuous-wave Doppler): A Doppler **discrete operating mode** in which a **continuous waveform** is generated.

depth of focus: For a **focusing transducer assembly**, with **transmit pattern** (j) is the distance along the **beam axis** between two specific points, P_1 and P_2, on opposite sides of the **pulse intensity integral** peak location, denoted z_{mjPII}. Here, P_2 is the nearest point on the far side of z_{mjPII} (i.e., $z > z_{mjPII}$) at which the **pulse intensity integral** PII(z) is equal to 0.5 times the maximum $PII(z_{mjPII})$. Similarly, P_1 is the point nearest z_{mjPII} on the transducer side (i.e., $z_{min} = z < z_{mjPII}$) at which PII(z) is equal to 0.5 times the maximum $PII(z_{mjPII})$, if such a point exists; if not, then P_1 is taken to be at the surface of the transducer.

Symbol: z_{mjPII}
Unit: centimeter, cm

derated intensity: The reduced value obtained when the **intensity** measured in water is adjusted by the **derating factor**.

$$I_a = I \times 10^{(-0.1af_cz)}$$

where:

a is the **derating factor**;
z is the distance from the source to the point of interest in cm;
f_c is the **center frequency**;
I_a is the **derated intensity**;
I is the **intensity**.

Symbol: I_a
Unit: Watt per square centimeter, W/cm^2

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derated pressure: The reduced value obtained when the **acoustic pressure** measured in water is adjusted by the **derating factor.**

$$p_a = p \times 10^{(-0.05 a f_c z)}$$

where:

a is the **derating factor;**
z is the distance from the source to the point of interest in cm;
f_c is the **center frequency;**
p_a is the **derated acoustic pressure;**
p is the **acoustic pressure.**

Symbol: p_a
Unit: Pascal, Pa

derating factor: A multiplicative factor applied to **acoustic output** parameters intended to account for ultrasonic attenuation of tissue between the source and a particular location in the tissue. As referred to in this standard, the average ultrasonic attenuation is assumed to be a 0.3 dB/cm-MHz along the **beam axis** in the body.

Symbol: a
Unit: decibel per centimeter - megahertz, dB $cm^{-1}MHz^{-1}$

discrete operating mode: One of the following system operations: A-Mode, **M-Mode**, static B-Mode, real-time B-Mode, **CW Doppler**, pulsed Doppler, static flow mapping, real-time flow mapping, or any other single display format for presenting clinical information.

drive voltage amplitude: The temporal-peak amplitude of an electrical drive **waveform** applied to a transducer or array of transducer elements.

Symbol: v
Unit: Volts, V

duty factor: The product of the **pulse duration** and the **pulse repetition frequency** for a pulsed **waveform.**

effective hydrophone diameter: Twice the **effective hydrophone radius**.

Symbol: d_e
Unit: millimeter, mm

effective hydrophone radius: The radius which is determined by comparison of the measured directional response at frequency f with the theoretical directivity function for the active element at that frequency. More specifically for use with this standard, the measured half angles at the -3 dB and –6 dB points of the hydrophone directivity pattern at a given frequency are employed in the **far field** directivity equation of a circular aperture to calculate radii, a_{e3} and a_{e6}, respectively, which are averaged to obtain an effective radius for the hydrophone.

Symbol: a_e
Unit: millimeter, mm

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end-of-cable loaded sensitivity: The ratio of the voltage at the end of any integral cable or connector of a hydrophone or hydrophone-amplifier combination, when connected to a specified electrical load, to the free-field **acoustic pressure** at the location of the hydrophone's active element. In general, the sensitivity is a function of frequency, f.

Symbol: $M_L(f)$
Unit: Volts per Megapascal, V MPa^{-1}

end-of-cable open-circuit sensitivity: The ratio of the open-circuit voltage at the end of any integral cable or connector of a hydrophone or hydrophone-amplifier combination to the free-field **acoustic pressure** at the location of the hydrophone's active element. In general, the sensitivity is a function of frequency, f.

Symbol: $M_c(f)$
Unit: Volts per Megapascal, V MPa^{-1}

energy fluence: The acoustic energy transmitted in the direction of acoustic wave propagation, per unit area normal to this direction, at the point considered during a given time period. It is equal to the time integral of the **instantaneous intensity** during the same time period.

energy fluence per pulse: The **energy fluence** during the duration of a single pulse. It is equal to the **pulse intensity integral**.

entrance beam dimensions: The dimensions of the –12 dB beam width where the beam enters the patient. For contact transducers, these dimensions can be taken as the dimensions of the radiating element, if so stated.

Symbol: x-z or y-z
Unit: centimeter, cm

entrance dimensions of the scan: For **autoscan** systems, are the dimensions of the area of the surface through which the **scanned** ultrasound beams enter the patient, consisting of all points located within the –12 dB beam width of any beam passing through that surface during the scan.

Symbol: (none)
Units: centimeter, cm

envelope: A smooth curve tangent to and connecting the peaks of successive cycles of a **waveform**.

exposure time: The total amount of time the **transducer assembly** is delivering **ultrasonic power** to the patient or to a specified anatomic region. For pulsed systems, the **exposure time** includes the intervals between pulses as well as the duration of the pulses.

Symbol: (none)
Unit: seconds, s

far field: That region of the field in which the acoustic energy flow proceeds essentially as though coming from a point source located in the vicinity of the **transducer assembly**. (For an unfocused **transducer assembly**, the farfield is commonly at a distance greater than $S/\pi\lambda$ where S is the **radiating cross-sectional area** and λ is the acoustic **wavelength** in the medium.)

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far field transition length: The distance from an unfocused transducer surface along the **beam axis** to the point given by $S/\pi\lambda$ (for circular sources), where S is the **radiating cross-sectional area** of the transducer.

Symbol: L
Unit: centimeter, cm

focal area: The **beam cross-sectional area** on the **focal surface**.

Symbol: (none)
Unit: square centimeter, cm^2

focal length: The distance along the **beam axis** from the **focal surface** to the **centroid** of the **radiating cross-sectional area** on the external surface of a **focusing transducer assembly**.

Symbol: (none)
Unit: centimeter, cm

focal surface: The surface which contains the smallest of all **beam cross-sectional areas** of a **focusing transducer assembly**.

Symbol: (none)
Unit: centimeter squared, cm^2

focusing transducer assembly: A **transducer assembly** in which the ratio of the smallest **beam cross-sectional area** to **radiating cross-sectional area** is less than one-fourth.

freeze mode: A mode involving **pulse-echo imaging** in which the imaging is stopped. Unless the **ultrasonic power** is zero during this mode, it shall be regarded as a **discrete operating mode** for labeling purposes.

geometrical hydrophone diameter: Twice the **geometrical hydrophone radius**.

Symbol: (none)
Unit: millimeter, mm

geometrical hydrophone radius: The radius defined by the physical dimensions of the hydrophone active element's electroded region.

Symbol: (none)
Unit: millimeter, mm

global maximum: The greatest value of a quantity evaluated over all times, over all locations, and over all **operating conditions** for any given operating mode.

Symbol: GM
Unit: unitless

hydrophone calibration: The process by which $M_c(f)$ or $M_L(f)$ of a hydrophone is measured and recorded at selected frequencies.

intensity: The acoustic **power** transmitted in the direction of acoustic wave propagation, per unit area normal to this direction, at the point considered. For measurement purposes, this point is restricted to

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points where it is reasonable to assume that the **acoustic pressure** and particle velocity are in phase, viz., in the **far-field** or the area near the **focal surface**.

intensity, instantaneous (i): The instantaneous acoustic **power** transmitted in the direction of acoustic wave propagation, per unit area normal to this direction, at the point considered. It is given in the **far field** by:

$i = p^2/\rho c$

where:

p is the instantaneous **acoustic pressure**;
ρ is the density of the medium;
c is the speed of sound in the medium.

Symbol: i
Unit: Watt per square-centimeter, W cm^{-2}

intensity, pulse-average: The ratio of the **pulse intensity integral** (**energy fluence per pulse**) to the **pulse duration**.

Symbol: I_{PA}
Unit: Watt per square-centimeter, W cm^{-2}

intensity, spatial-average temporal-average: For auto-scanning systems, is the **temporal-average intensity** averaged over the **scan cross-sectional area** on a surface specified (may be approximated as the ratio of **ultrasonic power** to the **scan cross-sectional area** or as the mean value of that ratio if it is not the same for each scan); for **non-autoscanning** systems, I_{SATA} is the **temporal-average intensity** averaged over the **beam cross-sectional area** (may be approximated as the ratio of **ultrasonic power** to the **beam cross-sectional area**.)

Symbol: I_{SATA}
Unit: Watt per square-centimeter, W cm^{-2}

intensity, spatial-peak pulse-average: The value of the **pulse-average intensity** at the point in the acoustic field where the **pulse-average intensity** is a maximum or is a local maximum within a specified region.

Symbol: I_{SPPA}
Unit: Watt per square-centimeter, W cm^{-2}

intensity, spatial-peak temporal-average: The value of the **temporal-average intensity** at the point in the acoustic field where the **temporal-average intensity** is a maximum, or is a local maximum within a specified region.

Symbol: I_{SPTA}
Unit: Watt per square-centimeter, W cm^{-2}

intensity, temporal-average: The time average of **intensity** at a point in space. For **non-autoscan** systems, the average is taken over one or more **pulse repetition periods**. For **autoscan** systems, the **intensity** is averaged over one or more **scan repetition periods** for a specified operating mode. For **autoscan** modes, the average includes contributions from adjacent lines that overlap the point of measurement. For **combined modes** the average includes overlapping lines, from all constituent **discrete operating mode** signals.

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Symbol: I_{TA}
Unit: Watt per square-centimeter, W cm^{-2}

intensity response factor: The received hydrophone voltage squared per unit of **intensity** in a plane wave of specified frequency f in water at a specified temperature:

$K_i^2 = 10^{-8} M_L^2 \rho c$,

where:

ρ is the density of the propagation medium in kg m^{-3};
c is the speed of sound of the propagation medium in m s^{-1};
M_L is the **end-of-cable loaded sensitivity**.

Symbol: K_i^2
Unit: volt squared centimeter squared per Watt, $V^2\ cm^2\ W^{-1}$

local laboratory: A laboratory other than a national standard laboratory at which calibrations and measurements, as called for in this standard, are performed.

m-mode: A **discrete operating mode** that provides a graphical representation over time of the locations of echoes along a fixed (**non-autoscanning**) sound path.

maximum drive voltage amplitude: The largest **drive voltage amplitude** that is applied to any element in the j^{th} **transmit pattern** in any **operating condition** allowed in clinical use by a specific system including both hardware and software configuration.

Symbol: v_{mj}
Unit: Volt, V.

measurement report: A complete documentation of the methods and results of measurements required to obtain the labeling quantities.

minimum measurement depth: For a transmit pattern j, is defined by the expression:

$$z_{min} = 1.5\sqrt{\frac{4}{\pi} A_{aprt}(j)} = 1.69\sqrt{A_{aprt}(j)}$$

where:

A_{aprt} is the area of the **active aperture.**

Symbol: z_{min}
Unit: centimeter, cm

No hydrophone measurements should be taken closer to the **transducer assembly** than the **minimum measurement depth.**

NOTE—This is equivalent to the break point depth (z_{bp}) of the AIUM/NEMA output display standard (AIUM/NEMA 1998, Equation 6.2.6.11-1).

non-autoscan (non-autoscanning): The emission of ultrasonic pulses in a single direction, where scanning in more than one direction would require moving the transducer manually.

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nonlinearity propagation parameter: A parameter characterizing the degree of nonlinearity in the propagation of an ultrasound beam. A value of less than 0.5 would indicate a linear condition, and a value above 1.5 would indicate a marked nonlinear condition.

Symbol: σ_m
Unit: unitless

operating condition: Any one combination of the possible particular **output control settings** for a **discrete operating mode** or **combined operating mode**.

output control settings: The settings of the controls affecting the acoustic output of an ultrasound instrument. Such controls would include but are not limited *to* the **power** output control, the focal zone control, and the imaging range control.

peak compressional pressure: At a specified point is the greatest magnitude of the positive **acoustic pressure** at any time during a complete acoustic pulse or continuous **waveform**.

Symbol: p_c or p_+
Unit: Pascal, Pa

peak rarefactional pressure: At a specified point is the greatest magnitude of the negative **acoustic pressure** at any time during a complete acoustic pulse or continuous **waveform**.

Symbol: p_r or p_-
Unit: Pascal, Pa

poled (spot-poled): A region in a ferroelectric material that has been polarized by the application of an electric field and which remains polarized after the electrical field has been removed.

power: A quantity describing the rate at which acoustic energy travels per unit time in the direction of propagation. Unless stated otherwise, all references to **power** measurements in this standard will be to temporal-average values.

Symbol: W
Units: Watts, W

pulse-average intensity: See **intensity**.

Symbol: I_{PA}
Unit: Watt per square-centimeter, W cm^{-2}

pulse duration: 1.25 times the interval between the time when the time integral of **intensity** in an acoustic pulse at a point reaches 10 percent and when it reaches 90 percent of the **pulse intensity integral**.

Symbol: PD
Unit: second, s

pulse-echo imaging: A two-dimensional visualization of anatomic echoes using pulsed ultrasound. It is also known as B-Mode or B-Scan imaging.

pulse intensity integral: The time integral of **instantaneous intensity**, for any specific point and pulse, integrated over the time in which the **envelope** of **acoustic pressure** or hydrophone signal for the specific

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pulse is nonzero. It is equal to the **energy fluence per pulse**. For a **transducer assembly** operating in a **non-autoscanning** mode, it is equal to the product of **temporal-average intensity** and **pulse repetition period**.

Symbol: PII
Unit: Joule per centimeter-squared, J cm^{-2}

pulse repetition frequency: For a pulsed **waveform**, is the number of pulses generated per second.

Symbol: PRF
Unit: Hertz, Hz

pulse repetition period: The reciprocal of the **pulse repetition frequency**.

Symbol: (none)
Unit: second, s

radiating cross-sectional area: The area of the surface at and parallel to the face of the active transducer element(s) and consisting of all points where the **acoustic pressure** is greater than –12 dB of the maximum **acoustic pressure** in that surface. The area of the active element(s) of the **transducer assembly** may be taken as an approximation for the **radiating cross-sectional area**.

Symbol: S
Unit: centimeter squared, cm^2

reference hydrophone: A stable hydrophone that has been calibrated by a national standards laboratory. It is used primarily for calibrating **working hydrophones** by the comparison method. It also can be used for the measurement of ultrasonic equipment acoustic output.

reference source: A source transducer whose **ultrasonic power** calibrated at one or more frequencies by a national standards laboratory under driving conditions repeatable in a **local laboratory**. Preferably, the transducer is constructed from an inherently stable piezoelectric crystal, such as quartz, or lithium niobate. It is used for calibrating radiation force balances and hydrophones.

scan cross-sectional area: For **auto-scanning** systems, is the area, on the surface considered, consisting of all points located within the **beam cross-sectional area** of any beam passing through the surface during the scan.

Symbol: (none)
Unit: centimeter squared, cm^2

scan format: The two dimensional spatial pattern of a sonographic image display. **Scan formats** include rectangular, sector, and trapezoidal types.

scan intensity integral: The sum of the **pulse intensity integrals** of all pulses arriving at a given point during a single **scan repetition period**.

Symbol: SII
Unit: Joule per centimeter-squared, J cm^{-2}

scan line: A single or multiple transmission of acoustic energy in a discrete position and direction during the formation of a complete scan.

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scan repetition frequency: The repetition frequency of a complete scan in angle or position, for **autoscan** systems only.

Symbol: SRF
Unit: Hertz, Hz

scan repetition period: The reciprocal of the **scan repetition frequency**.

scanned mode (auto-scanning): The electronic or mechanical steering of successive ultrasonic pulses or series of pulses through at least two dimensions.

slew rate: The rate of rise of output voltage of an amplifier in response to a voltage step input.

Symbol: SR
Unit: Volts per second, V sec^{-1}

spatial-average temporal-average intensity: See **intensity**.

Symbol: I_{SATA}
Unit: Watt per square-centimeter, W cm^{-2}

spatial-peak pulse-average intensity: See **intensity**.

Symbol: I_{SPPA}
Unit: Watt per square-centimeter, W cm^{-2}

spatial-peak temporal-average intensity: See **intensity**.

Symbol: I_{SPTA}
Unit: Watt per square-centimeter, W cm^{-2}

spot check: The comparison of a hydrophone voltage **waveform** to a **waveform record** to determine changes in hydrophone sensitivity, or the comparison of a force balance reading to the output of a **reference source** to determine changes in calibration.

temporal-average intensity: See **intensity**.

Symbol: I_{TA}
Unit: Watt per square-centimeter, W cm^{-2}

transducer assembly: The transducer(s), the transducer housing (probe), any associated electronic circuitry and any liquids contained in the housing, and the integral cable which connects the transducer probe to an **ultrasound console**.

transmit pattern: The combination, denoted by the index j, of a specific set of transducer beam-forming characteristics (determined by the transmit aperture size, apodization shape, and relative timing/phase delay pattern across the aperture resulting in a specific **focal length** and direction), and an electrical drive **waveform** of a specific fixed shape but variable amplitude.

Symbol: j
Unit: unitless

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ultrasonic power: The temporal average **power** emitted in the form of ultrasonic radiation by the **transducer assembly**.

Symbol: W
Units: Watts, W

ultrasound system: Consists of an ultrasound **transducer assembly** and an **ultrasound console**.

ultrasound console: That part of an **ultrasound system** to which the ultrasound **transducer assembly** is attached. The console provides the electronic circuitry for driving and controlling the ultrasound fields, as well as signal reception, processing, image display and other features.

unscanned mode (non-autoscanning): The emission of ultrasonic pulses in a single direction, where scanning in more than one direction would require moving the **transducer assembly** manually.

waveform: The graphical characterization of an acoustical or electrical parameter as a function of time.

waveform record: A permanent plot or photograph of a voltage **waveform** for a specific hydrophone when excited under specified conditions.

wavelength: The ratio of the speed of sound in the medium to the **center frequency**.

Symbol: λ
Unit: centimeters per cycle, cm cycle^{-1}

working hydrophone: A hydrophone used in a **local laboratory** for the majority of daily measurements. It is calibrated relative to the **reference hydrophone** by comparison, or calibrated relative to the **reference source** via planar scanning.

working source: A transducer whose **ultrasonic power** has been measured on a force balance at a **local laboratory**. It is used for hydrophone planar scanning, comparison calibrations, and **spot checks**. The **working source** is typically a piston-type, broad-band, ceramic transducer. The stability of a **working source** must be checked by frequent measurements with a force balance.

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Section 3
MEASUREMENT DEVICE CHARACTERISTICS

3.1 INTRODUCTION

This section discusses the equipment and equipment characteristics needed to perform the measurements and calibrations described in this standard. Specific equipment choices are related to the types of measurement and calibration procedures selected. The devices described are the hydrophone and force balance. The hydrophone measures **acoustic pressure** and, indirectly, **intensity** and **ultrasonic power**, while the force balance measures **ultrasonic power**. Valid data can be obtained only with properly qualified and calibrated devices; minimum requirements for them are outlined in this section. Specific information regarding calibration is given in Section 4.

3.2 SCOPE

Section 3.3 discusses, in a tutorial manner, aspects of hydrophone characteristics essential for good measurement practice, including: sensitivity (3.3.1), hydrophone/amplifier frequency response (3.3.2), **effective hydrophone diameter** (3.3.3), dynamic range (3.3.4), and hydrophone field perturbation (3.3.5). Guidelines for selecting a specific hydrophone for a specific measurement are given in 3.4. Additional equipment such as a hydrophone amplifier, a positioning system, and a **waveform** recorder are described in 3.5. Section 3.6 covers the general characteristics of a force balance system for measuring acoustic **power**.

3.3 HYDROPHONE CHARACTERISTICS

A hydrophone is an electroacoustic device designed to measure the spatial and temporal characteristics of an acoustic field in water with minimum disturbance to the field. Ideally, the hydrophone should provide an undistorted voltage **waveform** replica of the **acoustic pressure** at each point in the field. An essential requirement of a satisfactory probe is a linear relationship between **acoustic pressure** and the hydrophone or hydrophone-amplifier voltage output. The factor used to convert hydrophone voltage to **acoustic pressure**, known as the end-of-cable sensitivity of the hydrophone, is discussed in Section 3.3.1.

Presently available hydrophones are either of ceramic or PVDF construction. Ceramic hydrophones, unlike PVDF hydrophones, fail to meet the following important criteria necessary for high performance: extremely wide **bandwidth** and smooth, wide-angle directivity. PVDF hydrophones usually are of two types of construction: (1) needle, and (2) **spot-poled** membrane (Lewin, 1981; DeReggi et al., 1981; Bacon, 1982a; Harris, 1982; Preston et al., 1983; Platt, 1985). Needle hydrophones are so named because a small PVDF sensor element (typically 0.5 to 1 mm in diameter) is mounted on the end of a needle of approximately the same diameter. Membrane hydrophones are made of a thin sheet of PVDF polymer, which is stretched across a hoop. Though the hoop is large, only a small region in the center (0.5 to 1 mm in diameter), known as the "active element," is **poled** and electroded. Some membrane hydrophones consist of arrays of **poled** elements. **Spot-poled** membrane hydrophones are available in both single layer and bilaminar configurations; the bilaminar model has the best immunity to water conductivity and RF noise. For both types of hydrophones, the available **bandwidth** is inversely proportional to the thickness of the PVDF element. However, the **bandwidth** of a rigidly backed needle probe will be roughly half that of a membrane hydrophone having the same film thickness.

The size of the active element may be specified for a hydrophone in one of two ways: the "effective" size or the "geometrical" size. The **effective hydrophone radius** (a_e), or **effective hydrophone diameter** (d_e),

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is an experimentally determined value based on a directional response measurement, as described in Appendix C. The **geometrical hydrophone radius**, **geometrical hydrophone diameter** or, for the noncircular case, other geometrical dimension, is the result of a physical measurement of the active element's electroded region. Reported differences between the **effective hydrophone radius** and **geometrical hydrophone radius** may be due to variations in hydrophone construction, or small aperture effects (when the aperture is equal to or less than a **wavelength**). Also, for membrane hydrophones, differences may be due to directional dependence of the piezoelectric sensitivity (Bacon, 1982a), or a lack of uniform poling over the active element arising from fringe poling fields (Harris, 1988).

In general, a PVDF hydrophone should have a smooth directional response like that of an ideal, baffled circular piston. Operation is possible over a broad frequency range, but the directional response narrows with increasing frequency. At a given frequency, if the effective diameter of the hydrophone is larger than the beamwidth of the acoustic field being measured, or if variations in the acoustic field are very steep, spatial averaging may occur, resulting in an underestimation of the pressure field. There is a trade-off between sensitivity and spatial averaging; as the size of an active element gets smaller, the spatial averaging effects decrease, but so does sensitivity (see Appendix C.)

Hydrophones may be connected by a cable directly to a **waveform** recorder or, alternatively, an amplifier may be interposed between the hydrophone's active element and the recorder. This amplifier may be "external," i.e., connected by cable to the hydrophone housing, or it may be "integral," in which case it is built into the hydrophone housing.

Hydrophone amplifiers serve two purposes. They boost low amplitude signals to levels compatible with **waveform** recording devices. Also, they can help eliminate cable-related resonances that can occur at high frequencies. For the latter purpose, if an external amplifier is used, the cable connecting the amplifier to the hydrophone housing should be $\leq$ 15 cm long. The overall **bandwidth** of a hydrophone/amplifier into a load is dependent on the PVDF element, the cable length, and the preamplifier characteristics.

Ultrasound medical equipment often employs focused transducers that can create nonlinear propagation phenomena in the water, resulting in the generation of higher harmonics (see Appendix B — Nonlinear Effects). Pressure **waveforms** may contain frequencies much higher than the **center frequency** of the transmitting transducer. To faithfully capture the true shape of this **waveform**, the entire measurement system, comprising the hydrophone, amplifier, and **waveform** recording equipment, must have both a uniform frequency response and a sufficiently wide **bandwidth**.

3.3.1 Hydrophone Sensitivity

The **end-of-cable loaded sensitivity** of a hydrophone, $M_L(f)$, when used in a continuous single-frequency sound field of frequency f, is defined by:

$$M_L(f) = v/p, \qquad (3.3.1\text{-}1)$$

where v is the voltage amplitude developed across designated terminals of the hydrophone or hydrophone amplifier and p is the free-field **acoustic pressure**; i.e., the **acoustic pressure** existing in the field with the hydrophone absent. Designation of the electrical loading condition at the terminals is an integral part of the specification of $M_L(f)$. Also, $M_L(f)$ should be expressed explicitly as a function of f when it is important to emphasize that the hydrophone sensitivity may vary with frequency.

An **end-of-cable open-circuit sensitivity,** $M_c(f)$, is a convenient way of specifying sensitivity independent of loading conditions. If the hydrophone has output impedance, Z, and is connected to an electrical load (Z_a), then the two sensitivity factors are related by:

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$$M_L = M_C \sqrt{\frac{\{Re(Z_{el})\}^2 + \{Im(Z_{el})\}^2}{\{Re(Z_{el}) + Re(Z)\}^2 + \{Im(Z_{el}) + Im(Z)\}^2}} \qquad (3.3.1\text{-}2)$$

where Re and Im denote the real and imaginary parts of a complex impedance.

$M_c(f)$ is commonly used to compare the sensitivity of hydrophones calibrated under different load conditions, where the load and hydrophone impedances are specified as a parallel R and C circuit with values R_{el} and C_{el}, respectively. Table 3-1 lists typical hydrophone and load conditions, as well as M_L and M_c values, at 1 MHz for needle and membrane hydrophones commercially available.

To convert the R and C values specified in Table 3-1 to a real and imaginary impedance specified in Eq. 3.3.1-2, the following equations apply:

$$Re(Z_{el}) = \frac{R_{el}}{1 + \omega^2 R_{el}^2 C_{el}^2} \qquad (3.3.1\text{-}3)$$

$$Im(Z_{el}) = \frac{-\omega R_{el}^2 C_{el}}{1 + \omega^2 R_{el}^2 C_{el}^2} \qquad (3.3.1\text{-}4)$$

where the radian frequency is $\omega = 2\pi f$ and f is the frequency for which $M_c(f)$ is specified.

If the impedance of the hydrophone and load can be assumed to be capacitive, which often is the case if no hydrophone amplifier is used, then Eq. 3.3.1-2 reduces to:

$$M_L = M_C \frac{C}{C + C_{el}} \qquad (3.3.1\text{-}5)$$

where C is the hydrophone end-of-cable capacitance, including any integral cable and connector. Thus, under the assumptions leading to Eq. 3.3.1-5, M_L can be calculated for a load C_{el} if C and M_c are known. In a similar manner, if an **end-of-cable loaded sensitivity** M_{L1} is known for a particular capacitive load C_{el1}, then an **end-of-cable loaded sensitivity** M_{L2} for load C_{el2} can be found from:

$$M_{L2} = M_{L1} \frac{C + C_{el1}}{C + C_{el2}} \qquad (3.3.1\text{-}6)$$

Equations 3.3.1-5 and 3.3.1-6 are most useful when using an unamplified hydrophone, i.e., a hydrophone essentially comprised of the active element, housing, and cable, connected directly to an oscilloscope or other **waveform** recording device having known input capacitance and very high input resistance (e.g., 1 M).

There are two popular configurations for connecting the hydrophone to the **waveform** recording device; namely, (a) hydrophone, integral amplifier, and cable, and (b) hydrophone, cable, and external amplifier. In case (a), the amplifier response cannot be distinguished from the overall hydrophone-amplifier response. In case (b), the **end-of-cable loaded sensitivity** $M_L(f)$ may be specified either (i) at the external amplifier input terminals, in which case the amplifier gain must be known, or (ii) at its output terminals. In either case, the configuration and electrical load must be specified.

With respect to case (b), if $M_L(f)_i$ and $M_L(f)_o$ are the **end-of-cable loaded sensitivities** at the amplifier input and output, respectively, and if the amplifier gain into a specified electrical load at frequency f is G, then $M_L(f)_o = G\, M_L(f)_i$.

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A standard way of expressing M_L is in units of volts per MegaPascal (V/MPa) (where the Pascal, the SI unit of pressure, is equal to one Newton per meter squared). Often M_L appears in terms of dB relative to ("re") 1V/μPa, or:

$$M_L \text{ (dB re 1V/μPa)} = -240 + 20 \log_{10} M_L \text{ (V/MPa)}. \quad (3.3.1\text{-}7)$$

For medical ultrasound measurements, units of V/MPa are preferred.

Table 3-1
TYPICAL HYDROPHONE SPECIFICATION DATA AT 1 MHz (IEC, 1991b)

Hydrophone Type	End-of-Cable loaded sensitivity M_L (V/MPa)	Specified load for M_L R_{el} C_{el}	Cable length (m)	End-of-Cable capacitance or impedance	End-of-Cable open-circuit sensitivity M_c (V/MPa)
PVDF Needle-like 1 mm dia.	0.10	1 MΩ 30 pF	1	130 pF	0.123
PVDF Needle-like 0.6 mm dia.	0.032	1 MΩ 30 pF	1	130 pF	0.039
PVDF Membrane 1 mm dia.	0.098	50 kΩ 5 pF	0.7	Re(Z) = 170 Ω IM(Z) = -1220 Ω	0.102
PVDF Membrane 0.5 mm dia.	0.033	50 kΩ 5 pF	0.7	Re(Z) = 220 Ω IM(Z) = -1610 Ω	0.035

The sensitivity $M_L(f)$ can be determined from the voltage of a nonperturbing hydrophone placed in a known, linear, single-frequency pressure field. Two methods for obtaining $M_L(f)$, comparison, and planar scanning, are described in detail in Section 4. Other calibration techniques include those based on principles of reciprocity and time delay spectrometry (Pedersen et al., 1988).

A former way of expressing the sensitivity of a hydrophone is through the **intensity response factor** K_t^2 (Harris, 1985, 1988), defined by the relationship:

$$i(t) = [v(t)]^2/K_t^2, \quad (3.3.1\text{-}8)$$

where v(t) is the instantaneous voltage from the hydrophone when it is placed in an ultrasound field where the **instantaneous intensity** is i(t). This relationship holds when the local ultrasound field is such that the **acoustic pressure** and particle velocity are in phase, so that $i = p^2/\rho c$ (see **intensity** definition). Using the latter equation, together with Eq. 3.3.1-1, one obtains:

$$K_t^2 = 10^{-8} M_L^2 \rho c, \quad (3.3.1\text{-}9)$$

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in which ρ and c are, respectively, the density and speed of sound for the propagation medium; the units, for convenience, are chosen as follows:

ρ:	kg/m^3
c:	m/s
M_L:	V/MPa
K_t^2:	$V^2 W^{-1} cm^2$

In water at 24°C, the above equation becomes:

$$K_t^2 = 0.015\, M_L^2 \qquad (3.3.1\text{-}10)$$

For K_t^2 in the above units, Eq. 3.3.1-8 holds with i(t) in W/cm^2 and v(t) in V.

3.3.2 Hydrophone System Frequency Response

Ideally, a hydrophone should convert the **acoustic pressure waveform** directly into a voltage **waveform** replica. This replication implies that the hydrophone has a flat frequency response over a wide frequency band, or equivalently, $M_L(f)$ is constant. While such an idealized response is not obtainable, minimum conditions must be met. The following is required in this standard for a hydrophone or hydrophone-amplifier combination to be used in measurements on a device with **center frequency** f_c:

a. When used to measure a device with a **center frequency** f_c less than or equal to 15 MHz, the **end-of-cable loaded sensitivity** for the hydrophone or hydrophone-amplifier combination shall vary by less than ±3 dB over a frequency range extending from $f_c/2$ upward to either 5 f_c or 20 MHz, whichever is less. When used to measure a device with a **center frequency** f_c greater than 15 MHz, the **end-of-cable loaded sensitivity** for the hydrophone or hydrophone-amplifier combination shall vary by less than ±3 dB over a frequency range extending from $f_c/2$ upward to 40 MHz.

b. For all measurement data reported, the frequency response of the hydrophone should be specified, in order that those using the data can determine the measurement errors introduced by hydrophone frequency response effects.

c. Whenever possible, a hydrophone or hydrophone-amplifier combination with a frequency response greater than the minimum requirement specified in this section should be used. A hydrophone with an upper frequency limit of 8 f_c will provide more accurate measurement of high frequency/wide **bandwidth** sources exhibiting source nonlinear propagation distortion. A hydrophone with a lower frequency limit of $f_c/20$ will provide more accurate measurement of the **peak rarefactional pressure**, and thus a more accurate Mechanical Index, for all **amplitude modulated waveforms** (Harris, 1996). For **continuous waveforms**, the $f_c/2$ lower limit is sufficient.

d. To meet a lower frequency limit of $f_c/20$, **spot-poled** membrane hydrophones should be used, and the lower -3 dB limit of the hydrophone amplifier frequency response should be no greater than $f_c/20$. Because of diffraction effects around the tip, needle hydrophones will have difficulty meeting the $f_c/20$ requirement, so their use should be limited to **continuous waveforms**, or to those specific situations in which their transducer or beam geometry prevents the use of a membrane hydrophone (e.g., physical interference between the membrane and the transducer under test) (Fay et al 1994).

Factors governing the frequency response are the resonance and **bandwidth** of the PVDF material (determined by its thickness), resonance of the cable (determined by its length), spurious responses, and

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the flatness and 3 dB frequency of the amplifier (Lewin and Schafer, 1986; Smith, 1986). These factors compete and may either exaggerate or compensate each other.

A wide frequency response is required because of the generation of higher harmonics by nonlinear propagation in the water medium, as described in Appendix B. In water, asymmetry may develop between compressional and rarefactional regions of a pulse so that the **peak compressional pressure**, p_c, becomes much greater than the **peak rarefactional pressure**, p_r. The development of strongly distorted compressional peaks (see Fig. B-1) is associated with spectral components whose frequency is much higher than f_c. The degree of nonlinearity of a **waveform** is influenced by the pressure level on the transducer face, focusing gain, distance, and frequency. These effects can be evaluated by a **nonlinearity propagation parameter**, σ_m, discussed in Appendix B.

3.3.3 Effective Hydrophone Diameter

Equations 3.3.3-1 and 3.3.3-2 below may be used as a guideline for choosing the **effective hydrophone diameter**, d_e (Harris, 1985):

$$d_e < \frac{\lambda z}{2 d_s} \text{ if } z/d_s \geq 1 \qquad (3.3.3\text{-}1)$$

and

$$d_e < \frac{\lambda}{2} \text{ if } z/d_s < 1 \qquad (3.3.3\text{-}2)$$

where d_s is the source diameter or largest source dimension, z is the distance from the hydrophone to the source, and λ is the **wavelength**. If these criteria cannot be met, a **geometrical hydrophone diameter** (or greatest dimension) equal to or less than 0.6 mm shall be used.

When the criteria of Eqs. 3.3.3-1,2 cannot be met, the **effective hydrophone diameter** is too big and spatial averaging will occur. Averaging decreases the measured pressure amplitude from the actual value and causes lateral broadening of beamwidths. For more information refer to Appendix C.

3.3.4 Dynamic Range and Linearity

The **peak compressional pressure** p_c measured from diagnostic ultrasonic transducers can exceed 8 MPa; therefore, the linearity of the combined hydrophone-amplifier response must be measured over the full range of intended use. The PVDF material has an intrinsic linearity which has been measured up to pressures of 70 MPa or intensities of 330 kW/cm^2 (Meeks and Ting, 1984), so it is the linearity of the amplifier which must be checked. Specifications for amplifier linearity and dynamic range are given in Section 3.5.1.

3.3.5 Field Measurement Caution

Hydrophones perturb the acoustic field. For membrane-type hydrophones, the membrane reflects a portion of the acoustic field incident on it. For this reason, care must be taken to avoid standing waves when measuring continuous-wave fields (e.g., **CW Doppler**), and to avoid interference with multipath reverberation in pulsed field measurements. This can be accomplished by angling the membrane hydrophone with respect to the acoustic axis, and applying a directivity correction (Preston et al., 1983). Reflectivity data may be obtained from the manufacturer (also see DeReggi et al., 1981 and Preston et al., 1983). For membrane type hydrophones, outer hoop reflections may occur when the beam diameter exceeds the radius of the hoop. Reflections are present to a lesser extent for needle type probes.

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3.4 HYDROPHONE SELECTION AND MINIMUM REQUIREMENTS

Selection of a hydrophone depends on the characteristics of the acoustic fields to be measured, and hence on such factors as **transducer assembly** geometry, focal spot size, range of **acoustic pressure** levels, **center frequency**, noise environment (electrical and acoustic), and the presence of nonlinear distortion. For some applications, no currently available hydrophone will meet all criteria; therefore, the typical performance limits must suffice. Table 3-2 provides a summary of currently available hydrophone specifications. Table 3-3 provides a list of minimum hydrophone or hydrophone-amplifier specifications. Further information can be found in Shombert et al., 1982; IEC, 1991b; Smith, 1986; Preston, 1986; Lewin and Schafer, 1986; and Shombert and Harris, 1986.

If an amplifier is used with the hydrophone, then the frequency response specification in Table 3-3 must be met by the hydrophone-amplifier combination. To meet this specification, it may be necessary for the amplifier's frequency response to compensate for variations in the hydrophone's response, such as those due to thickness resonance effects.

Also, if an integral amplifier is not used, it may be advisable to reduce the cable length between the hydrophone housing and the **waveform** recording device or external amplifier to 15 cm or less if cable-related resonances are observed in the hydrophone signal. These resonances, which arise from finite amplitude distortion, appear as high frequency oscillations superimposed upon the hydrophone voltage **waveform** (see Bacon, 1982; Smith, 1986; Lewin et al., 1987; and Harris, 1988).

3.5 HYDROPHONE MEASUREMENT SYSTEM

Several pieces of equipment are essential for both **hydrophone calibration** and diagnostic ultrasound measurement; these include a hydrophone, amplifier, a water tank with positioning system, and an oscilloscope/**waveform** recorder.

3.5.1 Hydrophone Amplifier

Amplifiers used with hydrophones must meet the minimum specifications listed in Table 3-4.

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Table 3-2
TYPICAL HYDROPHONE SPECIFICATIONS

SPECIFICATION	NEEDLE TYPE	MEMBRANE TYPE
Directivity	close to ideal piston	close to ideal piston except for f_c < 2 MHz and for d_e < 0.5 mm
Dynamic Range	good, although high rms pressures may cause damage	good
Field Perturbation	minimal	minimal; in CW fields, standing waves may result
Usable Frequency Range (depends on PVDF thickness)	1 - 40 MHz	1 - 100 MHz
Linearity	Excellent	Excellent
Electrical Shielding	Excellent	Excellent in bi-laminar design; poor for co-planar
Geometrical Hydrophone Diameter (mm)	0.4 - 1.0	0.2 - 1.0
End-of-Cable loaded sensitivity (V/MPa)	0.03 - 0.1	0.02 - 0.1

Table 3-3
MINIMUM HYDROPHONE OR HYDROPHONE-AMPLIFIER COMBINATION SPECIFICATIONS

Material of Active Element	**PVDF**
End-of-Cable Loaded Sensitivity	> 0.01 V/MPa (–280 dB re 1 V/μPa)
Frequency Response	± 3 dB from $0.5f_c$ to $5f_c$ or to 20 MHz, whichever is less, if f_c is less than or equal to 15 MHz or to 40 MHz if f_c is greater than 15 MHz
Effective Hydrophone Diameter	Equations 3.3.3-1 and 3.3.3-2. If these criteria cannot be met, then choose a geometrical hydrophone diameter of = 0.6 mm. (See Table C.1 in Appendix C).

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Table 3-4
MINIMUM HYDROPHONE AMPLIFIER SPECIFICATIONS
(SEE SECTION 3.5.1.2 AND FIGURE 3-1)

Maximum input voltage	$> M_L p_{max}/G$
Maximum output voltage	$> M_L p_{max}$
Linearity	± 0.3 dB over hydrophone voltage range
Dynamic range	> 50 dB
Slew rate	$> 15 f_c M_L p_{max}$
Maximum output current	$> M_L p_{max}/\|Z_L\|$

3.5.1.1 Input and Output Impedance

The amplifier input and output impedances, as well as the recommended output load, shall be specified.

3.5.1.2 Maximum Input and Output Voltage Ratings

The maximum amplifier input and output voltage ratings, v_{Imax} and v_{Omax}, shall meet the following inequalities (see Figure 3-1):

$$v_{Imax} > M_L\, p_{max}/G \qquad (3.5.1.2\text{-}1)$$

and

$$v_{Omax} > M_L\, p_{max} \qquad (3.5.1.2\text{-}2)$$

where p_{max} is the estimated maximum value of the **acoustic pressure** p, G is the maximum amplifier gain, and the **end-of-cable loaded sensitivity** into load Z_L is $ML = v_o/p$.

As an example, for a p_{max} of 10 MPa (which corresponds to a plane wave **intensity** in water of about 7000 W/cm^2 and is a realistic upper bound for diagnostic ultrasound), a gain of one, and a hydrophone sensitivity M_L of 3×10^{-7} V/Pa (or –130 dB re 1 V/Pa), $v_{Imax} > 1.5$ V, and $v_{Omax} > 3$V. Few polymer hydrophones have sensitivities greater than this; in fact, many with **effective hydrophone diameters** less than 1 mm have sensitivities less than 10^{-7} V/Pa, which reduces the preamplifier input and output voltage rating requirements to 0.5 V and 1 V, respectively. None of these voltage values should pose a practical limitation.

3.5.1.3 Amplitude Linearity

The amplifier must be linear to within 0.3 dB over the range of hydrophone voltages encountered (at least 50 dB).

3.5.1.4 Slew Rate

The amplifier **slew rate** (SR) must satisfy the following inequality:

$$SR > 15 f_c M_L p_{max} \qquad (3.5.1.4\text{-}1)$$

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where f_c is the **center frequency**, and M_L and p_{max} are defined in Section 3.5.1.2.

NOTE—The **slew rate** can be no greater than the ratio of the maximum amplifier output current to the load capacitance. The load capacitance includes the sum of the cable capacitance and the input capacitance of the **waveform** recording device.

3.5.1.5 Maximum Output Current

Referring to Figure 3-1, the amplifier output current i must be sufficient to sustain, without distortion, the maximum output voltage v_{Omax} across the load impedance Z_L; i.e.,

$$i_{max} > \left(v_{O\,max}/|Z_L| = M_L p_{max}/|Z_L|\right) \qquad (3.5.1.5\text{-}1)$$

Here, Z_L includes the input impedance of the electrical load, as well as the impedance of the cable connecting the load to the amplifier out-put. If the inequality in Eq. 3.5.1.5-1 is not satisfied, then (i) Z_L can be increased, (ii) M_L can be reduced by choosing a hydrophone with a less sensitive active element, or (iii) an amplifier having a higher current rating can be chosen. In practice, Z_L can be increased by shortening the cable connecting the amplifier to the electrical load (e.g., the input of the **waveform** recording device). (It should be noted that the amplifier power supply current specification must be sufficient to supply I_{max}.)

3.5.1.6 Electrical Termination

The cable connecting the amplifier to the **waveform** recording device shall be terminated in its characteristic impedance, unless a cable length of less than 15 cm is used.

3.5.1.7 Signal-to-Noise Ratio

The signal-to-noise ratio of the combined hydrophone-amplifier system must be adequate to provide a 10 dB range above noise for the weakest signals measured from diagnostic systems. If planar scanning calibration is used, a signal-to-noise margin of greater than 20 dB is required for the **working source** or **reference source** levels and frequencies used.

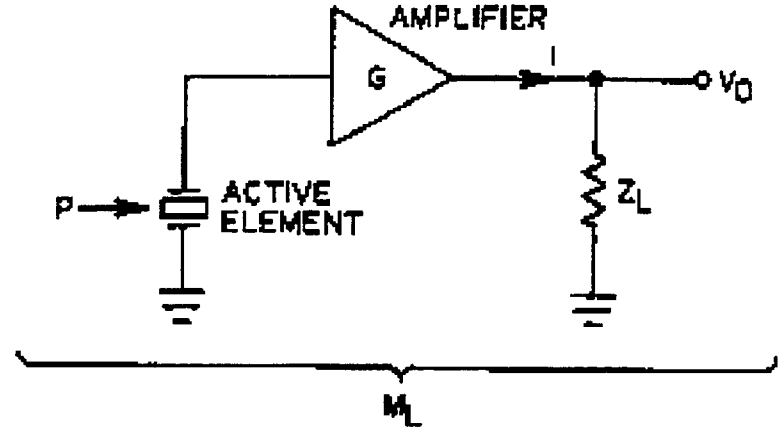


Figure 3-1
DIAGRAM OF HYDROPHONE AND AMPLIFIER

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Incident pressure P results in output voltage V_o across electrical load Z_L. Overall **end-of-cable loaded sensitivity** $M_L = V_o/P$. Amplifier has gain G and output current I.

3.5.2 WATER TANK

All measurements shall be performed in a suitable water tank in which the hydrophone, as well as the **transducer assembly** face under measurement, are immersed in water. The size of the tank is governed both by the type of calibration and the diagnostic equipment to be evaluated. This size should be large enough so reflections from the tank walls, preferably lined with a highly **anechoic material** (necessary for CW measurements), will not interfere with measurements.

Useful **anechoic materials** include packing foams (corrugated is better than flat, and foam should be deaerated by user), door mats, brushes, and materials developed for this purpose such as described in Chivers et al. (1981). For a discussion of water preparation, see Appendix E.

In general, the tank depth (or z dimensional axis, if appropriate) should be at least 1.3 times greater than either the approximate **far field** distance, $S/\pi\lambda$, or the maximum **focal length** of the **reference sources** used, where S is transducer area and λ is the **wavelength**. A dimensional margin of 30 to 100 percent should allow for adequate clearance and reduction of spurious effects.

3.5.3 POSITIONING SYSTEM

A micropositioning system is needed to move the hydrophone to any point in the acoustic field of a transducer at which measurements are required (see, e.g., Schafer and Lewin, 1988). A system capable of translation along three orthogonal axes with a reproducibility of at least $\pm 0.15/f_c$ mm is recommended, where f_c is in megahertz. The axis perpendicular to the active element of the hydrophone should be made parallel to the **beam axis** of the transducer. In addition, the capability of rotation about one and preferably two axes, x and y, should be provided. Note that either the hydrophone or the transducer can be selected to remain stationary in a tank set-up.

3.5.4 OSCILLOSCOPE/WAVEFORM RECORDER

For measurements that are made frequently, a computer-controlled transient recorder or digital oscilloscope with sampling rates of 100 MHz is recommended. With the aid of a computer, calculations on **waveforms** can be executed automatically with better accuracy and reproducibility than is possible with manual methods. For infrequent measurements, an analog scope with a delayed sweep and a **bandwidth** of 50 MHz or greater and a Polaroid camera can form the basis of a primitive **waveform** capture system. Optical probes mounted in XY translators (plotters) or digitizing pens connected to calculators or computers can be used for manual digitization by tracing the photographed **waveform**. Because of the high frequency content of **waveforms**, many time-sample points are needed for accuracy and repeatability. A sampling interval of $50/f_c$ ns or 10 ns, whichever is greater, should be sufficiently small, where f_c is in megahertz. A record of the **waveform** can either be plotted or photographed in the latter system.

When recording the **waveform** with a digital oscilloscope or transient recorder, the gain should be adjusted to allow at least seven significant bits in the digitized **waveform.**

3.5.5 COMMERCIALLY AVAILABLE MEASUREMENT SYSTEMS

Automated systems that perform many of the measurements called for in Section 5 are commercially available (Preston, 1988).

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3.6 FORCE BALANCE CHARACTERISTICS

A force balance based on principles illustrated in Figs. 3.2 and 3.3 (adapted from IEC, 1992b) shall be used for measuring **ultrasonic power** from a diagnostic instrument. While radiation force methods are the preferred approach for the measurement of total acoustic **power,** hydrophone methods may also be used as long as extreme care is taken to assure measurement accuracy (see Section 5.6.2).

When the transducer is directed toward a target, the ultrasound beam tends to displace the target from its equilibrium position. This tendency results from a radiation force whose magnitude can be measured in various ways. In one arrangement, an electronically generated constraint force of magnitude (F) is applied, which is just sufficient to prevent the displacement. This quantity F is equal to the radiation force; from acoustical principles it is proportional to the desired **ultrasonic power**. It is not necessary that the ultrasonic beam be projected upward as shown in Figs. 3.2 and 3.3; in other arrangements, the beam is directed downward, or horizontally.

Instruments based on the force-balance principle are becoming commercially available for measuring the **ultrasonic power** emitted by diagnostic devices. Use of reliable commercial instruments for this purpose may reduce the requirements on time and expertise for laboratory staff. Alternatively, in some laboratories it may be preferable to construct a force-balance system from components; this option is discussed in Section 3.6.1.

Whether the force balance **power** meter is a commercial device or one built from components, it should be so designed and constructed that, when operated properly, the measurement of **ultrasonic power** by its use is reproducible to within a standard deviation of 10%.

If a hydrophone is used to measure the total **power,** this must be explicitly stated in any **measurement report**.

3.6.1 Constructing a Force Balance from Components

Recent information on setting up and operating a force-balance system is given in IEC (1992b), IEEE (1990), and Carson and Banjavic (1980), the latter reference also containing detailed drawings and lists of parts. Central to the system is an electrobalance of adequate sensitivity and stability; the requirements here depend on the expected range of **power** outputs for the equipment to be measured. For a system of the type represented in either of Figs. 3.2 or 3.3, an ultrasound beam transmitting a total **power** of 1 mW will exert a radiation force equivalent to the weight of 68 μg. It is recommended that the balance operate on a "feedback" (or "null") principle; i.e., the determination of radiation force should be made by providing a measured counterforce which results in zero displacement of the balance arm.

Other required components of the system include the target; ideally, this is to be either (i) perfectly absorbing, for the arrangement of Fig. 3.2, or (ii) perfectly reflecting, for the arrangement of Fig. 3.3. Materials and designs for approaching these ideals are described in IEC (1992b) and Carson and Banjavic (1980). The target area must be large enough relative to the **beam cross-sectional area** or (in a scanning mode) **scan cross-sectional area** so that the measured radiation force corresponds to the total **ultrasonic power**; this consideration is taken up quantitatively in IEC (1992b).

In the arrangements of Figs. 3.2 and 3.3, the target, hung by a thin wire from the balance, is immersed in water within the measurement vessel, fabricated of clear plastic. The water is degassed to minimize disturbances caused by gas bubbles or cavitation. Vibration isolation may be needed if the system is set up in a mechanically noisy environment; minimizing the target volume (which may require a trade-off with needs for a large target area) helps to reduce disturbances from vibration (Rooney, 1973).

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The water temperature must be uniform throughout the vessel to avoid disturbances caused by convection currents; in some arrangements this condition is sought by using a water jacket of controlled temperature (Rooney, 1973).

In the figure below, 1 = source transducer; 2 = absorbing target suspended in water bath; 3 = tare weight.

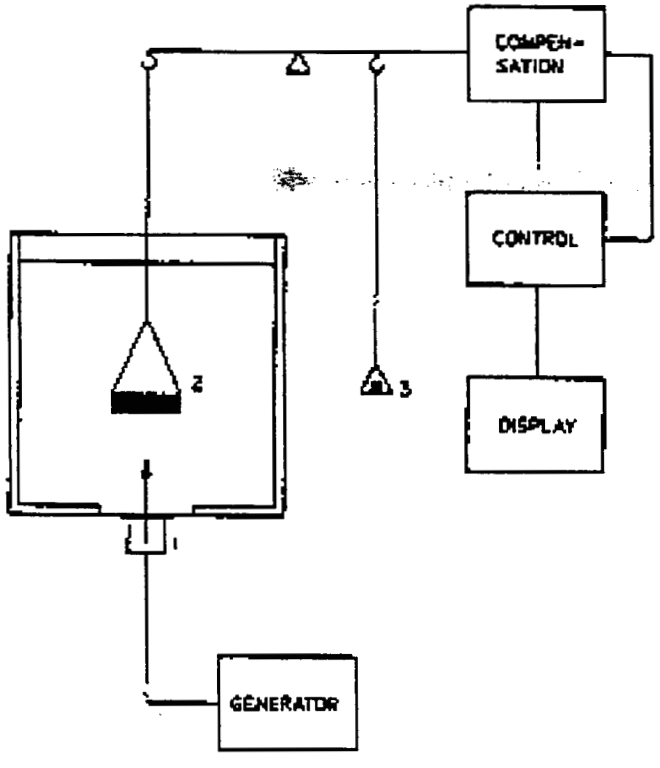


Figure 3-2
RADIATION FORCE BALANCE SYSTEM WITH ABSORBING TARGET

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In the figure below, 1 = source transducer; 2 = reflecting target suspended in water bath; 3 = Tare weight.

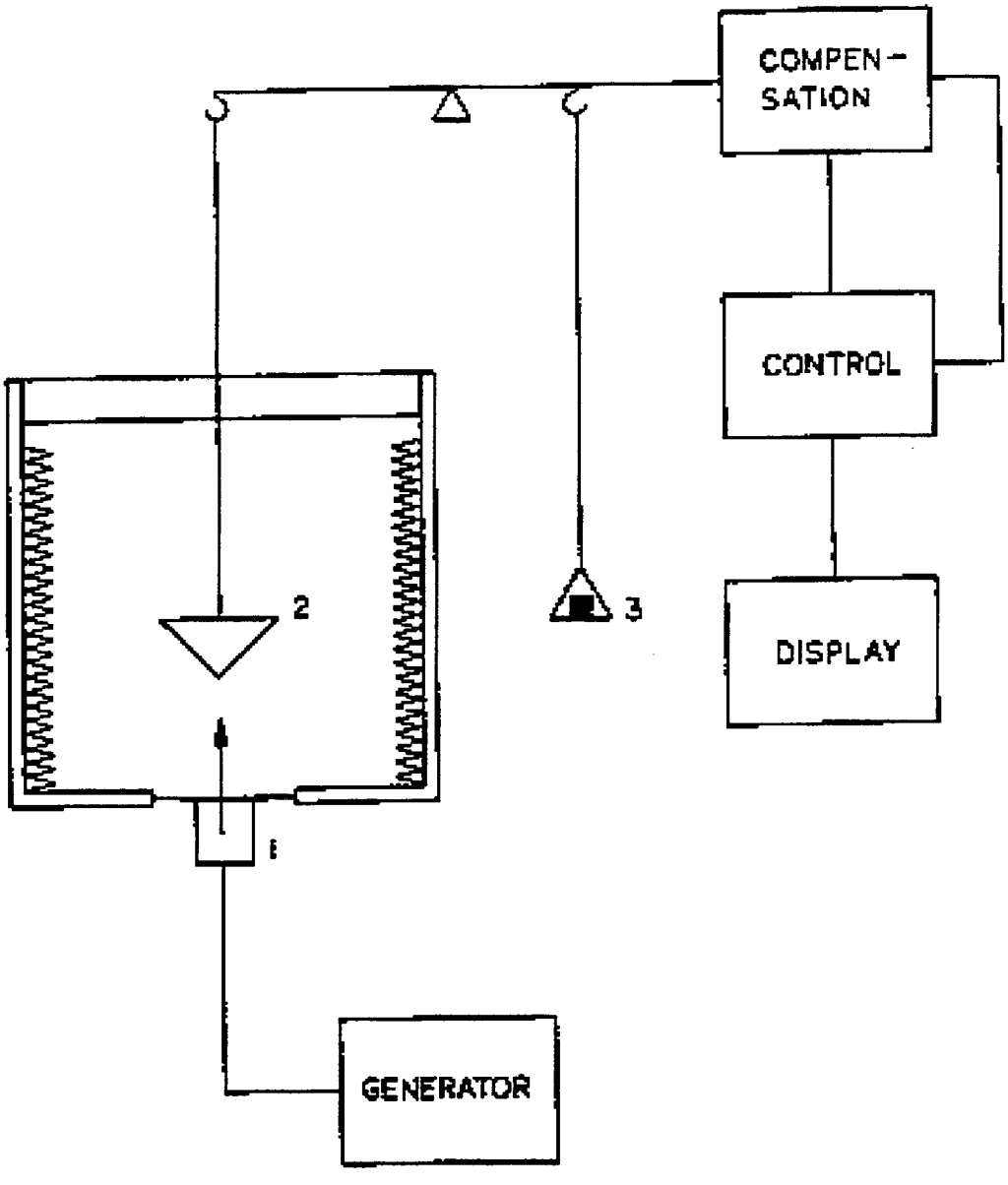


Figure 3-3
RADIATION FORCE BALANCE SYSTEM WITH REFLECTING TARGET AT 45° ANGLE TO DIRECTION OF PROPAGATION

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In the arrangements of Figs. 3.2 and 3.3, an acoustic window is provided at the bottom of the measurement vessel. This window is a thin sheet of plastic (such as polyethylene) which has been stretched across an opening in the bottom plate; a watertight seal is made with O-rings, or by some other means. To minimize the perturbing effects of the window, it should be as thin as practical (~10-15 mm), and it should be positioned at an oblique angle relative to the **beam axis** (Beissner, 1982).

In a measurement of **ultrasonic power**, a **transducer assembly** of interest is placed in acoustic contact with the window by means of a suitable coupling medium. The arrangement simulates the situation in clinical practice in which a transducer is placed in acoustic contact with a patient. When the transducer is actuated by its driving system, it generates an ultrasound beam that propagates through the coupling medium and plastic membrane into the water in the measurement vessel. Since the plastic window is flexible the transducer can, and should, be oriented suitably relative to the target.

Existence of the ultrasound beam causes acoustic streaming, a steady circulatory motion, to be set up in the water. Effects of this streaming on the target are reduced by placing a thin acoustically-transparent membrane across the beam just below the target. Also, the effects of nonlinear losses on force balance measurements (see Appendix B) can be minimized or prevented by reducing the source-to-target distance.

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Section 4
CALIBRATION METHODS

4.1 INTRODUCTION

The calibration procedure involves transferring hydrophones and ultrasound sources of accurately known characteristics from a national standards laboratory to the user's **local laboratory**, where the ultrasound field measurements are to be performed. This section describes a force balance calibration method and two **hydrophone calibration** procedures: a comparison technique and the planar scanning technique. A step-by-step summary of the main calibration procedures is outlined with reference to traceability. Finally, the calibration methods are explained in detail.

This section concludes with a discussion of **hydrophone calibration** above 20 MHz.

4.2 TRACEABILITY AND THE CALIBRATION PROCESS

One of the objectives of this standard is to provide accurate and precise means by which ultrasonic field parameters can be measured. This entails careful consideration of both the accuracy and the precision of the measurement process. The accuracy is determined from the closeness of the result to the "true" value, whereas the precision is determined by the reproducibility with which such a measurement can be made, irrespective of whether the measurement is close to the true or actual value.

The precision is influenced by the characteristics of the hydrophone, the translation stage, the oscilloscope, and other physical measurement equipment. The precision can be treated on a statistical basis by performing repeated measurements and calculating the spread of means and standard deviations for the data.

Accuracy, on the other hand, is the extent to which a measurement conforms to a "true" value as defined by a national standards laboratory for the particular measurement process under consideration. To ensure accuracy in an ultrasound field measurement, the process and equipment used for the measurement must ultimately be traceable to a national standards laboratory.

Two fundamental devices are calibrated: force balances, which respond to acoustic **power**, and hydrophones, which respond to **acoustic pressure**. A force balance is calibrated by checking its response to a calibrated source transducer, or **reference source**, which has been calibrated at one or more frequencies by a national standards laboratory. The national standards laboratory provides operating and drive conditions that must be duplicated when the **reference source** is used in a **local laboratory** to produce a known and traceable **power** output. Preferably, the **reference source** should be constructed of quartz or another inherently stable piezoelectric crystal. The air-backed lithium niobate **reference source** provided by the US National Bureau of Standards (Fick et al., 1984) is suitable for use as a **reference source**, although any stable source calibrated by a national standards laboratory can serve as a **reference source**.

A hydrophone is calibrated most directly by a comparison technique in which the hydrophone's sensitivity is compared to that of a similar hydrophone calibrated at a national standards laboratory. A hydrophone obtained from such a laboratory for use as a **reference hydrophone** is calibrated at a laboratory with reference to, for example, a laser interferometric measurement of particle displacement in the acoustic field (Bacon, 1988), from which the pressure can be derived. A **reference hydrophone calibration** may be checked at a **local laboratory** by planar scanning; its stability is checked by comparison or planar scanning. [Reciprocity, either alone or in combination with time delay spectrometry, also has been used for calibrating hydrophones (IEC, 1987; Ludwig and Brendel, 1988; Pedersen et al, 1988).]

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The **reference source** and **reference hydrophone** are intended primarily for traceability to a national standards laboratory only. A **local laboratory** also should maintain a **working source** and a **working hydrophone** for the majority of actual measurements. The acoustic output of a **working source** is traceable to a **reference source** (and thus a national standards laboratory) via a force balance measurement at a **local laboratory**. A **working source** normally is used in routine **hydrophone calibration** and stability checks using the comparison or planar scanning technique, both described below. A **working source** typically is a broadband ceramic transducer which, while potentially less stable than the **reference source**, is often more convenient to use because (a) it is more readily available, and (b) its shorter impulse response makes it suitable for pulsing applications. The stability of the **working source** must be checked via a force balance measurement as part of the calibration process.

A **working hydrophone** is a hydrophone that has not necessarily been calibrated at a national standards laboratory. Instead, it is calibrated at a **local laboratory** relative to a **reference hydrophone** by the comparison technique, or relative to a **reference source** via the planar scanning technique.

To accomplish a comparison calibration, a **reference source** or **working source**, and its associated electronics, provides the reference **acoustic pressure** field for the hydrophone comparison procedures. When the **reference hydrophone** is placed in the field of the source, **waveforms** of its output voltage are recorded. Next, the output **waveforms** of the **working hydrophone**, placed in the same locations as the **reference hydrophone**, are recorded. These **waveforms** are used to determine the **working hydrophone** sensitivity, and, when recorded at periodic intervals, to check both **reference hydrophone** and **working hydrophone** stability.

To accomplish a calibration check using the planar scanning technique, a measurement of **ultrasonic power** is related to the hydrophone sensitivity via a spatial and temporal integration of the square of the **acoustic pressure** over the radiated pressure field (see, e.g., Herman and Harris, 1982). The **ultrasonic power** of a **working source** with well-behaved spatial and temporal characteristics is measured with a force balance, or, alternately, a **reference source** calibrated at a national standards laboratory may be used. If a force balance is used, it must be calibrated by measuring the output of a **reference source** whose output **power** has been measured at, or is traceable to a national standards laboratory. Although the pressure-squared integral can be related in this way to the **ultrasonic power** of the source transducer, this indirect process involves additional complexity. Therefore, the planar scanning method is recommended primarily for **spot checks** of the comparison calibration; however, if a **reference hydrophone** is not available, then planar scanning is an acceptable approach for determining **working hydrophone calibration**.

For a **reference hydrophone** calibrated at a national standards laboratory, the sensitivity can be specified in terms of either the **end-of-cable open-circuit sensitivity**, $M_c(f)$, or **end-of-cable loaded sensitivity**, $M_L(f)$ (see Section 3.3.1). If the **reference hydrophone** has no integral or external amplifier, then $M_c(f)$ commonly is specified. If the **reference hydrophone** has an integral amplifier, then $M_L(f)$ and the electrical loading conditions (e.g., into 50 ohms) would be specified. If the **reference hydrophone** has an associated external amplifier, then $M_L(f)$ at the amplifier input could be computed using Equations 3.3.1-2 or 3.3.1-5. Additionally, for this latter case, the national standards laboratory may specify $M_L(f)$ for the **reference hydrophone**/external amplifier combination, along with the electrical loading conditions. It should be recognized that the **reference hydrophone** sensitivity provided by the national standards laboratory may have to be converted to the value of $M_L(f)$ appropriate to the particular **local laboratory** measurement set-up.

Because hydrophones potentially are fragile devices and subject to wear and abuse, it is highly desirable for **local laboratories** to maintain a number of **working hydrophones** that are used for the majority of actual measurements. The **reference hydrophone** normally is used solely to calibrate **working hydrophones**.

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The calibration process additionally involves statistically establishing the "error bounds" or the degree of uncertainty of the measurement procedure and equipment, as described in Appendix A. This is accomplished by performing repeated calibrations of the **working hydrophone** and recording the results to establish the uncertainty for the procedure. This uncertainty must then be combined with the uncertainty reported for the output measurements of **ultrasound systems**.

As an alternative to calibrations at a **local laboratory**, it is permissible to have calibrations performed by an independent testing laboratory which maintains traceability to a national standards laboratory.

For the measurement data reported under this standard, the devices used (**working hydrophone**, **working source**) shall have been calibrated or **spot checked** within the month prior to the measurement. This calibration requirement is not necessary for non-reference measurements.

4.3 OUTLINE OF CALIBRATION PROCEDURES

The major steps in the recommended calibration procedures are diagrammed in Figure 4-1. The circled numbers in the figure are the step numbers. The three main procedures are the calibration of the force balance and **working source** (steps 1–4), **local laboratory** checks of a **reference hydrophone** (steps 5–7 and 10), and calibration of a **working hydrophone** (steps 8–10).

Detailed information about each step can be found in the section number in brackets after each step number listed below.

If a malfunction of either the force balance or one of the reference devices (source or hydrophone) is suspected, then a three-way intercomparison, e.g., steps 3 and 6, will help identify the cause.

1. National Standards Laboratory Calibration of **Reference Source** [see Section 4.4.2]

   A source transducer is obtained from a supplier and is sent to a national standards laboratory. At this laboratory, the source transducer is calibrated under reproducible excitation conditions to produce known **power** levels, W_r, at certain frequencies, thus establishing the source as having primary absolute **ultrasonic power** traceability to the laboratory. This source transducer is then referred to as a **reference source**. More than one **reference source** may be necessary to cover the desired frequency range.

2. Calibration of Force Balance [see Section 4.4.3]

   Once the **reference source** is received at the **local laboratory**, and it is excited under the same conditions and frequencies, it can be used to calibrate a force balance. This process is repeated several times, as prescribed in Appendix A, to determine the uncertainty of the calibration.

3. Periodic **Spot Checks** of Force Balance and **Reference Source** [see Section 4.4.4]

   Each year, or more frequently if a change is suspected, the force balance and **reference source** are **spot checked** to see if they are performing as intended. If significant deviations are detected, either repair, adjustment, or recalibration of the force balance, or recalibration of the **reference source** at the national standards laboratory may be warranted.

4. Calibration and **Spot Checks** of **Working Source** [see Section 4.4.5]

   The **working source** should be calibrated at specified conditions and frequencies using a force balance. This calibration should be **spot checked** at least monthly, or more frequently if a change is suspected.

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5. National Standards Laboratory Calibration of **Reference Hydrophone** [see Section 4.5.1]

   The **reference hydrophone** is obtained by first purchasing a hydrophone from a supplier, and then sending it to a national standards laboratory or an independent testing laboratory maintaining traceability for sensitivity calibration at a desired number of frequencies.

6. Comparison **Waveform Records** for **Reference Hydrophone** [see Section 4.5.2]

   The **reference hydrophone** is tested at the **local laboratory** by setting up a **reference source** or **working source** and the **reference hydrophone** at prescribed frequencies and separation distances. For each case, calculations are performed on each **waveform** and the **waveforms** are recorded at all calibration frequencies. These **reference hydrophone waveforms** are used for future comparison calibrations of **working hydrophones** and for stability checks. Repeated measurements are used to determine system measurement error, E_2 (see Appendix A).

7. Periodic **Spot Checks** of **Reference Hydrophone** [see Section 4.5.3]

   Periodically, at least annually, the source transducer and **reference hydrophone** are set up in the same way as described in step 5, and the **waveforms** obtained are compared with those recorded earlier to determine if significant changes beyond the measurement error bounds have occurred.

8. **Working Hydrophone** Comparison Calibration [see Section 4.6]

   A **working hydrophone** is obtained by first purchasing a hydrophone from a supplier, and then calibrating it locally. The recommended procedure is the comparison method, in which the **working hydrophone** is put in the same configuration as that used in testing the **reference hydrophone** (as described in step 5). By direct comparison of the new **working hydrophone's** recorded **waveforms** to those recorded for the **reference hydrophone**, the new **working hydrophone's** sensitivity can be established within a system measurement error. For an alternative **working hydrophone calibration**, see step 10 below.

9. Periodic **Spot Checks** of **Working Hydrophone** [see Section 4.7]

   Periodic **spot checks** are made at least annually, to determine if the **working hydrophone** is performing consistently by comparing its present **waveforms** to those recorded in step 7, under the same testing circumstances. Significant changes warrant recalibration and possible further investigation.

10. **Hydrophone Calibration** Checks via Planar Scanning [see Section 4.8]

    An alternative method for checking the calibration of a **reference hydrophone** is to perform the planar scanning technique at each calibration frequency. Also, the calibration of a **working hydrophone** can be checked by planar scanning (in the temporary absence of a **reference hydrophone**). The planar scanning is performed using either a **reference source**, or a **working source** with known **power** output as determined from a force balance measurement. The integrated total **power** of the source as measured by the hydrophone, W_h, is related to the **end-of-cable loaded sensitivity**, $M_L(f)$, through equations and the known **ultrasonic power**, W_r. The quantity W_r is obtained either from the **reference source** calibration or measured by a force balance.

Although the planar scanning technique is useful, it is not as simple as the comparison calibration technique, and therefore the comparison method is preferred.

For the measurement data reported under this Standard, the devices used (**working hydrophone, working source**) shall have been calibrated or **spot checked** within the month prior to the measurement. This calibration requirement is not necessary for non-reference measurements.

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4.4 CALIBRATING THE FORCE-BALANCE SYSTEM

The requirements of this section shall apply over the range of acoustic **powers** applicable to the **equipment** under test.

4.4.1 Fundamental Force Balance Equations

From the theory of physical acoustics, the radiation force in the ideal situations represented by Figures 3.2 and 3.3 is given by W/c, where W is the **ultrasonic power** emitted by the source and c is the speed of sound. Letting F be the radiation force, we obtain the basic force-balance equation:

$$W = Fc \qquad (4.4.1\text{-}1)$$

In SI units, W is in watts, F in newtons, and c in meters per second. The balance is usually calibrated in grams as units of weight. Taking the newton as the gravitational force exerted on a mass of 0.102 kg and taking the speed of sound in water as 1500 meters per second, one obtains the working equation:

Power in milliwatts W = 0.0147 × reading from the balance in micrograms (4.4.1-2)

Equation 4.4.1-2 is valid for an absorbing target (Figure 3-2) and a reflecting target with a 45 degree target angle (Figure 3-3).

The basic equation, Eq. 4.4.1-1, has received considerable support from a theoretical standpoint and, to some extent, has been tested experimentally. In practice, however, the conditions are always less than ideal, and some of the assumptions made in deriving Eq. 4.4.1-1 are not completely valid. It is therefore recommended that the force balance system (whether a commercial unit or one built from components) be tested periodically by using a **reference source(s)**.

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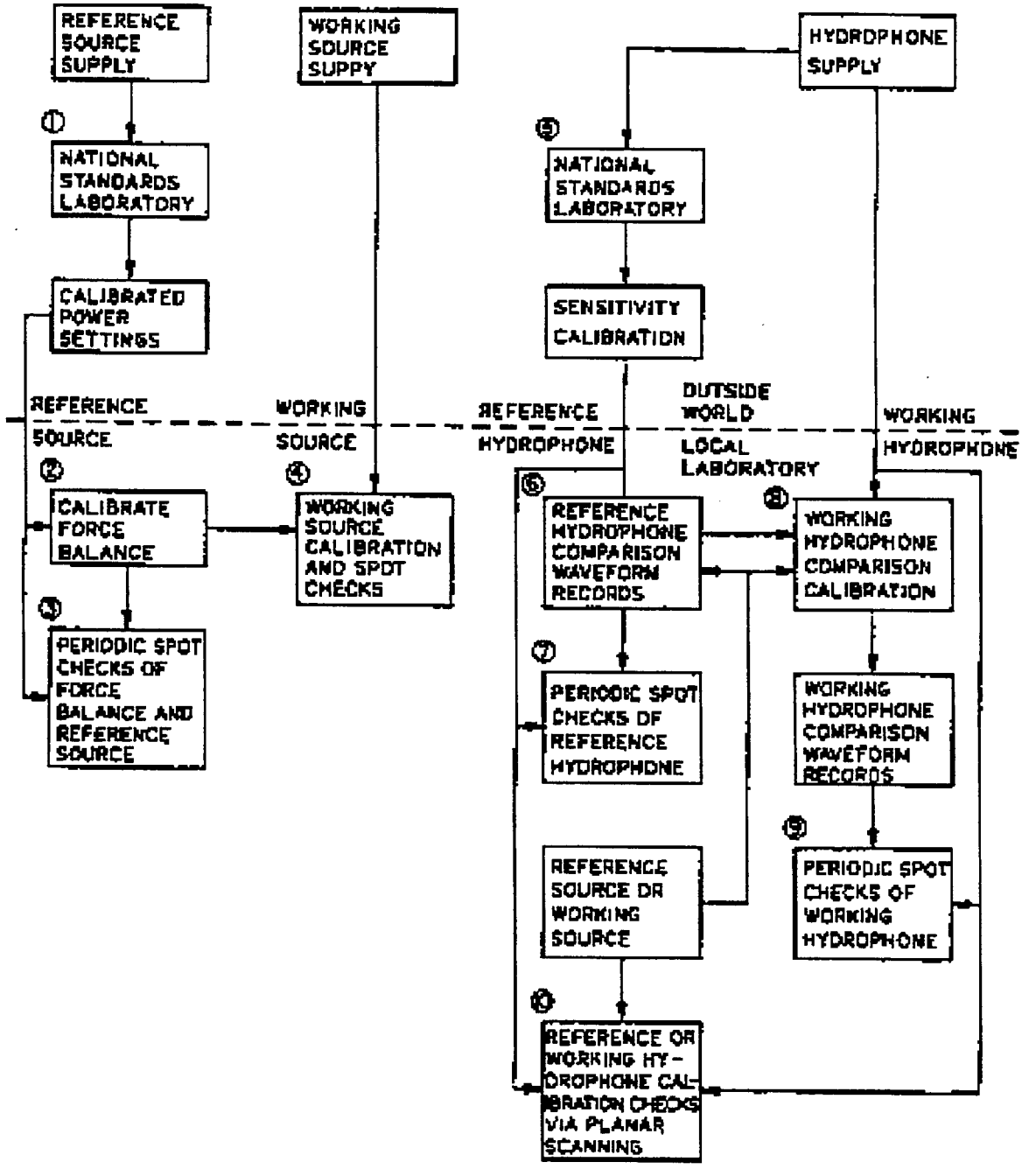


Figure 4-1
DIAGRAM OF MAJOR STEPS IN THE RECOMMENDED CALIBRATION PROCEDURES

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4.4.2 Reference Source Transducers

Reference source transducers, when driven electrically in a specified manner, provide an absolute **ultrasonic power** level. Such **reference sources** have been calibrated by a national standards laboratory at known **power** levels at one or more frequencies under specified conditions (see, e.g., Fick et al., 1984).

4.4.3 Force Balance Calibration

To calibrate a force balance, a **reference source** is mounted appropriately in the force balance tank. The combination of the **reference source** and any driving signal source shall produce harmonics no greater than –40 dB relative to the output **power** at the calibration frequency. The **reference source** shall be driven at the prescribed conditions necessary to attain the desired known **ultrasonic power** output, W_r. The force balance is checked, and adjusted if necessary, so that its reading is brought into agreement with the known **ultrasonic power** output, W_r, at each calibration frequency. Alternatively, a frequency dependent correction factor C(f) for the force balance equation can be determined empirically at each calibration frequency. (Theoretically, C(f) is equal to unity.) This process shall be repeated several times as described in Appendix A to determine the error E_2 associated with the process.

4.4.4 Force Balance Linearity Verification

This section describes the procedures and requirements necessary to verify that the radiation force balance (RFB) acoustic output **power**, W_m, is linearly proportional to the input acoustic **power** W_r, over the range of expected device acoustic outputs.

4.4.4.1 Linearity Verification Procedure

Couple the **reference source** to the radiation force balance and drive the **reference source** at its calibrated acoustic output. The **reference source** acoustic output **power** (Wr_{max}) should be equal to or greater than the maximum total acoustic **power** anticipated in future diagnostic ultrasound **equipment** characterization measurements. For each calibration frequency, adjust the **reference source** drive level to decrease the source acoustic output **power** in approximately 0.1 Wr_{max} steps from Wr_{max} to 0.1 Wr_{max}. For each step (i), measure Wr(i) and record the **drive voltage amplitude** $v_a(i)$.

4.4.4.2 Force Balance Linearity Requirements

The best straight line fit shall be calculated for the data set $[W_r(i), v_a^2(i)]$ using the method of least squares, and the % error E(i) of each measured $W_r(i)$ from the best fit line. The force balance response shall be considered linear if abs [E(i)] = 20% for all E(i) at each of the calibration frequencies. Otherwise, the acoustic output response is considered nonlinear.

If the acoustic output is found nonlinear, then the radiation force balance should be either repaired, adjusted, or recalibrated, or the **reference source** should be recalibrated at the national standards laboratory, before the radiation force balance is used to characterize diagnostic ultrasound equipment. For the case where response is linear for low **drive voltage amplitude** levels but deviates from linear response at high **drive voltage amplitude** levels (saturation effects), a linear response function may be derived by deleting the higher **drive voltage amplitude** level points, one at a time, and recalculating the best fit line until the acoustic output linearity requirements are met.

4.4.5 Spot Checks of Force Balance and Reference Source

Any force balance intended for use in characterizing diagnostic equipment shall be tested against a **reference source** at least annually per requirements stated in Section 4.3-4.

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Testing should be performed more often if conditions or suspicions warrant. At that time, the **reference source power** output should be measured and compared against previous weekly readings, as a check of RFB stability and repeatability. If a discrepancy results, re-calibration and/or repair of the RFB, and/or checks of the **working source** should be performed until the problem is corrected. If balance readings of **ultrasonic power** differ from those specified for the **reference source** by an amount greater than the established system measurement error E_2 (see 4.4.3), repair or adjustment of the force balance is required; alternatively, the **reference source** may be malfunctioning and must be repaired, replaced, or sent to a national standards laboratory for absolute recalibration. Performing the procedure in 4.5.3 will help to isolate the device needing attention.

4.4.6 Calibration and Spot Checks of Working Source

The **working source** should be calibrated using the force balance at least annually per Section 4.3.4, or more often if conditions or suspicions warrant. If balance readings of **ultrasonic power** differ by an amount greater than the system measurement error E_2 for the initial calibration, repair or adjustment of the **working source** or force balance is required. Performing the procedure in 4.4.5 will help to isolate the device needing attention. (See Corbett, 1988, for a discussion of calibrating a **working source**.)

4.5 LOCAL LABORATORY CHECKS OF REFERENCE HYDROPHONE

4.5.1 Arrival of the Reference Hydrophone

The **reference hydrophone** is one for which a sensitivity $M_L(f)$ or $M_C(f)$ has been measured directly by a national standards laboratory. These calibration data shall be reported at several frequencies over the working range for which the hydrophone is intended. At a minimum, the **hydrophone calibration** must be reported at four frequencies, separated by at least 2.5 MHz, from 1 to 10 MHz. Beyond 15 MHz, absolute calibration of the hydrophone is not possible at present. However, a national standards laboratory may be able to provide a relative frequency response to at least 40 MHz by using either nonlinear propagation theory or a membrane-type hydrophone as a reference.

Care must be taken to ensure that no damage that may affect the calibration occurs to the hydrophone in shipment or after receipt. Such care normally includes shipment at temperatures between approximately +5°C and +40°C.

4.5.2 Comparison Waveform Records

A **reference source** or **working source** transducer must be driven at a frequency close to a calibration frequency with a narrow-band quasi CW (10–15 cycles) gated sinusoidal burst with enough amplitude to give a clear and reproducible pressure **waveform** when the **reference hydrophone** is located in the **far field** of the source. The **reference hydrophone** location and source pulse length must be adjusted so that there will be a flat amplitude region of the pulse in which there are no overlapping reflected signals. Both the source transducer and **reference hydrophone** should be allowed to stabilize in the water for at least 10 minutes before the calibration is performed. Air bubbles shall be removed from both the source transducer and **reference hydrophone.**

NOTE—Small air bubbles formed on the hydrophone active area can severely affect the sensitivity of the device. A strong squirt of water directed at the hydrophone surface usually is effective for removing air bubbles.

Using the scanning and positioning system described in Section 3.5.3, the **reference hydrophone** is located on the **beam axis** of the source transducer. The **reference hydrophone** should be scanned in a raster pattern to ensure that the point of maximum pressure at the given axial distance is located. The **waveform** generated by the **reference hydrophone** is then recorded using the oscilloscope or digitizing

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system specified in Section 3.5.4. To display a stationary time **waveform** on the oscilloscope, a trigger synchronous with the excitation of the source transducer must be provided. The time delay between the excitation trigger and the arrival of the pulse at the **reference hydrophone** can be used to determine the distance of the hydrophone from the source. Because water velocity and attenuation are functions of temperature, a consistent water temperature must be chosen, maintained, and recorded for these measurements.

The source transducer should be driven at frequencies corresponding to those for which a sensitivity, $M_L(f)$ or $M_c(f)$, has been supplied by the national standards laboratory. Note that if $M_c(f)$ is provided by the national standards laboratory, the $M_L(f)$ for the particular **local laboratory** set-up has to be determined (see Sec. 3.3.1) before any **waveform** computations can be made.

For each frequency, f, the **waveform** shall be recorded digitally or photographically, and the mean square **acoustic pressure**, or equivalently **temporal average intensity**, along with the **peak compressional pressure** and **peak rarefactional pressure** must be computed. The measurements must be repeated several times so that the system error E_2 at each frequency can be determined as described in Appendix A. These **waveform** data can be used as a basis for determining possible future changes through **spot checks** and for evaluating the sensitivities of **working hydrophones** at the same temperature. At a minimum, **spot check** shall be done annually.

The planar scanning technique, described in Section 4.8 and Appendix H, also can be used to check the calibration of the **reference hydrophone**.

4.5.3 Spot Checks of the Reference Hydrophone

Each month, the **reference hydrophone** should be **spot checked** by repeating measurements in the configuration used on its arrival. As a minimum, this **spot check** shall be done annually. By direct comparison of **waveform** data to the data recorded earlier, the long term stability of the **reference hydrophone** can be established. A calibration log should be kept to track any changes in hydrophone behavior. If differences exceeding the measurement error bounds for the **temporal average intensity** or peak pressures are observed, the **reference hydrophone** or calibrating equipment may have changed. If the source and related equipment are unchanged, as checked on a force balance, then repair, replacement, or recalibration of the hydrophone at a national standards laboratory will be required.

4.6 THE COMPARISON PROCEDURE FOR THE WORKING HYDROPHONE

4.6.1 Introduction

After confirmation of the accuracy of the **reference hydrophone**, a comparison procedure is performed whereby the **acoustic pressure** field of a **reference source** or **working source** transducer is first characterized at a point on-axis in the **far field** using the **reference hydrophone** (Section 4.5.2), and then compared to the response measured using a **working hydrophone** to be calibrated. In this procedure, great care must be taken to locate and orient both the **reference hydrophone** and **working hydrophone** at exactly the same location in the **acoustic pressure** field of the source. Also, source excitation conditions must be the same. If the **reference hydrophone** and **working hydrophone** have different **effective hydrophone diameters**, then the transmitted beam variations as a function of radial distance at the measurement location should be negligible over the larger **effective hydrophone diameter**. Otherwise, a correction to account for different **effective hydrophone diameters** must be made (Preston et al, 1988; Schafer and Lewin, 1988).

NOTE—To ensure adequate frequency response of the **working hydrophone**, an additional comparison of the spectral consistency of the pulse from the source, as recorded by the two hydrophones, can be made. For this measurement it may be more meaningful to pulse the source with a broadband impulse, although for a CW source the harmonics generated due to nonlinear propagation can be used also.

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The most convenient way to perform this broadband comparison is to use a membrane hydrophone having a thickness of 12 mm or less as the reference. Either an integral amplifier or an external amplifier with short (≦ 15 cm) hydrophone cable should be used. The –1 dB **bandwidth** of the amplifier should be ≥50 MHz. The amplifier also should meet the minimum requirements of Table 3-4. Under these conditions, the relative frequency response of the **working hydrophone** can be obtained from the ratio of the frequency responses of the **working hydrophone** and the reference membrane hydrophone, when a broadband source transducer is used (Bacon, 1982; Harris, 1988).

4.6.2 Determination of End-of-Cable Loaded Sensitivity of the Working Hydrophone

The **end-of-cable loaded sensitivity** $M_L(f)$ in V/Pa of the **working hydrophone** at a given frequency f in water at a specified temperature is calculated from new **working hydrophone** measurements and the corresponding **waveform records** of the **reference hydrophone** as:

$$M_L(f)_w = M_L(f)_r (h_w/h_r)^{1/2} \quad (V/Pa) \tag{4.6.2-1}$$

where $M_L(f)_w$ and $M_L(f)_r$ are the **end-of-cable loaded sensitivities** of the **working hydrophone** and **reference hydrophone**, respectively, and:

$$h_w = \frac{1}{T}\int_0^T V_w^2(t)dt \quad (V^2) \tag{4.6.2-3}$$

$$h_r = \frac{1}{T}\int_0^T V_r^2(t)dt \quad (V^2) \tag{4.6.2-4}$$

Here, $V_w(t)$ and $V_r(t)$ are the hydrophone **waveforms** in volts recorded from the **working hydrophone** and **reference hydrophone**, respectively, and T is a time interval over which these voltage **waveforms** repeat themselves. For a CW source, T is any integral multiple of (1/f); for a repetitively pulsed source, T is any integral multiple of (1/PRF). For pulsed **waveforms**, T also can be the sampling interval over which the **waveform** is recorded, assuming no signal is present at the beginning or end of the interval.

4.7 SPOT CHECKS OF WORKING HYDROPHONE

Periodically, the **working hydrophone** should be **spot checked** by repeating measurements in the configuration used on its arrival, using either the comparison or the planar scanning technique (see Section 4.3). As a minimum, this **spot check** shall be done annually. By direct comparison of **waveform** data to the data recorded earlier, the long term stability of the **working hydrophone** can be established. At least for the first month of use, a daily log shall be kept to track any changes in hydrophone behavior. If differences exceeding the measurement uncertainty in $M_L(f)$ are observed, the **working hydrophone** or calibrating equipment may have changed. If the source and related equipment are unchanged, as checked on a force balance, repair, replacement, or recalibration of the hydrophone will be required.

The frequency of the **spot checks** depends on the long and short term stability of the hydrophone. The recommended procedure is to **spot check** the hydrophone daily before use so that the user can be assured that the hydrophone is functioning properly. At least for the first month of use, a daily log should be kept to establish how stable the hydrophone is and also to determine system uncertainty. Based on these data, less frequent **spot checks** may be adequate. However, at a minimum, monthly checks should be made of the **working hydrophone** stability/calibration.

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4.8 PLANAR SCANNING CHECKS OF HYDROPHONES

Planar scanning calibration (see Appendix H for details) can provide an alternative means of cross-checking hydrophone sensitivities (below 10 MHz) obtained by comparison or other calibration methods. For information about how different calibrating methods compare, including planar scanning (see Preston et al, 1988; Gloersen et al, 1982).

Planar scanning calibration is useful for checking the **reference hydrophone** both on its arrival or whenever changes in its performance are suspected. In those cases in which the **working hydrophone** is the **reference hydrophone**, planar scanning checks will be made on the receipt of the hydrophone and at least at six month intervals. **Spot checks** of the **working hydrophone calibration** and/or stability should be made at least monthly (see Section 4.3).

Note that greater care is required with the planar scanning technique above 6 MHz; however, the sensitivities so obtained should be within the system measurement uncertainty and differences should be no greater than ±15%, when compared to sensitivities obtained otherwise (by a national standards laboratory or by the comparison method).

4.9 HYDROPHONE CALIBRATION ABOVE 20 MHz

Hydrophone calibration above 20 MHz can be accomplished using a method based on predicting the effect of finite amplitude propagation in a transducer field (Bacon, 1982b, Bacon, 1990a). Calibration services traceable to national standards laboratories using this method are available. Once a hydrophone has been calibrated using this method, other hydrophones can be calibrated via the technique of substitution in a nonlinear field, as described in Bacon, 1990b, and Smith and Bacon, 1990.

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Section 5
DIAGNOSTIC ULTRASOUND MEASUREMENT PROCEDURES

5.1 INTRODUCTION

Recommended procedures for measuring the acoustic and geometric parameters are detailed in this section. Alternative methods may be used as long as they can be shown to be equivalent to those outlined in this section.

Results from alternative methods that exceed the corresponding values as measured using the procedures in this section should be noted.

Systematic and random errors relative to any alternative methods must be determined and these data provided in the final **measurement report** and in labeling, when appropriate. The **measurement report** consists of complete documentation of the methods and results of measurements required to obtain the labeling quantities. **Waveform records**, for example, would be included. The report should be retained by the manufacturer to help answer future questions.

The recommended methods of this section are selected to be as consistent and straightforward as possible, even though they may not have the accuracy of more thorough techniques such as those used in national standards laboratories. The procedures are described in sufficient detail to make the performance of these measurements possible for the widest number of potential users of this standard. It is neither reasonable nor efficacious to attempt to provide step by step procedures that could be used by a first-time user with no previous experience in quantitative acoustic measurements, as defined in this standard. Such procedures cannot be made general enough to meet the wide variety of acoustic fields, equipment, and available personnel for which this standard is intended. When the procedures outlined in this section are followed, measurements can be made with reasonable accuracy using basic instrumentation. Sufficient information is provided, and with straightforward modifications and a basic understanding of the concepts involved, the user of this standard should be able to apply these procedures to more elaborate multi-mode or unique instruments.

Because of the nature of acoustic output measurements and the great potential for accumulated error, the extreme care and precision required from the user to obtain accurate, reliable results cannot be overstated. It is strongly recommended that people new to the performance of acoustic output measurements as described in this standard familiarize themselves completely with the equipment and procedures before attempting a formal series of measurements. A series of repetitive "pre-measurements" to establish reproducibility and familiarity with the specific equipment in use is suggested.

All measurements are to be performed in bubble-free water using apparatus equivalent to that specified in Section 3 as selected in this section. General outlines of the measurements are presented in Section 5.2.

It also will prove helpful to read several of the references that use a variety of related techniques, some of which form the basis for these recommended procedures (Carson and Banjavic, 1980; Harris, 1985; Preston, 1986; Duck and Starritt, 1986; CDRH, 1985; RPB, 1982; IEC, 1991b; Smith, 1986; Shombert and Harris, 1986; Harris, 1982; Jones et al, 1981; Martin, 1986; Lewin, 1981; Pedersen et al, 1988; Schafer and Lewin, 1988).

5.2 OUTLINE OF MEASUREMENT PROCEDURES

A careful set of cross checks is required to assure continued stability of equipment and accuracy of acoustical measurements. Figure 5-1 shows the relationships between procedural steps (in ellipses) recommended for carrying out measurements and cross checks and the devices used in carrying them

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out (in boxes). The **working source** or **reference source** consists of a transducer, whose output is stable while in use with the radiation force balance and a stable pulser or pulse burst generator that drives it. Optional procedures and relations are presented by dashed figures and lines. The procedural steps, listed by number in Figure 5-1, are as follows:

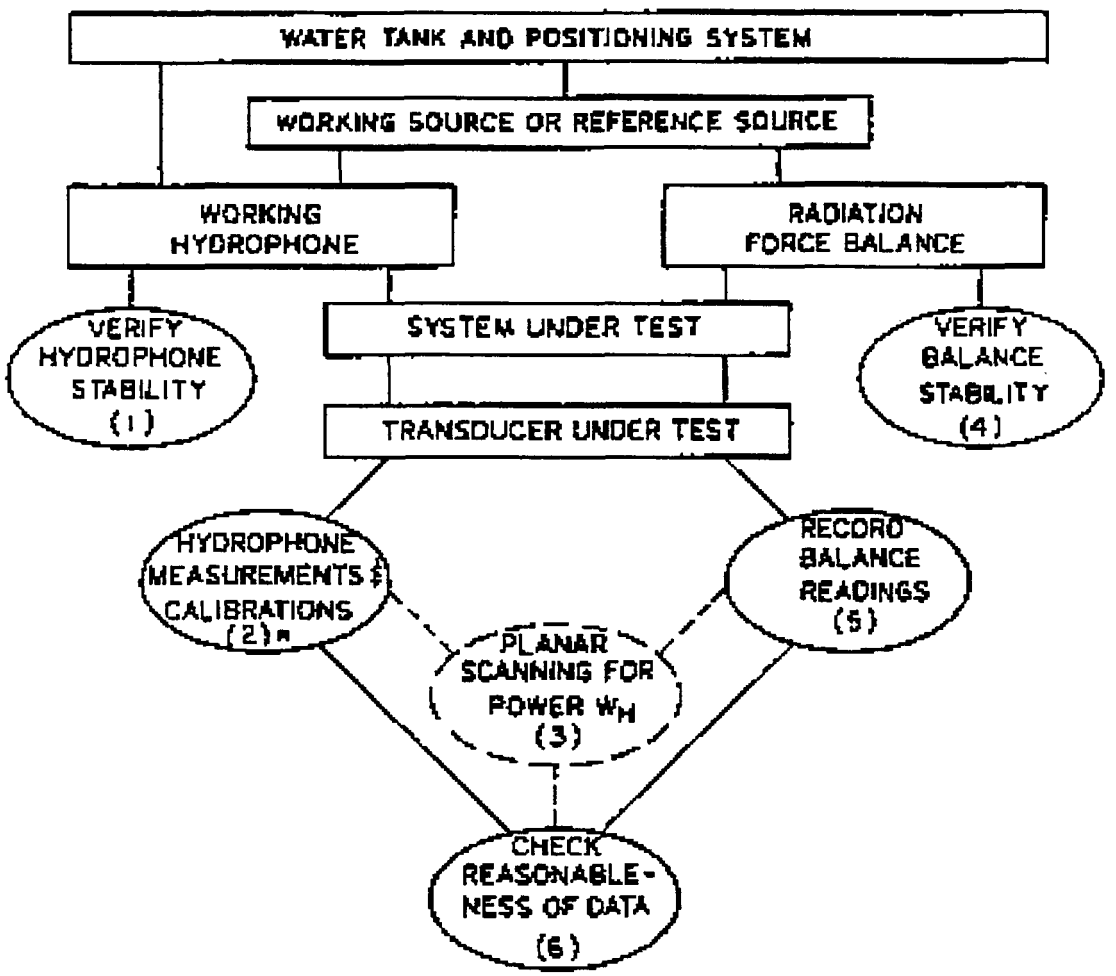


Figure 5-1
RELATIONSHIPS BETWEEN PROCEDURAL STEPS (IN ELLIPSES) RECOMMENDED FOR CARRYING OUT MEASUREMENTS, CROSS CHECKS, AND THE DEVICES USED IN CARRYING THEM OUT (BOXES)

See Figure 5-2.

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a. Immediately prior to a set of measurements, verify the stability of the hydrophone (and source) with a measurement of p_r, at the point of maximum I_{SPPA}, on the axis of the **reference source** or **working source**. The standard deviation of such measurements, carried out from time to time, should be no more than 5 percent.

b. For the system under test, perform hydrophone measurements and calculations to measure the pressures, intensities, and associated quantities listed in Section 2 as required for system labeling. These measurements are outlined in more detail in Figure 5-2. The measurements are repeated for each **discrete operating mode** and for the **combined mode** that yields the highest values of certain labeling quantities.

c. If a radiation force balance is unavailable for step 5 below, or if a comparison between the hydrophone and the balance is desired, place the **working hydrophone** in the field, perform planar scanning, and compute the total transmitted **power** W_h for the desired modes and control settings. Such comparisons between the hydrophone and balance are usually worthwhile checks.

d. Verify the stability of the force balance (and source) with a measurement of the **ultrasonic power**, W from the **working source** or **reference source**, the latter being operated at the settings that were employed in step 1. The standard deviation of such measurements, carried out from time to time, should be no more than 3 percent.

e. At the same settings of the system under test that were used for measuring the maximum I_{SPTA} in water, record the balance output for the **ultrasound system** under test, coupling and decoupling the transducer to the balance N times, where N > 3. Compute the system **ultrasonic power**, W_b, and the measured standard deviations, particularly the standard deviation between couplings.

f. Check the internal consistency and reasonableness of the data. The **power** determined with the balance and hydrophone, W_b and W_h, should agree within the expected uncertainty (two standard deviations). See Appendix A—Statistical Considerations.

Figure 5-2 is an outline of procedures for measurement of the labeling quantities for a given **non-autoscan** mode. The procedures are given in more detail in Section 5.4.

5.3 EQUIPMENT AND SETUP

The measurements called for in Sections 5.3–5.5 will be performed for the transmitted beam with a hydrophone and associated amplifier, properly terminated as described in Section 3 of this document. The excitation source and standard transducer used to perform the calibration of the hydrophone system must meet the requirements as outlined in Sections 3 and 4 for assurance of proper termination, calibration, and traceability to a national standards laboratory. Section 5.4 testing is performed in a **non-autoscan mode** and Section 5.5 testing in an **autoscanning mode**. Figure 5-2 provides a testing flow chart to assist the operator in acquiring the proper data at the proper location and sequence in the procedure.

5.3.1 Equipment Required

5.3.1.1 Polyvinylidene Fluoride (PVDF) Hydrophone—The hydrophone may include a preamplifier that is either an integral part of the hydrophone or is coupled to the hydrophone output by properly terminated cables. Adequate frequency response and directivity for the transducers under test are essential. The frequency response and directional characteristics of the hydrophone as a function of frequency are generally supplied in the specifications by the hydrophone manufacturer or calibration service. Refer to Sections 3.3–3.5 of this standard for further information.

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5.3.1.2 X, Y, Z motion positioning device with the capability of two orthogonal angle adjustments (i, m) on either the hydrophone or source mountings (see Figures 5.3a and b).

5.3.1.3 Digital **waveform** processing oscilloscope (see Section 3.5.4 for specifications)—A conventional analog oscilloscope is generally inadequate for determining the location of maximum I_{SPTA}. The oscilloscope will suffice if a stepless gate and square and integrate circuitry that operates over the measurement **bandwidth** is available.

5.3.1.4 **Working source** or **reference source** transducer and driver, with known output as specified in Section 4, should be used for stability checks of the measuring system.

5.3.1.5 A direct electronic trigger source from the instrument under test—In the event a reliable trigger source is not available from the instrument under test, an alternate method that provides some success is the use of a ceramic or PVDF probe hydrophone as an auxiliary scope trigger source, or an unshielded wire to pick up the RF signal radiated by the main bang.

5.3.1.6 Water tank filled with water conditioned as explained in Appendix E; see also Appendix K—Rationale for Measurements in Water.

5.3.1.7 Computation facility whereby the data obtained from the oscilloscope can be processed to generate the desired values—This may be as simple as a calculator or as elaborate as a computer with on-line digitization and report generation capability .

5.3.1.8 Hard copy capability (film or plotter).

5.3.2 Set-up

5.3.2.1 General Set-up

Assemble the water tank and x,y,z positioning device onto a sturdy and vibration free surface so as to minimize external vibrations. Care should be taken in the setup to prevent inadvertent jarring of the equipment during the measurement process. Install the **working source** or **reference source** transducer and the calibrated hydrophone in their respective mounts.

5.3.2.2 Source Transducer and Hydrophone Alignment Procedures for the Device to be Characterized

The specific alignment procedure is dependent on the assembly and hydrophone in use. The following is a complete procedure that can provide training and assurance of skill in measurements. Simpler procedures will work, but will depend on quality of the apparatus and the skill of the user.

Mount the **working source** and align its beam, or at least check its alignment, so that the beam is parallel to the z axis of the x,y,z positioning device. This can be accomplished by maximizing the pulse-echo signal from a flat surface that is known to be normal to the z axis, such as the wall of the scanning tank or a plate on the hydrophone holder. See Figures 5.3a and b. A dial indicator is useful in establishing and verifying that the plate is normal to the z axis and parallel to the x,y scan plane (x is the scan direction). With the hydrophone at a distance from the source greater than 1.3 times the **far field transition length**, scan in x and y and maximize the received hydrophone signal to center the hydrophone on the **beam axis**. Then rotate the hydrophone about its active element in two orthogonal angles, r_x and r_y, and maximize the signal so the **beam axis** coincides with the direction along which the hydrophone is most sensitive. It cannot be assumed that this direction is parallel to the axis of the housing except possibly with a membrane hydrophone. When using a membrane type hydrophone, it is possible to achieve very accurate alignment by maximizing the echo reflected off the membrane surface.

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With the **reference source** or **working source** being driven at a standardized setting for hydrophone stability checks (step 1 in Section 5.2), position the source in z to the range for which previous data have been taken. Scan in x and y to verify that the hydrophone is still on the axis of the beam. Record the signal level and verify that it is the same, within your hydrophone stability specifications, as was achieved at the last calibration of the hydrophone. Significant misalignment indicates a failure in the above procedures and the need for their repetition.

The attainment of the same signal level, as in previous tests, indicates facility with the measurement procedures as well as stability of the equipment and water medium. Use of simpler procedures that rely on the assumption that the acoustic axis on the hydrophone or source is aligned with a mechanical axis or marker should be avoided due to the critical nature of this alignment.

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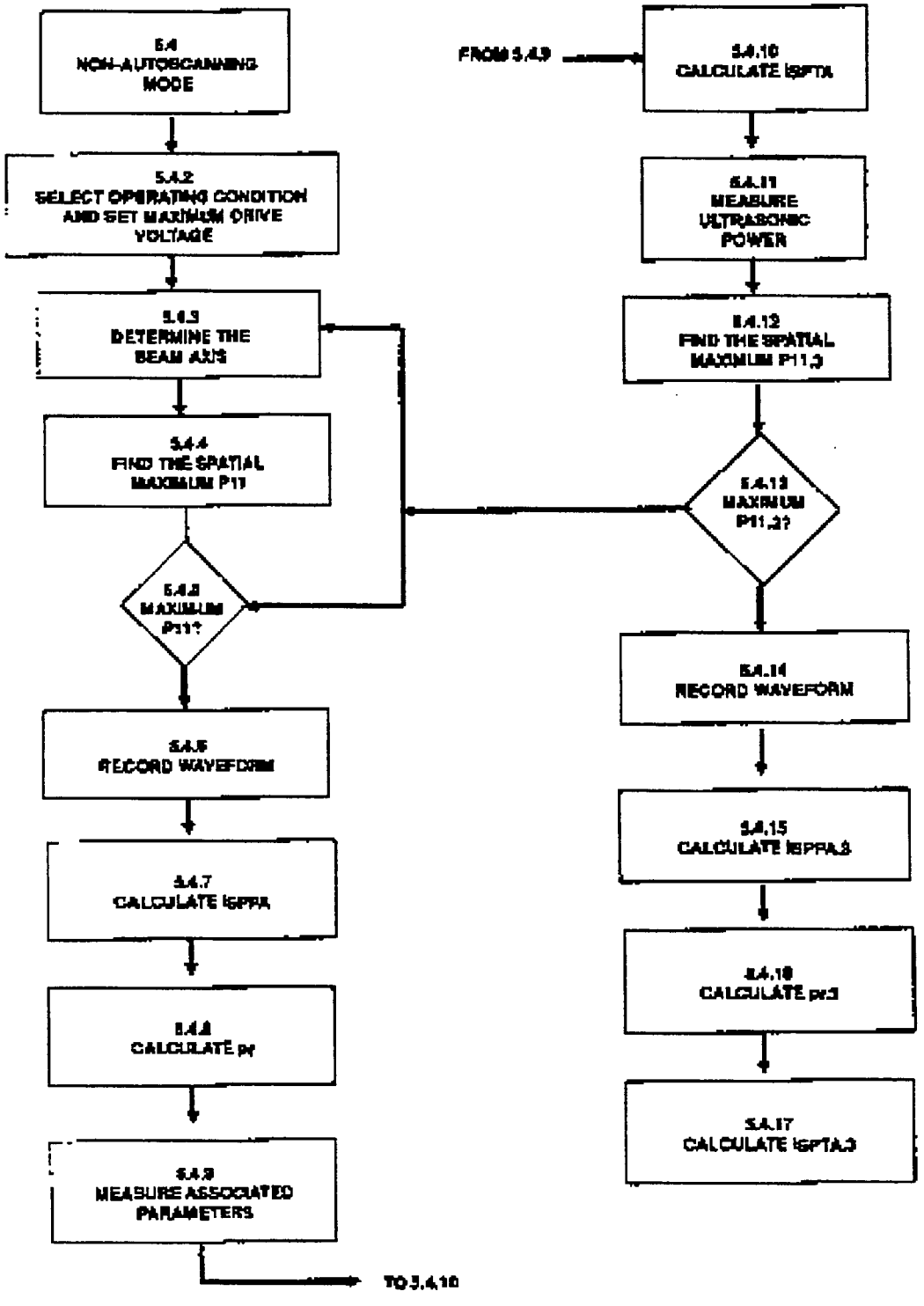


Figure 5-2
MEASUREMENTS AND CALCULATION REQUIREMENTS FOR SYSTEM LABELING

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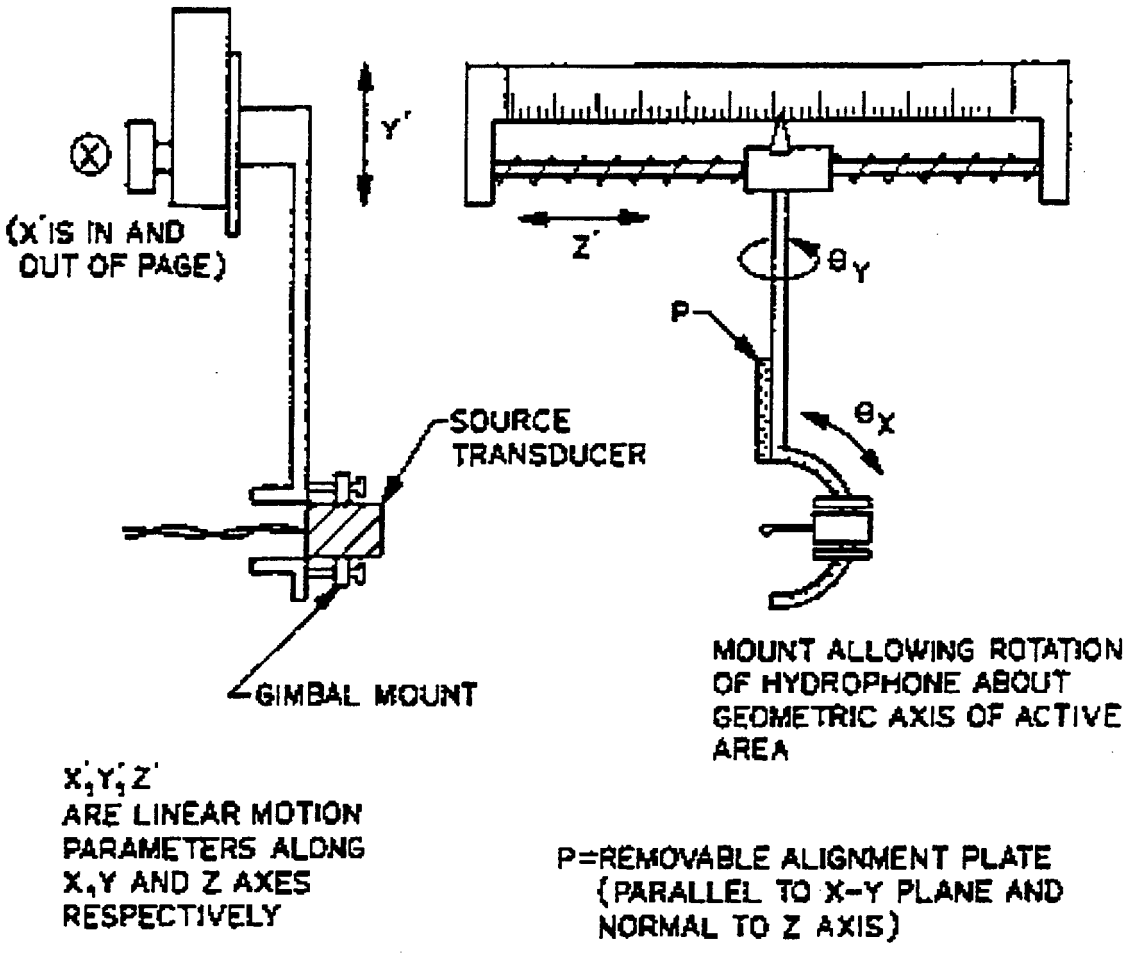


Figure 5-3a
EXAMPLE OF A HORIZONTAL SCANNING MECHANISM

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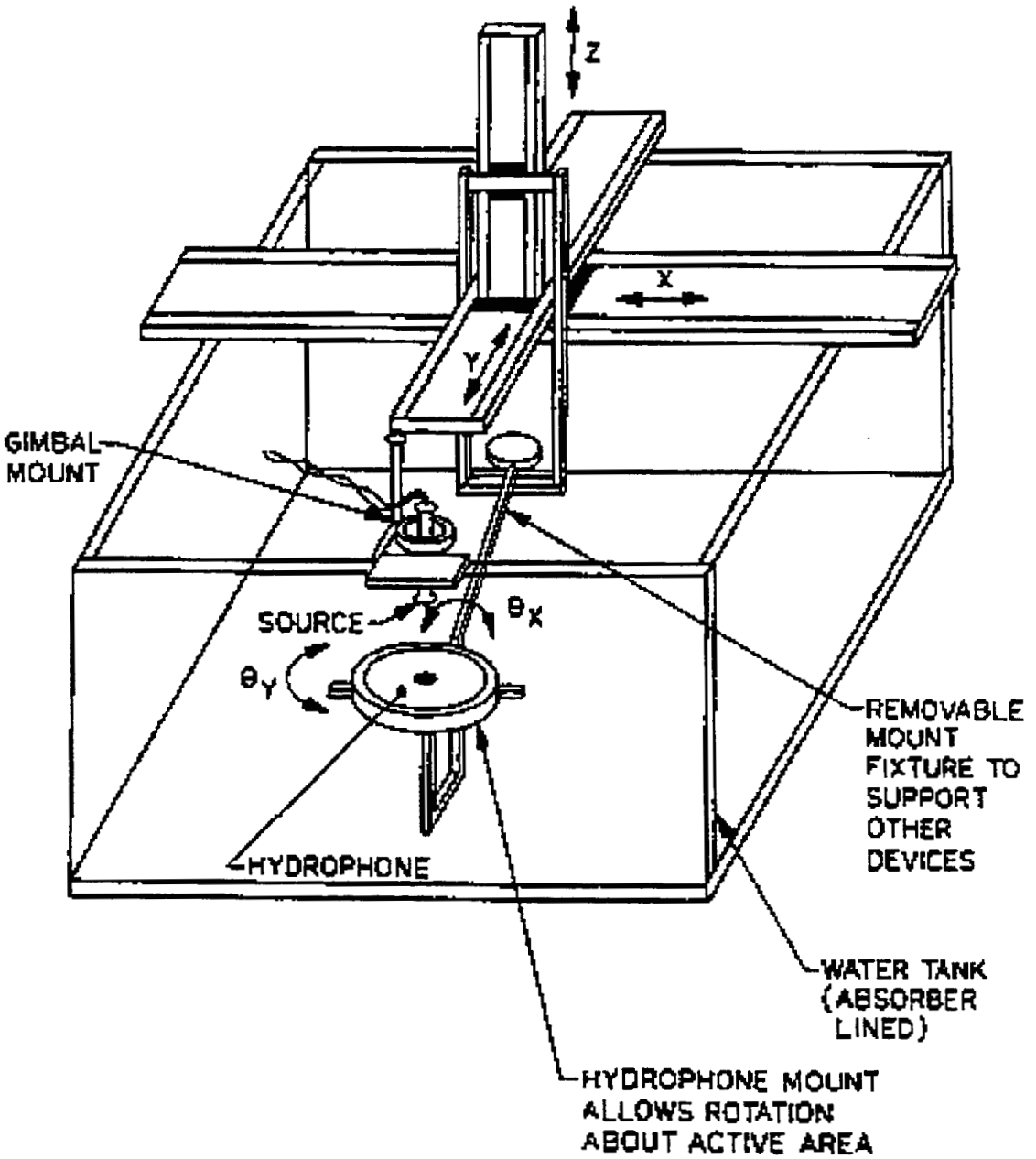


Figure 5-3b
EXAMPLE OF A VERTICAL SCANNING SYSTEM

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This type of alignment is a critical part of the entire measurement procedure, particularly when performed on the system under test. Extreme care should be taken to ensure that it is done properly. As with all critical maximizations by alignment or positioning, extreme care means that the alignment or positioning must be readjusted to confirm that the alignment or position found is a true maximum and not just a local or erroneous maximum.

A log of the values and **waveform records** obtained from the **working source** should be maintained.

5.3.2.3 Setup and Alignment of the Transducer Under Test

Replace the source transducer with the transducer to be tested. With the system under test operating with a fixed beam, e.g., in M- or A-mode, repeat the alignment procedures given immediately above in Section 5.3.2.2. That is:

- Align the beam of the transducer under test (the source transducer) with the z axis of the positioner. Figure 5-2 lists each of the steps necessary to accomplish the complete testing for the **non-autoscan mode** as outlined in Section 5.4.
- Align the hydrophone in the center of the beam at a point well into the **far field** of the source, e.g., greater than 1.3 times the near-to-**far field transition length**.
- Verify that the orientation of the hydrophone yields the maximum response.
- Scan in z until the temporal peak of the hydrophone signal is maximized.
- Verify that the hydrophone is still on the **beam axis**.

If the **ultrasound system** under test has no stationary beam mode or difficulty is encountered in synchronizing with the scan or **pulse repetition period**, a second hydrophone, mounted so as not to obstruct the field detected by the PVDF hydrophone (ideally mounted under the primary hydrophone), can be used as an alternate external trigger source. For scanning modes, the trigger hydrophone often is mounted on the edge of the scan plane such that the first pulse of the scan is detected most strongly. For stationary beam modes, the hydrophone should be mounted at a greater distance from the source than the measurement hydrophone. Instruments which have no "front panel" **M-mode** function may have an internal test mode that emulates **M-mode** sufficiently to permit acoustic output measurements with a stationary beam. Consult the manufacturer of the specific instrument under test for details.

5.4 MEASUREMENT OF INTENSITIES AND PRESSURE IN NON-AUTOSCAN SYSTEM

5.4.1 Reference Location for Intensity and Pressure Measurements

The location of the maximum free-field **pulse intensity integral** (PII) shall be used as the reference location for the measurement of I_{SPTA}, I_{SPPA}, p_r, and f_c. Further, the **pulse intensity integral** shall be used as the referenced quantity in the measurement of beam profiles and depth of field. The location of the maximum derated **pulse intensity integral** shall be used as the reference location for the measurement of $I_{SPTA.3}$, $I_{SPPA.3}$, and $p_{r.3}$.

Further, for any **transmit pattern** (j) to be tested, the **maximum drive voltage amplitude** (v_{mj}) shall be used when determining the locations of the maximum free-field **pulse intensity integral** and the maximum derated **pulse intensity integral**. The location of the maximum free-field **pulse intensity**

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integral is denoted z_{mjPII}, and the location of the maximum derated **pulse intensity integral** is denoted $z_{mjPII.3}$.

Once these locations have been established using the procedures given below, the reported intensities and pressures may then be determined for any **drive voltage amplitude**.

For **equipment** which produces **continuous waveforms**, the **pulse intensity integral** is not a meaningful parameter, and the location of maximum **temporal average intensity** shall be used instead of the location of the maximum **pulse intensity integral** for the measurement of I_{SPTA}, p_r, and f_c. The location of the maximum derated **temporal average intensity** shall be used instead of location of the maximum derated **pulse intensity integral** for the measurement of $I_{SPTA.3}$ and $p_{r.3}$. Further clarification of the procedures to be used for **equipment** which produces **continuous waveforms** is given in Section 5.4.18.

NOTE—It is assumed that an on-line wide-band digital oscilloscope sampling in accordance with Section 3.5.4 with multiple programmable functions or a digital oscilloscope with an associated computing controller is available. If not, the procedures described may be carried out by use of a hand calculator. Because of the tedious and error-prone nature of this manual technique, it is not recommended for extensive data collection. It may be indicated for measurements made at previously specified locations.

5.4.2 Select Operating Condition and set Maximum Drive Voltage

Select the **operating condition** to be tested. This will involve a specific **drive voltage amplitude** and **transmit pattern** (j). There may be different **operating conditions** which maximize various reporting parameters (e.g., I_{SPPA}, I_{SPTA}, p_r, $I_{SPPA.3}$, $I_{SPTA.3}$, and $p_{r.3}$). All the settings and relevant conditions shall be recorded and included in the **measurement report** so that this set-up can be repeated.

NOTE—If the **output control settings** which maximize a given reporting parameter are not known, an iterative process may be necessary in order to find this maximum value. In general, with more complex systems, a detailed understanding of the interaction of the operating parameters (pulser voltage, aperture, **focal length**, etc.) will be necessary in order to predict a priori which **output control settings** will produce the maximum desired reporting parameter.

For the subject **transmit pattern** (j), the **drive voltage amplitude** shall be set to the **maximum drive voltage amplitude** (v_{mj}), resulting in the maximum free-field **pulse intensity integral** for that **transmit pattern**.

5.4.3 Determine the Beam Axis

Repeat, if necessary, the alignment procedure accomplished in Section 5.3. Verify that the free-field **pulse intensity integral** as a function of position ($PII(j,v_{mj},r')$) of the transducer under test is maximized locally in all coordinate directions where:

$$PII = \frac{\int_{t_1}^{t_2} v_h^2(t)dt}{10^4 \rho c M_L^2(f_c)} \qquad (5.4.3\text{-}1)$$

where ρ is density (kg/m^3), c is the speed of sound (m/s), $M_L(f_c)$ is the hydrophone **end-of-cable loaded sensitivity** expressed in V/Pa, $v_h(t)$ is the voltage from the hydrophone, PII is the **pulse intensity integral** (J/cm^2), and the integration is performed over the time interval (t_1 to t_2) for which the hydrophone signal for the specific pulse is non-zero. See Equation 3.3.1-7 to convert M_L in dB to M_L in V/MPa.

A useful starting point for finding the maximum **pulse intensity integral** is the location of the maximum **peak compressional pressure** along the axis.

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5.4.4 Find the Spatial Maximum Pulse Intensity Integral

The maximum free-field **pulse intensity integral** and the position at which it occurs shall be determined by moving the hydrophone along the z axis and determining the **pulse intensity integral** at each of a series of positions. In order to avoid near-field variations, this axial scan shall be made no closer to the surface of the **active aperture** than the **minimum measurement depth** z_{min}, where:

$$z_{min} = 1.5\sqrt{\frac{4}{\pi} A_{aprt}(j)} = 1.69\sqrt{A_{aprt}(j)} \quad (cm) \qquad (5.4.4\text{-}1)$$

and A_{aprt} is the area of the **active aperture**. The location at which the free-field **pulse intensity integral** $PII(j,v_{mj},z)$ is maximized over the range $z = z_{min}$ is denoted z_{mjPII}.

5.4.5 Verification of Maximum $PII(j,v_{mj},z_{mjPII})$

The maximum $PII(j,v_{mj},z_{mjPII})$ point shall be verified by testing the surrounding points in all coordinate directions. If a maximum has not been found, the procedure beginning at step 5.4.3 shall be repeated.

If it is necessary to test other **output control settings** to maximize output, repeat the overall procedure beginning at 5.4.2.

5.4.6 Waveform Recording

The hydrophone **waveform** at the maximum $PII(j,v_{mj},z_{mjPII})$ point should be recorded photographically or with a digital **waveform** recorder (see Section 3.5.4 and Figures 5.4 and 5.5). The **output control settings** at which these **waveforms** are taken should also be recorded.

NOTE—These **waveforms** and **output control settings** may be recorded for each of the independent operational modes of the system under test for inclusion in the **measurement report**.

5.4.7 Calculate the Spatial-Peak Pulse-Average Intensity (I_{SPPA})

The **spatial-peak pulse-average intensity** (I_{SPPA}) taken at the location ($z = z_{mjPII}$) for any **drive voltage amplitude**, shall be calculated by:

$$I_{SPPA}(j,v) = PII(j,v,z_{mjPII}) / PD \quad (W/cm^2) \qquad (5.4.7\text{-}1)$$

where PD is the **pulse duration** expressed in seconds and v is the **drive voltage amplitude**.

Note that while the location for this measurement ($z = z_{mjPII}$) was found using the **maximum drive voltage amplitude** (v_{mj}), the **spatial-peak pulse-average intensity** (I_{SPPA}) may be calculated for any **drive voltage amplitude**.

5.4.8 Calculate the Peak Rarefactional Pressure (p_r)

The **peak rarefactional pressure** p_r, taken at the location ($z = z_{mjPII}$) for any **drive voltage amplitude**, shall be calculated by:

$$p_r(j,v) = \left| \frac{v_h}{M_L(f_c)} \right| \quad Pa \qquad (5.4.8\text{-}1)$$

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where v_h is equal to the hydrophone's output voltage in volts corresponding to the **peak rarefactional pressure** p_r, v is the **drive voltage amplitude**, and the hydrophone **end-of-cable loaded sensitivity** ($M_L(f_c)$) is expressed in V/Pa.

5.4.9 Associated Parameters

5.4.9.1 Pulse Repetition Frequency (PRF)

The **pulse repetition frequency** shall be measured by means of a miniature hydrophone in water using the equipment specified in Section 5.2.1 or electronically by the use of a frequency counter as appropriate.

5.4.9.2 Center Frequency

The **waveform** shall be measured using the oscilloscope with the hydrophone/amplifier system located at $z = z_{mipii}$. The hydrophone's output voltage shall be used to generate a frequency spectrum display from which the **center frequency** (f_c) parameters shall be determined. One of the following shall be adequate for generating this frequency spectrum:

a. An automatic spectrum analyzer with an operating range encompassing the frequency **envelope** of the detected signal.

b. A computational system capable of performing Fourier transforms and either displaying the spectrum or calculating the desired values.

The **center frequency** for the transducer under test shall be determined and the pertinent values calculated by:

$$f_c = (f_1 + f_2) / 2 \quad \text{(MHz)} \qquad (5.4.9\text{-}1)$$

where f_1 and f_2 are the most widely separated frequencies in the main lobe at which the hydrophone voltage spectrum is –3 dB (71 percent) of its maximum value. In the analog or digital spectrum analysis or sampling, change the sweep rate or number of points in the FFT, respectively, to assure that f_1 and f_2 do not shift. If they do, f_1 and f_2 may be stabilized by either: (1) decreasing the sweep rate of the spectrum analyzer, or (2) increasing the temporal record length, which may be accomplished by increasing the number of points in the FFT while holding the temporal sampling interval constant.

5.4.9.3 Beam Profile and Other Geometrical Parameters

The **depth of focus** and other beam profile parameter measurements shall be made with reference to the maximum **pulse intensity integral** location ($z = z_{mipii}$) for that **operating condition**.

To determine the **depth of focus**, the **pulse intensity integral** shall be evaluated at the two points P_1 and P_2 along the **beam axis** at which the **pulse intensity integral** is one half the value of PII(j,v, z_{mipii}) for that **operating condition**. P_2 is the nearest point beyond z_{mipii} (i.e., $z > z_{mipii}$) at which the **pulse intensity integral** is one half the value of PII(j,v, z_{mipii}). P_1 is the point nearest z_{mipii} on the transducer side (i.e., $z_{min} = z < z_{mipii}$) at which the **pulse intensity integral** is one half the value of PII(j,v, z_{mipii}), if that point exists; if not, then P_1 shall be taken as the surface of the transducer.

To determine the –6 dB beam width in either the x (in-plane) or y (out-of-plane) directions, the **pulse intensity integral** shall be evaluated at the two points perpendicular to the **beam axis**, along the desired

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direction, at which the **pulse intensity integral** is one quarter the value of maximum PII(j,v, z_{mjPII}) for that **operating condition**.

Measurement procedures and examples of the remaining parameters for a single-element transducer (which may easily be applied to a multi element transducer) are well defined in references AIUM, 1982; Hams, 1985; Shombert and Robinson, 1983.

Beam profile and **entrance beam dimensions** for noncircular apertures shall be measured in both the x-z scan plane (in-plane) and the y-z scan plane (out-of-plane) directions to adequately characterize the beam.

Assurance that the ultrasound beam is symmetrical about the z-axis in the plane where the maximum PII(j,v, z_{mjPII}) is located is obtained by moving the hydrophone laterally in that plane. For a single element, circular diameter transducer, the beam profile parameters are similar to Figure 5-6. For a rectangular sector scanner, the beam profiles are plotted in two directions, ± x and ± y, as shown in Figure 5-7. Plots of beam profiles are shown in Figure 5-8a for a circular aperture and in Figure 5-8b for a rectangular one.

5.4.10 Calculate the Spatial-Peak Temporal-Average Intensity (I_{SPTA})

The **spatial-peak temporal-average intensity** (I_{SPTA}) taken at the location ($z = z_{mjPII}$) for any **drive voltage amplitude**, shall be calculated by:

$$I_{SPTA}(j,v) = PII(j,v, z_{mjPII}) \cdot PRF \quad (W/cm^2) \qquad (5.4.10\text{-}1)$$

where PRF is the **pulse repetition frequency** in Hz, as defined in Section 5.4.9.1, and v is the **drive voltage amplitude**.

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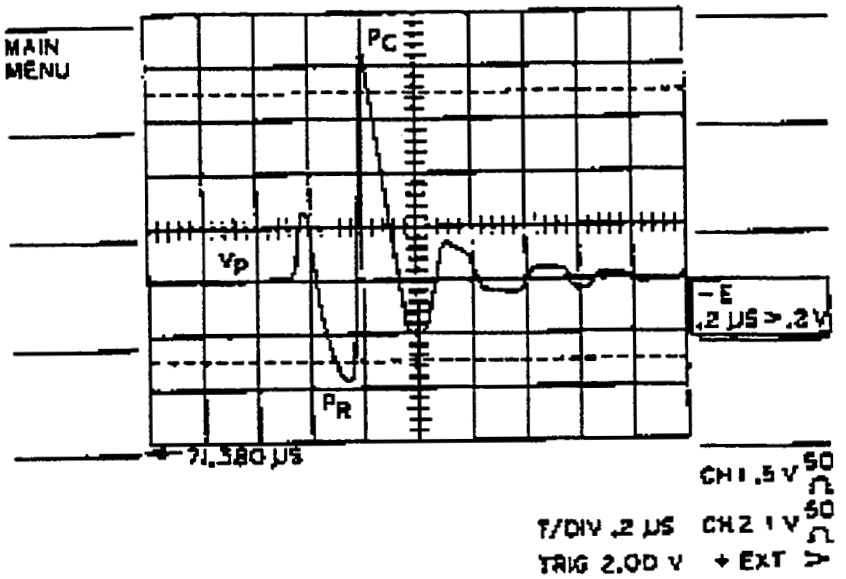


Figure 5-4
SPATIAL PEAK VOLTAGE WAVEFORM SIGNAL (V_p) AS SEEN AT MAXIMUM I_{SPPA} LOCATION

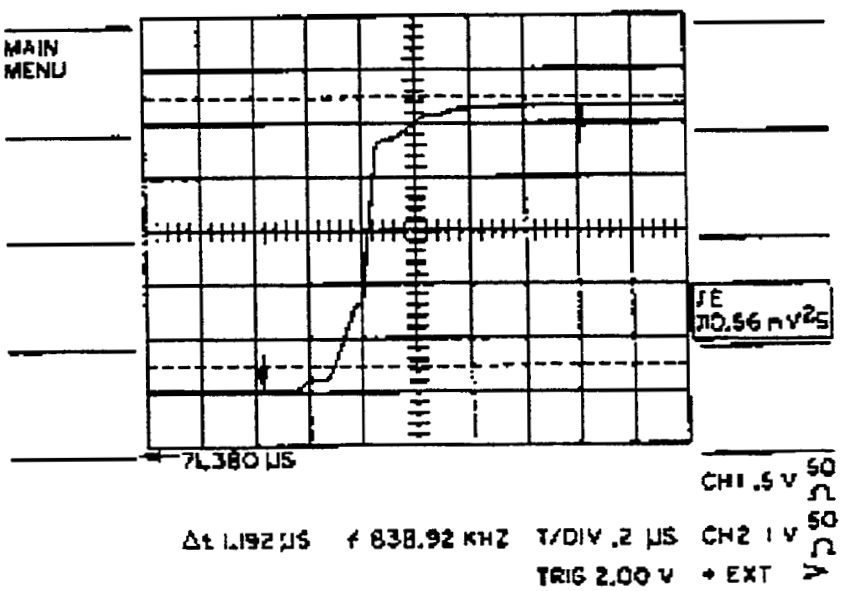
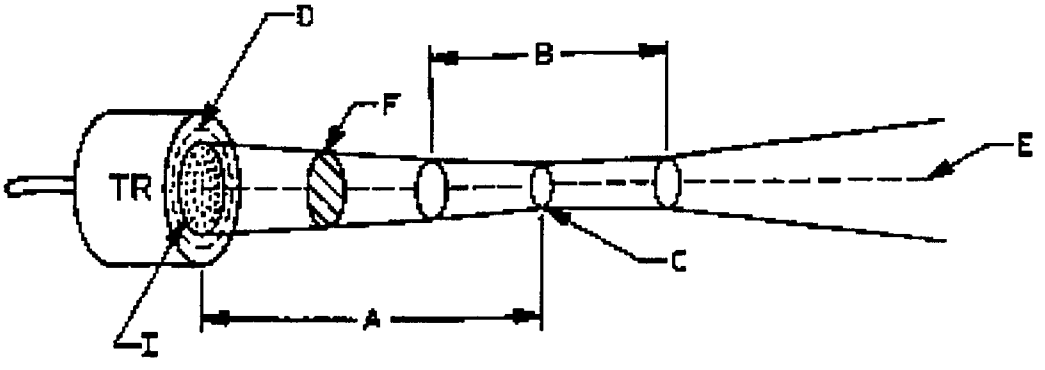
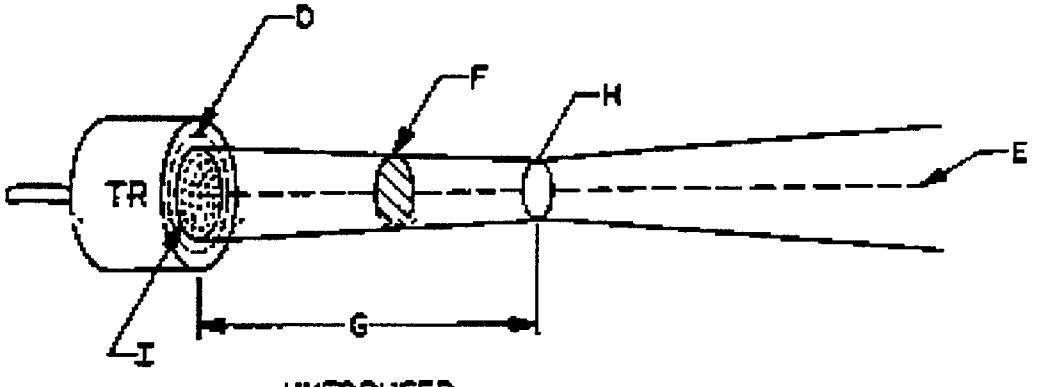


Figure 5-5
A TYPICAL PULSE INTENSITY INTEGRAL (PII) WAVEFORM

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FOCUSED



UNFOCUSED

A = FOCAL LENGTH
B = DEPTH OF FOCUS (CM)
C = FOCAL AREA (CM^2)
D = RADIATING CROSS-SECTIONAL AREAS
E = BEAM AXIS
F = BEAM CROSS-SECTIONAL AREA (CM^2)
G = TRANSITION DISTANCE = $\frac{S}{\pi A}$
H = BEAM CROSS-SECTIONAL AREA AT TRANSITION DISTANCE (CM^2)
I = ENTRANCE BEAM DIMENSIONS (CM^2)

Figure 5-6
BEAM PROFILE PARAMETERS FOR FOCUSED AND UNFOCUSED SINGLE-ELEMENT TRANSDUCERS

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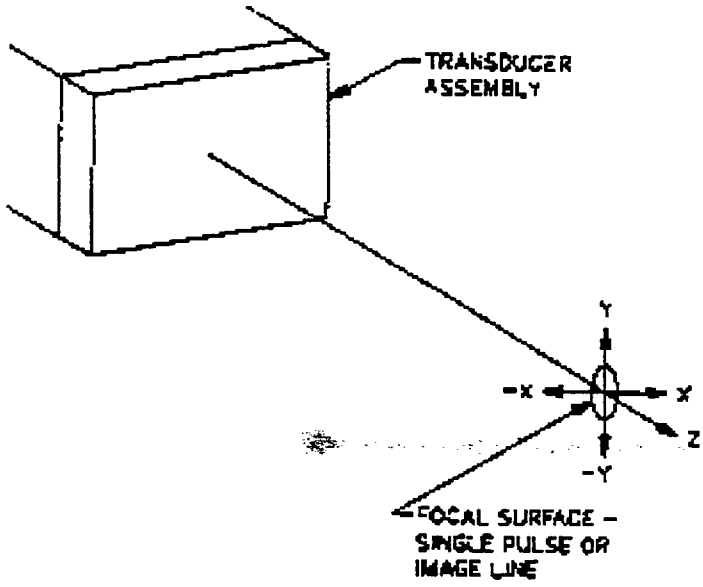


Figure 5-7
BEAM GEOMETRY AT THE FOCUS OF ONE PULSE (I.E., IMAGE LINE) FOR THE SECTOR SCANNING RECTANGULAR TRANSDUCER ASSEMBLY

The z axis is the **beam axis** for the image line being depicted. The x-y plane is the image plane.

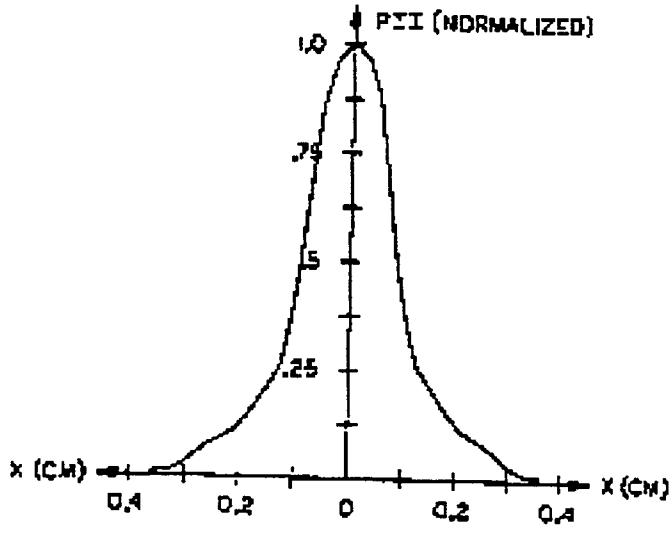


Figure 5-8a
PLOT OF PII (NORMALIZED J/CM^2) ALONG A DIAMETER THROUGH THE FOCUS OF A CIRCULAR SOURCE TRANSDUCER

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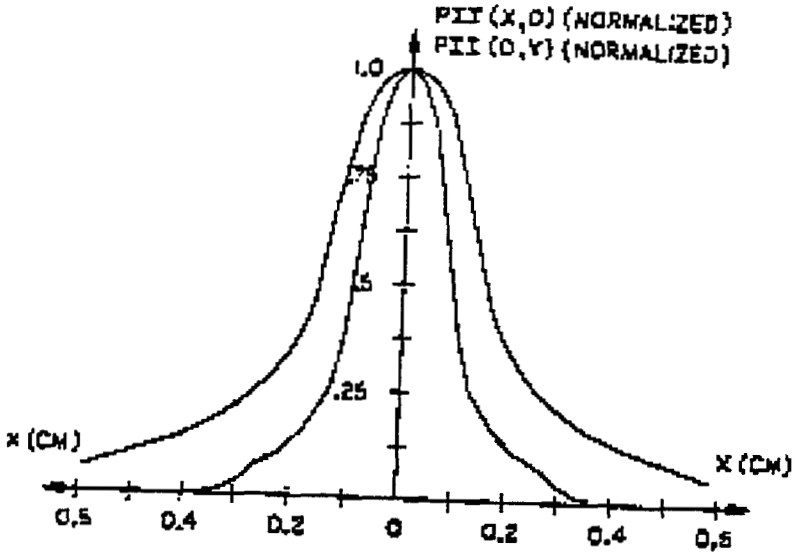


Figure 5-8b
PLOTS OF PII (NORMALIZED J/CM²) THROUGH THE FOCUS OF A RECTANGULAR TRANSDUCER ASSEMBLY

The x and 7 axis plots are taken along lines that intersect and are parallel to the sides of the transducer assembly. See Figure 5-7.

5.4.11 Measure the Ultrasonic Power

The **ultrasonic power** (W) shall be measured according to the procedures of Section 5.6.

5.4.12 Find the Spatial Maximum Derated Pulse Intensity Integral

The maximum derated **pulse intensity integral** $PII_{.3}(j,v_{mj},z)$ and the position at which it occurs shall be determined by moving the hydrophone along the z-axis, toward the transducer under test, in an iterative fashion, searching for the maximum derated $PII_{.3}(j,v_{mj},z)$, where derated parameters will now be indicated with a .3 subscript. In order to avoid near-field variations, this axial scan shall be made no closer to the surface of the **active aperture** than the **minimum measurement depth** z_{min}. The location at which the derated **pulse intensity integral** $PII_{.3}(j, v_{mj},z)$ is maximized over the range $z = z_{min}$ is denoted $z_{mjPII.3}$.

The following equation shall be used to calculate the derated **pulse intensity integral**, $PII_{.3}(j,v_{mj},z)$:

$$PII_{.3}(j,v_{mj},z) = \exp(-0.23 * 0.3 * f_c * z) * PII(j,v_{mj},z) \qquad (5.4.12\text{-}1)$$

where f_c is the frequency expressed in MHz (Section 5.4.9.2) and z is the distance (one way) in cm along the **beam axis** from the **transducer assembly** to the measurement point.

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5.4.13 Verification of the Spatial Maximum $PII_{.3}(j,v_{mj},z_{mPII.3})$

The maximum $PII_{.3}(j,v_{mj},z_{mPII.3})$ point shall be verified by testing the surrounding points in all coordinate directions. If a maximum has not been found, the procedures beginning at step 5.4.3 shall be repeated.

5.4.14 Waveform Recording

The hydrophone **waveform** at this location should be recorded as described in Section 5.4.6.

5.4.15 Calculate the Derated Spatial-Peak Pulse-Average Intensity ($I_{SPPA.3}$)

The derated **spatial-peak pulse-average intensity** ($I_{SPPA.3}$), taken at the location ($z = z_{mjPII.3}$) for any **drive voltage amplitude**, shall be calculated by:

$$I_{SPPA.3}(j,v) = PII_{.3}(j,v,z_{mjPII.3})/PD \quad (W/cm^2) \qquad (5.4.15\text{-}1)$$

where PD is **pulse duration** expressed in seconds and v is the **drive voltage amplitude**.

Note that while the location for this measurement was found using the **maximum drive voltage amplitude** (v_{mj}), the derated **spatial-peak pulse-average intensity** ($I_{SPPA.3}$) may be calculated for any **drive voltage amplitude.**

5.4.16 Calculate the Derated Peak Rarefactional Pressure ($p_{r.3}$)

The derated **peak rarefactional pressure** $p_{r.3}$, taken at the location ($z = z_{mjPII.3}$) for any **drive voltage amplitude**, shall be calculated using Equation 5.4.8-1, and multiplying by the **derating factor** expressed as:

$$p_{r.3}(j,v) = p_r(j,v,z_{mjPII.3}) * \exp(-0.115 * 0.3 * f_c * z_{mjPII.3}) \qquad (5\text{-}4\text{-}16\ 1)$$

where f_c is defined in Section 5.4.9.2, $z_{mjPII.3}$ is described in 5.4.12, and v is the **drive voltage amplitude**.

5.4.17 Calculate the Derated Spatial-Peak Time-Average Intensity ($I_{SPTA.3}$)

The derated **spatial-peak temporal-average intensity** ($I_{SPTA.3}$), taken at the location ($z = z_{mjPII.3}$) for any **drive voltage amplitude**, shall be calculated by:

$$I_{SPTA.3}(j,v) = PII_{.3}(j,v,z_{mjPII.3}) * PRF \quad (W/cm^2) \qquad (5.4.17\text{-}1)$$

where PRF is the **pulse repetition frequency** in Hz, as defined in Section 5.4.9.1, and v is the **drive voltage amplitude.**

5.4.18 Measurement Methods for Equipment Which Produces Continuous Waveforms

For **equipment** which produces **continuous waveforms**, the **pulse intensity integral** is not a meaningful parameter, and the maximum **temporal average intensity** $I_{TA}(j,v_{mj},z)$ shall be used instead of the **pulse intensity integral** for the measurement of I_{SPTA}, p_r, and f_c. The maximum derated **temporal average intensity** $I_{TA.3}(j,v_{mj},z)$ shall be used instead of the derated **pulse intensity integral** for the measurement of $I_{SPTA.3}$ and $p_{r.3}$. The **temporal average intensity** is defined by:

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$$I_{TA} = \frac{1}{nT} \frac{\int_0^{nT} v_h^2(t)dt}{10^4 \rho c M_L^2(f_c)} \qquad (5.4.18\text{-}1)$$

where T is the period of the hydrophone voltage $v_h(t)$, and n is an integer. If an arbitrary integration time is used, (e.g., the data capture window of a digital oscilloscope) then the integration time shall be greater than 10T, to reduce the errors inherent in integrating over a nonintegral number of cycles.

At low amplitudes where the **waveform** is sinusoidal, Equation 5.4.18-1 may be simplified:

$$I_{TA} = \frac{0.5V_0^2}{10^4 \rho c M_L^2(f_c)} \qquad (5.4.18\text{-}2)$$

where V_0 is the amplitude of the **waveform**. If the **waveform** has undergone any nonlinear distortion (Appendix B), then Equation 5.4.18-1 shall be used rather than 5.4.18-2. As a guideline, if the positive and negative voltage levels differ by more than ten percent, Equation 5.4.18-1 should be used.

In order to measure **equipment** which produces **continuous waveforms**, the procedures of Sections 5.4.2-6 shall be performed, with the exception that the **temporal-average intensity** $I_{TA}(j,v_{mj},z)$ shall be the parameter to be maximized. By definition, the **spatial-peak temporal-average intensity** shall be found at the location determined by this modified search procedure. Sections 5.4.8, 5.4.9.2 shall then be performed as described (Sections 5.4.7 and 5.4.9.1 have no meaning for **continuous waveforms**). The parameters described in Section 5.4.9.3 shall then be determined, again using the **temporal-average intensity** instead of the **pulse intensity integral**. The **ultrasonic power** (W) shall be measured according to the procedures of Section 5.6.

Sections 5.4.12-14 shall be performed using the derated **temporal-average intensity** defined by:

$$I_{TA.3}(j,v_{mj},z) = \exp(-0.23 * 0.3 * f_c * z) * I_{TA}(j,v_{mj},z) \qquad (5.4.18\text{-}1)$$

The derated **peak rarefactional pressure** $p_{r.3}$ shall be determined using Section 5.4.16, and the results of the modified search procedure just described. By definition, the derated **spatial-peak temporal-average intensity** $I_{SPTA.3}$ shall be found at the location determined by this modified search procedure.

5.5 MEASUREMENT FOR INTENSITY AND PRESSURE IN AUTOSCAN MODE

In **autoscan mode**, a series of interrogating beams are steered through a succession of azimuthal (i.e., in-plane lateral) directions within a single or succession of target planes. The rate at which this azimuthal scanning pattern is repeated is the **scan repetition frequency** (SRF); the inverse of this rate, the **scan repetition period**, is the time over which **intensity** is averaged in order to calculate **temporal average intensity**.

In the simplest **autoscan mode**, all transmitted beams exhibit the same focal characteristics along their respective **beam axes**; the beams differ only in the orientation of the **beam axes**. Thus, the temporal peak and pulse average parameters of all beams (considered separately), as well as the **autoscan mode** itself, are identical. The temporal average parameters for the mode are determined by the pulse-average parameters of an individual beam, the degree of spatial overlap of the beams in the formation of the overall scan, and the **scan repetition frequency**.

In more complex **autoscan modes**, the transmitted beams may exhibit two or more sets of focal characteristics. In some systems, certain scanning modes may employ two or more distinct focal patterns,

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each focused at a different depth, to create a single, overall scan. In still other systems, such as phased array sector devices, beam focal characteristics may vary with steering angle as well. In these more complex modes, the temporal-peak and pulse-average parameters for a given mode are determined by the maximum values that occur for any beam within the scan. The temporal average parameters for the mode are determined by the pulse-average parameters of the different beam types, the degree and pattern of spatial overlap of the different beam types in the formation of the overall scan, and the **scan repetition frequency**. In the most general case, precise measurement of temporal average parameters in these modes involving multiple focal patterns can be extremely complex, tedious, and time consuming.

In yet another class of systems, the plane of examination is automatically swept through the target space in the elevation direction. Thus, while the scanning pattern may appear to be repetitive in the range-azimuth plane, the scanning pattern is not repetitive at any point in the target volume due to motion of the scan plane. Nevertheless, as considered in this Standard, this elevation motion is disregarded and **temporal average intensity** parameters are determined over the period of repetition in the range-azimuth plane.

Stated simply, the general principles for measuring acoustic output parameters for **autoscan modes** can be summarized as follows:

a. Temporal-peak and pulse-average parameters for the mode are determined by the temporal-peak and pulse-average quantities of the individual beams considered separately. Such parameters as **scan repetition frequency, pulse repetition frequency** and such factors as spatial overlap of beams, do not affect temporal-peak and pulse-average parameters for the mode.

b. Temporal average parameters are determined by the cumulative effects of the overlap of beams generated during the **scan repetition period**. As the most important such parameter, **temporal average intensity** for an Auto Scanning mode, when measured at a point, is determined by the sum of the **energy fluences** at a point resulting from the various beams during the scan, and the **scan repetition frequency**.

5.5.1 Introduction to Autoscan Measurements in Combined Modes

Autoscan, in **combined modes**, refers to those operational conditions of the scanning instrument where the beam shape, focus, amplitude, or pulse length change within a single scan; a single scan being one cycle of a repetitive sequence of emitted acoustic pulses. More specifically, **autoscan modes** are those conditions where the scanning of the beam cannot be stopped and the beam measured with the knowledge that the measured data is consistent throughout the entire scan. A simple example would be a B-mode image with a Doppler signal interleaved through some smaller part of the overall scan plane in the form of a single point interrogation or a 2-D flow image.

By its very nature, measurement in **autoscan modes** can be, at best, difficult without detailed information regarding the sequence, sources, and direction of the transmitted beams. This level of detail may be available from the manufacturer; if not, tedious scanning of scan plane with a hydrophone becomes the required means for defining the pulse sequence of a particular front panel setting. Complex array systems using interleaved transmit foci for each of the different **combined modes** make this an undesirable, if not unreliable, approach.

Proceeding further with **autoscan** measurements without accurate pulse sequence information is not recommended. In this case, the **non-autoscan** data defining each operational mode which make up the **autoscan combined mode** as measured in Section 5.4 will suffice as an adequate definition of the acoustic output capacity of the instrument/probe under evaluation.

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NOTE—The technical staff of a manufacturer is assumed to be sufficiently knowledgeable about their equipment to be able to perform complete **autoscan** measurements.

In **combined autoscan modes**, each instrument manufacturer's scheme of operation is considerably varied. Algorithms to assist in identifying the control setting "region" producing the values under search can be very useful. An example of one such algorithm is given in Appendix G. A step by step procedure unique to the individual instrument under test should be developed and followed.

Because of the difficulties and complexities described above, the remainder of this section does not detail technical and mathematical procedures for obtaining the desired values but, instead provides only guidelines.

5.5.2 Measurement of I_{SPTA} in Combined Autoscan Modes

The basic equation determining the **spatial-peak temporal-average intensity** in an **autoscan mode** is given as the global spatial maximum within the scan plane of the following:

$$I_{SPTA} = \underset{\text{over}(x,z)}{\text{maximum}} \sum_{i=0}^{n} PII_i(x,0,z)\ SRF \qquad (5.5.2\text{-}1)$$

where PII_i (x, 0, z) is the **pulse intensity integral** (or **energy fluence per pulse**) of the i-th beam as measured at the point (x, 0, z), SRF is the **scan repetition frequency**, and n is the number of beams.

NOTE—For sector formats, θ is the azimuthal dimension variable, y is the elevation, and r is the range variable. Thus, for rectilinear formats, the scan plane is described by (x,0,z); for sector formats, the scan plane is given by (θ,0,r).

The summation in 5.5.2-1, indicating the contributions of all the pulses that affect point (x, y, z) during a single scan, can be defined as the **scan intensity integral** (SII) at a general point:

$$SII(x,y,z) = \sum_{i} PII_i(x,y,z) \qquad (5.5.2\text{-}2)$$

Thus, just as PII (x, y, z) is the time integral of **intensity** at a point due to a single pulse, SII (x, y, z) is the time integral of **intensity** at a point during a single scan, resulting from all the pulses during the scan that insonify the point, either on- or off-axis.

Thus, for **auto-scanning** systems:

$$I_{SPTA} = \underset{\text{over }(x,z)}{\text{maximum}} SII(x,0,z)\ SRF \qquad (5.5.2\text{-}3)$$

analogous to the equation for **non-autoscanning** systems:

$$I_{SPTA} = \underset{\text{over }(x,z)}{\text{maximum}} PII(x,0,z)\ PRF \qquad (5.5.2\text{-}4)$$

Certain simplifications are possible when all of the beams comprising the scan share the same focal properties (aperture size, focal depth, etc.), and are at an equal spacing in the azimuthal direction at a given range such that:

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$$PII_i(x, y, z) = PII_0(x-x_i, y, z) \quad (5.5.2\text{-}5)$$

In such case, the SII(x,y,z) may be expressed as the summation:

$$SII(x,y,z) = \sum_i PII_0(x - x_i, y, z) \quad (5.5.2\text{-}6)$$

where $PII_0(x-x_i, y, z)$ is the **pulse intensity integral**, measured at (x, y, z) of a beam whose axis passes through ($x = x_i$, $y = 0$, z), where $x_i = x - i\,\Delta x$, $\Delta x(z)$ is the azimuthal spacing between beams at range z and i is the number of lines which overlap the point during one **scan repetition period**.

Further simplification is possible in the limit as $\Delta x(z)$ becomes small in comparison to the beam pattern (i.e., beam overlap factors predominate in the summation forming SII (x, y, z)), and edge effects near the lateral edges of the scan plane can be ignored. Then it can be shown that SII (x, y, z) ceases to be dependent on x, and can be approximated as:

$$SII(y,z) = \frac{\int PII_0(x,y,z)dx}{\Delta x(z)} \quad (5.5.2\text{-}7)$$

Thus, when all beams making up the scan share the same focal properties, and they are at a constant azimuthal spacing at a given range, and beam spacing is small, then:

$$I_{SPTA} = \underset{\text{over } z}{\text{maximum}} \frac{\int PII_0(x,0,z)dx}{\Delta x(z)} SRF \quad (5.5.2\text{-}8)$$

Thus measurements can be made at one central location in the scan plane or by scanning a stationary beam.

In this case, where all beams in the scan have the same focal properties, the total **power** W can be expressed as:

$$W = \iint PII_0(x,y,z)\,dxdy(X/\Delta x)SRF \quad (5.5.2\text{-}9)$$

where the area integral of $PII_0(x, y, z)$ is the total acoustic energy per pulse (constant for all z) and X is the linear width of the scan. Hence, ($X\Delta x$) is the number of pulses per scan.

Combining the above, an expression for I_{SPTA} can be given as:

$$I_{SPTA} = \underset{\text{over } z}{\text{maximum}} \frac{\int PII_0(x,0,z)dx}{\iint PII_0(x,y,z)dxdy} \frac{W}{X} \quad (5.5.2\text{-}10)$$

Note that the ratio of the two integrals above has the dimensions of reciprocal width of a scan of equal **power** and elevational **intensity** profile, i.e., an energy equivalent elevation width $D_y(z)$. Thus,

$$I_{SPTA} = \underset{\text{over } z}{\text{maximum}} \frac{W}{D_y(z)X} \quad (5.5.2\text{-}11)$$

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where $D_y(z)$ is given by:

$$D_y(z) = \frac{\iint PII_0(x,y,z)dxdy}{\int PII_0(x,0,z)dx} \qquad (5.5.2\text{-}12)$$

and where $D_y(z)$ may vary with the particular beam type.

Still further simplification may be justified, however, in an important class of cases in which the elevation focus properties (aperture size, aperture weighting (apodization) and focal depth) of all beams are identically determined by a fixed mechanical lens or other means (as in sequenced linear arrays and linear phased arrays). In these cases, the integral in 5.5.2-7 can be separated because the y axis beam pattern is independent of x. Equation 5.5.2-7 is separated as:

$$\int PII_0(x,y,z)dx = \int PII_{0x}(x,z)dx \;\; PII_{0y}(y,z) \qquad (5.5.2\text{-}13)$$

Likewise, the area integral in 5.5.2-9 may be expressed as:

$$\iint PII_0(x,y,z)dxdy = \int PII_{0x}(x,z)dx \int PII_{0y}(y,z)dy \qquad (5.5.2\text{-}14)$$

Thus, in the case where the beam patterns are separable, the energy equivalent width D_y can be expressed as:

$$D_y(z) = \frac{\int PII_{0y}(y,z)dy}{PII_{0y}(0,z)} \qquad (5.5.2\text{-}15)$$

In this important case, the location of minimum $D_y(z)$, which is also the location of maximum I_{SPTA}, is identical for all beam patterns sharing the same elevation focal characteristics. Even where there may be multiple transmit azimuth apertures and focal points, if all beams share the same elevation focus and aperture, as well as lateral scan dimension X, then 5.5.2-8 may be stated as:

$$I_{SPTA} = \underset{\text{over } z}{\text{maximum}} \frac{\sum W_k}{D_y(z)\ X} \qquad (5.5.2\text{-}16)$$

where W_k is the total acoustic **power** in the scan associated with the k-th azimuthal beam pattern.

While 5.5.2-16 is directly applicable to rectilinear formats, a similar expression holds for sector formats. As defined above, the azimuthal variable can be expressed as θ, and the range variable given as r. When the azimuthal size of the scan plane is given as θ, and under the conditions cited above (ignoring edge effects and assuming narrow beam spacing compared to the azimuthal beam widths):

$$I_{SPTA} = \underset{\text{over } z}{\text{maximum}} \frac{\sum W_k}{D_y(r)\ r} \qquad (5.5.2\text{-}17)$$

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Again, W_k is the total acoustic **power** in the scan associated with the k-th azimuthal beam pattern, steered in a sector format. Note that in the sector case, I_{SPTA} is not maximized where $D_y(r)$ is minimum (as I_{SPTA} is minimized for the rectilinear format where $D_y(z)$ is minimum). Rather, sector format I_{SPTA} in 5.5.2-17 is maximized at the range r where the product $D_y(r)$ x r is minimized. Under the above assumptions, the location of this minimum for $D_y(r)$ x r is the same, however, for all beam patterns having the same elevation focus characteristics.

5.6 POWER MEASUREMENTS

The measurement method shall provide acoustic **power** measurements consistent with those of a calibrated radiation force balance measurement. The measurement method of acoustic **power** shall be traceable to NIST or other comparable national standards.

Where acoustic **power** is detected using a radiation force balance, the radiation force balance shall be calibrated using a **reference source** transducer with acoustic **power** traceable to a national standards laboratory. Where acoustic **power** is determined using hydrophone planar scanning methods, the **working hydrophone** sensitivity shall be determined using a **reference source** transducer or **reference hydrophone** traceable to a national standards laboratory. The entire planar scanning system accuracy shall be verified using a **reference source** transducer for which the acoustic **power** is traceable to a national standards laboratory.

5.6.1 Force Balance Methods

5.6.1.1 Measurement Methods

Force balance systems, equations governing their operation, and procedures for testing them are described in 3.6 and 4.4. In a **local laboratory,** a calibrated force balance system should be used for periodic comparisons with **reference sources, working sources,** and pulser drivers.

It is the primary function of the force balance system to measure **ultrasonic power** emitted by diagnostic systems. While making radiation force balance (RFB) measurements, care should be taken to ensure that the radiation force balance target intercepts the total **acoustic output power** emitted by the **source transducer.** The **source transducer and** RFB target should be positioned so that the effective **beam cross-sectional area's** dimensions are less than the corresponding RFB target dimensions, and the beam is centered on the RFB target. Procedures for measuring unfocused transducers driven by diagnostic systems are the same as for measuring **reference sources** or **working sources.** When measuring focused transducers, tests should be performed to detect nonlinear response due to the saturation of the water medium. For diagnostic systems, the ultrasound is usually emitted in pulses. Whether the ultrasound is pulsed or not, it is the **ultrasonic power** that is given by Equation 4.4.1-2, since the radiation force measured is a temporal average.

It is necessary to know which aperture or ultrasound line creates the greatest intensities since some lines may carry more energy or focus more tightly than others. If measuring a **non-autoscan** mode or an **autoscan** mode with the sweep arrested, the **power** measurements must be made using this line.

It is strongly recommended that, with the exception of measurements of **power**/unit length (Section 5.6.1.6), all measurements, **autoscan, non-autoscan,** or **combined modes** be made with the beam sweep arrested, with all pulses coming from the aperture creating the greatest intensities. This ensures that all ultrasound beams strike the absorbing target at an angle of incidence of no more than 10 degrees from normal.

The PRF corresponding to the system settings being measured must be known, particularly if these measurements are to be used to compare with data collected using a hydrophone raster scan (see

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Section 5.6.2). Likewise, for multimode and unique systems, the sequencing of the pulses (i.e., how many B-mode, Doppler etc. lines/second/frame) must be known. For **autoscan** and **non-autoscan combined modes**, one can measure each separately, provided each portion is pulsed exactly the same way when separated as when combined.

Because ultrasound heats the absorbing target in a force balance, the buoyancy, and thus the measured weight of the absorbing target, will drift with **exposure time**. In addition, from power-on to power-off, an overshoot of the target occurs and a short, damped oscillation period follows as the target settles. Therefore, a short delay time is necessary before taking data after power-on/power-off. Since the target weight also drifts due to cooling and heating of the chamber fluid, an extrapolation technique is necessary in order to accurately determine the target weight at power-on/power-off.

One extrapolation technique is to take a weight reading and then turn power on (this is the time zero power-off/power-on) (Carson et al., 1978). Take a power-on weight reading at 10 seconds and another at 20 seconds. Use the 10 and 20 second readings to extrapolate back to the time zero power-off/power-on weight. If R(t) is the balance reading at time t:

$$R(0) = 2R_{10} - R_{20} \qquad (5.6.1.1\text{-}1)$$

Repeat the procedure, but going from power-on to power-off. Wait a sufficient period of time before repeating the cycle. The power-off period allows the water and target to cool down. Note that the target cools down slower than it warms up. There should be no systematic difference between the magnitudes of the power-off to power-on and power-on to power-off measurements. Any such differences may indicate a significant warm-up or shut-down time of the system under test and an alternative method of interrupting the transmitter voltage may be required. The difference between the power-off (time zero) and power-on (interpolated back to time zero) weights is then divided by the 68 mg/mW conversion factor to get the uncorrected **power** measurement. Figure 5-9 illustrates the interpolation.

Because the ultrasound beam is attenuated somewhat during travel to the target (due to fluid (Kaye & Laby, 14th ed.) and membrane attenuation), a correction factor must be applied to the measured value. Acoustic calibration of the balance over the **working frequency range** is required (see Section 4.4).

Averaging a number of measurements will produce more accurate results. In addition, the transducer under test shall be decoupled from the balance, recoupled, realigned and another series of measurements taken. The number of measurements between recouplings (N1) shall be five or more; the number of recouplings (N2), three or more. The average and standard deviation for each set of N1 readings shall be found, as shall the standard deviation between the N2 averages. The reported **power** shall be the average **power** of the N2 sets (see Appendix A).

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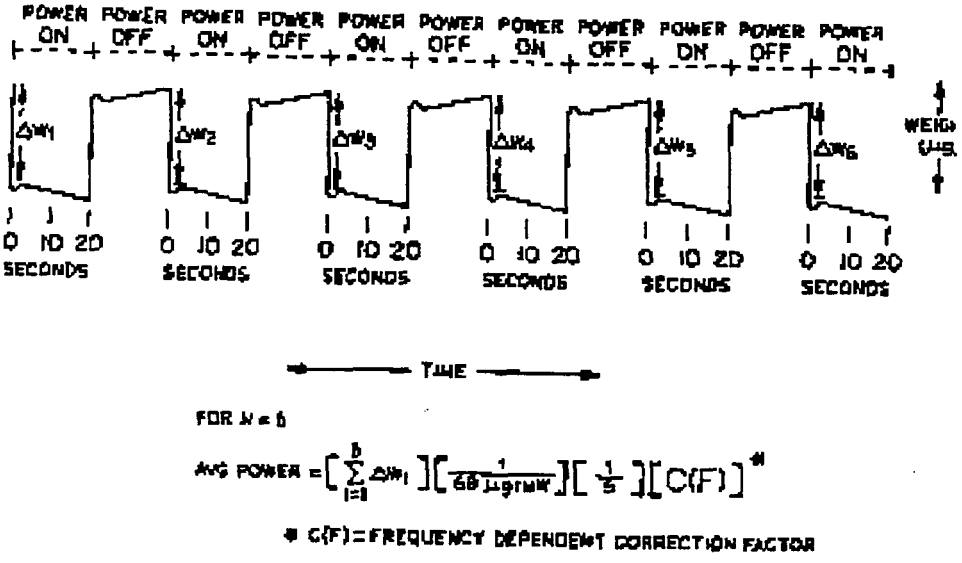


Figure 5-9
ILLUSTRATION OF AN R.F.B. MEASUREMENT OF ONE SEQUENCE OF N = 5 CYCLES

Extrapolation technique is shown. Sequence should be repeated three or more times with the transducer recoupled each time.

5.6.1.2 Aperture Considerations

For transmit apertures $\leq$ 3/4 of the corresponding radiation force balance target dimensions, the transducer-target separation distance shall be the smaller of 1 cm or 1/2 the distance to the focal point, where the focal point is determined as the position of maximum PII on the **beam axis** with the diagnostic ultrasound equipment operating at the **maximum drive voltage amplitude** (v_{mj}), for the **transmit pattern** (j) being tested, and such that the **acoustic output** linearity requirements of Section 5.6.1.3(b) are met.

For transmit apertures > 3/4 of the corresponding radiation force balance target dimensions, the transducer-target separation distance shall be selected so that the **beam cross-sectional area's** major and minor dimensions are less than 3/4 of the corresponding radiation force balance target dimensions, and such that the **acoustic output** linearity requirements of Section 5.6.1.3(b) are met.

Absorbing targets with dimensions on the order of 20 mm to 25 mm wide are recommended. This size permits small transducer-target distances. Targets with larger dimensions often cause unacceptably noisy measurements. For large aperture transducers, increase the transducer target distance or use a collimator (see references in Section 1) to meet the linearity requirements specified in Section 5.6.1.3(b).

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5.6.1.3 Focused Beam Power Measurement Linearity Test

a. Measurement procedure:

For each discrete **transmit pattern** (j), the acoustic **power** data shall be measured over the range of **drive voltage amplitudes** (v_a) that can be applied to the **transmit pattern.** A constant **pulse repetition frequency** shall be used for the entire set of measurements. Data shall be taken for at least 10 equally spaced **drive voltage amplitude** squared intervals over the entire voltage range, and acoustic **power** vs. v_a^2 plotted to determine **acoustic output** linearity per the criteria outlined in Section 5.6.1.3(b).

b. Linearity requirements:

The best straight line fit shall be calculated for the data set [W(i), v_a^2(i)] using the method of least squares, and the % error E(i) of each measured W(i) from the best fit line. The radiation force balance response shall be considered linear if abs [E(i)] $\leq$ 20% for all E(i). Otherwise, the **acoustic output** response is considered nonlinear.

For the case where **acoustic output** response is linear for low **drive voltage amplitude** levels, but deviates from linear response at high **drive voltage amplitude** levels (saturation effects) a linear response function may be derived by deleting the higher **drive voltage amplitude** level points, one at a time, and recalculating the best fit line until the **acoustic output** linearity requirements are met.

c. Determining the causes of nonlinearity:

The following techniques may be used to determine the cause of nonlinear **acoustic output** response:

1. If possible, defocus the beam, leaving all other **transmit pattern** parameters unchanged, and repeat the above linearity test.

2. Decrease the transducer-target distance and repeat the linearity test. Increase the radiation force balance target diameter if necessary to keep the beam dimensions < 3/4 of the corresponding target dimensions.

3. Calculate the **nonlinearity propagation parameter** σ_m. If σ_m is greater than 0.5, then it is likely that nonlinear loss may have occurred.

Nonlinearity is caused by the acoustic **power** measurement set up as described in Section 5.6.1.3(d), if the **nonlinearity propagation parameter** $\sigma_m > 0.5$ and defocusing and/or decreased transducer-target distance results in linear response.

Given linear response with a nonfocused **reference source,** nonlinearity is most likely caused by the system/transducer combination if **nonlinearity propagation parameter** $\sigma_m < 0.5$ and nonlinearity persists after the beam is defocused and/or the target distance is decreased.

d. Nonlinear response due to acoustic power measurement set up:

If it is determined, according to Section 5.6.1.3(c) of this standard, that **acoustic output** nonlinear response is due to the acoustic **power** measurement equipment, then either:

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1. The acoustic **power** measurement set up shall be adjusted, and the radiation force balance calibration and linearity shall be rechecked per the procedures in Sections 4.4.3 and 4.4.4 of this standard.

2. A linear response correction function shall be derived by extrapolating from the lower **drive voltage amplitude** level data points per the procedure recommended in Section 5.6.1.3(b) of this standard. This function shall be used to generate reference data in determining acoustic **power** at higher **drive voltage amplitude.**

e. Nonlinear response due to the system/transducer combination:

If it is determined, according to Section 5.6.1.2(c) of this standard, that the **acoustic output** nonlinear response is due to nonlinearities resulting from the system/transducer combination and/or **duty factor** or voltage variations, then the system acoustic **power** calculation routine should model the **acoustic output** nonlinear effects.

5.6.1.4 Non-Autoscan Force Balance Procedure

The procedures described in Section 5.6.1.1 shall be used when measuring acoustic **power** using a force balance. Included in this **non-autoscan** procedure are **autoscan** and **combined operating modes** where the sweep of the beam has been arrested.

a. Calibrate balance and system per Section 4.4.

b. Compare aperture size to force balance target size and, if necessary, make adjustments per Section 5.6.1.2.

c. For focused transducers, verify force balance linearity per Section 5.6.1.3.

d. Determine the "worst-case" aperture of the imaging device.

e. Apply couplant to the transducer and couple it to the balance membrane such that the ultrasound beam strikes the target. Dimpling of the balance membrane is not necessary provided that sufficient couplant is maintained between the transducer and balance membrane. If possible, use the 2-D mode to verify the beam alignment. Mechanically secure the transducer in place.

f. Starting from power-off, take a weight reading and switch power on. Take weight readings at 10 and 20 seconds. Extrapolate back to the time zero power-off/power-on weight. Use the following equation to determine **power**:

$$\textbf{Power}\ (\text{mW}) = [\text{ABS}(W2 - W1)/68] \times C(f) \qquad (5.6.1.3\text{-}1)$$

where:

W2 = power-off, time zero weight (μg)
W1 = power-on, time zero weight (μg)
C(f) = frequency dependent attenuation correction factor determined during balance calibration (Section 4.4.3)

g. Repeat weight/**power** measurement N1 times where N1 is greater than or equal to 5. Find the average **power** and standard deviation of the set of values.

h. Decouple the transducer from the membrane, recouple and re-align.

i. Repeat steps F–H a total of N2 times where N2 = 3.

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5.6.1.5 Autoscan Force Balance Procedure

It is recommended that **autoscan** and **combined modes** be measured with the sweep arrested (where possible). This is to prevent errors due to the ultrasound beams not striking the target at the optimum angle. A special target specifically designed for the transducer in question, such that the incident ultrasound beams strike the target optimally, would otherwise be necessary.

In a combination **scanned** mode with more than one type of **transmit pattern** (j) employed during the scan period, the acoustic **power** shall be considered separately for different **transmit patterns**, when necessary to permit accurate measurement of acoustic **power.**

When performing these measurements with the beam scan arrested, the measured **acoustic power** shall be corrected to compensate for any beam former related output variability dependent on beam angle, and/or linear position.

In some systems, input electrical **power** and the resulting output is often increased for non-normal scan angles because of decreased element (reception) sensitivity off axis.

When performing these measurements with the beam scan operating, the radiation force balance target and source shall be positioned such that the effective **beam cross-sectional area** intercepts the target over the entire extent of the scan. For angularly scanning sources, the measured output shall be corrected to compensate for any radiation force balance directivity if the maximum beam angle perpendicular to the target plane exceeds 10°.

The measured radiation force is proportional to the cosine of the half angle of the sector, the angle that the direction of wave propagation deviates from the direction for which the radiation force balance is calculated. At a 10° half angle, the maximum acoustic **power** error is 1.5%.

More detailed information on **power** measurements using radiation force balances is contained in references Carson and Banjavic, 1980; Fick et al., 1984; Preston, 1986.

5.6.1.6 Measurement of Acoustic Power per Unit Length W/X(j,v_s) in Scanned Modes

While employing the following methods to mask all the acoustic **power** except that originating within a 1 cm azimuthal width of the **scanned active aperture,** the remaining acoustic **power** transmitted shall be measured according to the procedures in Section 5.6.1.5.

In locating the masks described in this standard, the 1 cm wide aperture emitting the largest amount of acoustic **power,** resulting in the largest measured value of W/X(j,v_s), shall be exposed.

The acoustic **power** accuracy from the 1 cm wide aperture shall be viewed as allowing forward passage of all the acoustic **power** from the central 1 cm wide aperture of the transducer within ± 20%.

When a radiation force balance target is used to limit the azimuthal (image plane) aperture, its geometry and composition shall be such as to detect all forward emissions from a 1 cm wide strip immediately in front of the scanhead and not to detect emissions from outside that 1 cm wide strip within the requirements of this section.

The 1 cm mask and 1 cm wide target techniques described in this section have somewhat different sources of error. Agreement of the two methods of defining the apertures should give reasonable confidence that the aperture is defined accurately. Use of an absorbing mask or limited width radiation

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force balance absorber to limit detection to a 1 cm linear width at the front surface of the active scan aperture is recommended for mechanical sector probes, or third party testing of all probes.

The following sections describe windowing techniques using a 1 cm wide slit absorber, a 1 cm wide radiation force balance target, or electronic masking techniques:

a. One cm aperture in a mask:

When a mask is used, its geometry and composition shall be such as to eliminate transmitted acoustic **power** except that emitted by the designated 1 cm width of the active array, to allow passage of all forward emissions from that 1 cm width and to agree with the accuracy and other requirements of this section.

The scanhead front surface shall be coplanar with the mask surfaces as illustrated in Figure 5-10. This requirement maintains consistency with Section 5.6.1.6(b). The ultrasonic attenuation of the mask shall be at least 30 dB and its window's inside walls shall be lined with a material of at least 90% reflectance to prevent loss by the walls. The length of the slit shall be at least twice the elevation dimension of the transducer under test.

As a check of these two requirements, acoustic **power** measurements should be made with two mask thicknesses. The measurements should be made in a scanning mode on each scanhead/ system under measurement, and should agree within 10%.

Figure 5-10 is a sketch of a suggested mask geometry. A material with a maximum attenuation coefficient and minimum impedance mismatch with water is recommended. Materials are available commercially which are well matched to water (reflection coefficient = -30 dB) and have a loss in the range of 45 dB/cm at 3.5 MHz. Additional attenuation can be provided by sandwiching a stainless steel, closed pore foam or other high or low impedance reflector between two layers of the ultrasonic attenuating material.

For measurement of the acoustic **power** per unit length, the mask slit should be aligned with respect to the transducer under test and its imaging plane as illustrated in Figure 5-11. With mechanical sector scanners and curvilinear arrays, lateral positioning is critical. Scanhead probe holders and jigs will be helpful in this regard. It is anticipated that for **beam axis** alignment within ± 5° of the normal to the mask plane and target plane and scan plane alignment within ± 5° of the normal to the sides of the slit are sufficient for the purposes of this test (see Figure 5-11).

b. One cm wide radiation force balance target:

As an alternative to the use of an aperture limiting mask, the measurement of the acoustic **power** per unit length may be made using a 1 cm wide radiation force balance target. When the 1 cm wide radiation force balance target is used, it must be placed immediately in front of the scanhead, and its geometry and composition shall be such that it detects all and only the acoustic emissions from a 1 cm wide strip of the scanhead.

To meet the accuracy requirements of this section, and the linearity requirements of Section 5.6.1.3 of this standard, the target to transducer distance should be less than 10λ [$\lambda = 1.5/f_c$, where f_c is expressed in MHz] or 3 mm, whichever is greater.

As a check of target performance, acoustic **power** measurements should be made with two target thicknesses. The measurements should be made in a scanning mode on each scanhead/system under measurement, and should agree within 10%.

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To minimize measurement errors due to reverberations, caution must be exercised to ensure that reflected acoustic energy (e.g., from the transducer or air-water interface) does not impinge onto any surface of the target. Further, the orientation of the target's long axis should remain perpendicular to the scan plane as illustrated in Figure 5-12.

c. Creating a 1 cm azimuthal wide window using electronic control means:

Where the system control scheme and transducer geometry allow, masking of a 1 cm wide aperture may be accomplished electronically by de-energizing the aperture outside this area provided that the acoustic **power** emitted within the 1 cm wide aperture is not affected by the electronic masking.

Electronic means for masking the **active aperture** for a 1 cm wide aperture is recommended, where feasible, with electronically controllable linear arrays (sequenced, phased, or combination).

5.6.2 Alternate Power Measurement/Calculation Using a Hydrophone and Planar Scanning in Non-Autoscan Mode

Radiation force balance techniques are the primary method for measuring acoustic **power.** However, **ultrasonic power,** W, may be measured for labeling purposes with a hydrophone instead of a radiation force balance. The accuracy and precision generally will not be as high as with the force balance, but at relatively low **powers,** a higher uncertainty may be acceptable. When making acoustic **power** measurements with hydrophones, extreme care should be taken to select the proper transducer-to-hydrophone water path length. The path length should be selected such that both the particle velocity and **acoustic pressure** are in phase.

The linearity requirements of Section 5.6.1.3(b) for radiation force balance measurements of acoustic **power** also are applied to hydrophone techniques. If the linearity conditions cannot be met for the combination of water path length, measurement equipment (hydrophone, amplifier, oscilloscope, etc.) and range of voltages of the diagnostic ultrasound **equipment** under test, then a range of measurement linearity should be determined for system voltages and a linear extrapolation technique should be used to calculate acoustic **power** at high (nonlinear) voltages. Whatever portion of the acoustic **power** measurement nonlinearity is found to be due to nonlinear output response of the ultrasonic scanhead/system combination should be modeled to reflect the nonlinear **acoustic output.**

Hydrophone measurements of acoustic **power** shall be performed only with the beam scan arrested.

A measurement of **ultrasonic power,** W_h, with the hydrophone, also is extremely useful for comparison with the balance-determined **ultrasonic power,** W_b, as an independent check on all the measurements and calibrations. When the **hydrophone calibration** at a given frequency is in question, the measured **power,** W_h, in Section 5.6.2.4-3, may be replaced by W and the equation used to determine an effective **hydrophone calibration** factor, M_L, for the ultrasound frequency spectrum being measured. The limited accuracy of this approach should be noted.

The derivation of the planar scanning equations is the same for this **power** measurement of the system under test (the **ultrasound system**) as it is for **hydrophone calibration**; see Appendix H for that derivation. The scanning techniques and calculations also are similar to those for **hydrophone calibration** in Appendix H.

5.6.2.1 Verification of Planar Scanning Power Measurement Methodology

The accuracy of the planar scanning measurements and calculations shall be estimated by performing the planar scanning measurement of **power** on the standard **reference source** at calibration frequencies of

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the **reference source** which bracket the **center frequency** of the device under test (e.g., 3.2 MHz and 4.1 MHz for a 3.5 MHz device). The resulting measured **power** shall be compared to the **power** produced by the **reference source.** For the measurement, a **hydrophone calibration** factor $M_L^2(f_c)$ obtained by a method other than the planar scanning performed on the same measurement systems used to make the scanhead acoustic **power** measurements shall be available and shall be used. The uncertainty of the results shall be less than the uncertainty specified in Section 4.8.

5.6.2.2 Determining Water Path Length

For focusing transducers, water path lengths shall be defined in terms of the parameters stated in the definition of **depth of focus.** For a given **transmit pattern** (j), the hydrophone shall be positioned at a distance Z such that $Z > (Z_{min}, P_1)$ and $< Z_{mjPII.0}$ (i.e., $\max[Z_{min}, P_1] < Z < Z_{mjPII.0}$).

For nonfocusing transducers, water path length shall be set beyond the **far field transition length.**

5.6.2.3 Linearity Test

a. Measurement procedure:

The same requirements shall apply as specified in Section 5.6.1.3 of this standard, where for each discrete **transmit pattern** (j), the hydrophone is positioned on axis at a location determined per Section 5.6.2.2.

For a given **transmit pattern** (j), the hydrophone's temporal **waveform** at the **maximum drive voltage amplitude** level should be noted. Obvious nonlinear distortion indicates the need for corrective action.

b. Linearity requirements:

The requirements of Section 5.6.1.3(b) shall apply.

c. Determining the causes of nonlinearity:

The following techniques may be used to determine the cause of nonlinear **acoustic output** response:

1. Vary the **drive voltage amplitude** level from maximum to minimum value while observing the temporal **waveform.** Note evidence of nonlinear distortion at high **drive voltage amplitude** levels, with little or no nonlinear distortion at low **drive voltage amplitude** levels.

2. Calculate the **nonlinearity propagation parameter** σ_m. If $\sigma_m > 0.5$, then the nonlinear loss may have occurred even if there is no obvious **waveform** distortion.

3. If possible, defocus the beam leaving all other **transmit pattern** parameters unchanged. Reset the hydrophone depth for an appropriate far-field position, and repeat the linearity test.

4. Decrease the transducer-hydrophone distance to the minimum value specified in Section 5.6.2.2 of this standard, and repeat the linearity test.

Nonlinear response is most likely attributable to the acoustic **power** measurement set up as described in Section 5.6.2.3(d). If the **nonlinearity propagation parameter** $\sigma_m > 0.5$, obvious nonlinearities are observed at high **drive voltage amplitude** levels and performing (3) and (4) results in linear response.

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Nonlinear response is most likely the result of the system/transducer combination if the **nonlinearity propagation parameter** $\sigma_m < 0.5$ and nonlinear response persists after performing (3) and/or (4).

d. Nonlinear response due to acoustic **power** measurement set up:

If it is determined, according to Section 5.6.2.3(c) of this standard, that nonlinear **acoustic output** response is due to the acoustic **power** measurement equipment, then either:

1. The transducer-to-hydrophone distance shall be adjusted to the minimum value specified in 5.6.2.2 of this standard and linearity shall be verified.

2. If necessary, the amplitude of the hydrophone **waveform** shall be reduced such that it does not exceed the dynamic range specifications of the amplifier.

3. A linear response correction function shall be derived by extrapolating from the lower **drive voltage amplitude** level data points per the procedure recommended in Section 5.6.1.3(b). This function shall be used as reference data in determining acoustic **power** at higher **drive voltage amplitude** levels.

e. Nonlinear response due to the system/transducer combination:

If it is determined, according to Section 5.6.2.3(c), that nonlinear **acoustic output** response is due to nonlinearities resulting from the system/transducer combination and/or **duty factor** or **drive voltage amplitude** limitations, then the system acoustic **power** calculation routine should model the nonlinear effects.

5.6.2.4 General Methodology and Equations

After the source transducer and hydrophone have been aligned and the **waveform** recorded at the point determined per 5.6.2.2, the time averaged voltage squared integral, h(x,y,z) (Equation 5.6.2.4-1), for each **transmit pattern,** j, must be measured and calculated at a number of points across the beam cross-section (perpendicular to the **beam axis**).

$$h_j(x,y,z) = \frac{1}{T_j}\int_0^{T_j} [V_j(x,y,z,t)]^2 dt \qquad (5.6.2.4\text{-}1)$$

Here, V_j is the hydrophone output voltage for **transmit pattern** j, and T_j is the **pulse repetition period** for **transmit pattern** j.

Let:

$$H_j(z) = \iint S_j \; h_j(x,y,z)dxdy \qquad (5.6.2.4\text{-}2)$$

where S_j is the surface of a plane normal to the **beam axis** of **transmit pattern j,** at the depth z determined per 5.6.2.2.

Each scan, over each surface S_j, shall include at least the region within which h_j (x,y,z) exceeds 0.25% of its maximum value in that plane. The lateral displacement of adjacent points in the x and y directions should either be less than 1.5 λ or a distance over which h_j varies by less than 1 dB.

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The total hydrophone measured **power**, W_h, is:

$$W_h(j) = \frac{1}{\rho c}\left[H_j(z) \Big/ \left(M_L(f_{cj})\right)^2\right] \qquad (5.6.2.4\text{-}3)$$

For **combined modes**, the following equation applies:

$$W_h = \sum_{j=1}^{\#\ \text{transmit pattern}} W_h(j) \qquad (5.6.2.4\text{-}4)$$

Note that when a **hydrophone calibration** is desired, $M_L(f_{cj})$ can be obtained by measuring each $W_h(j)$ by other means, i.e., RFB measurements (see Appendix H).

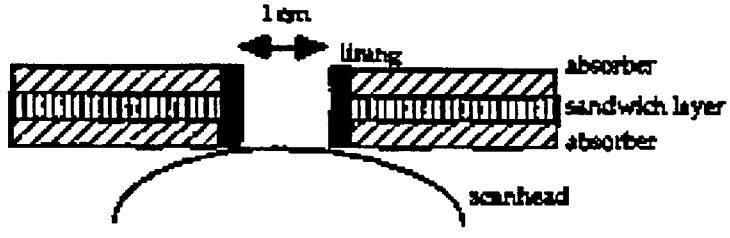


Figure 5-10
SUGGESTED 1 CM WIDE APERTURE MASK

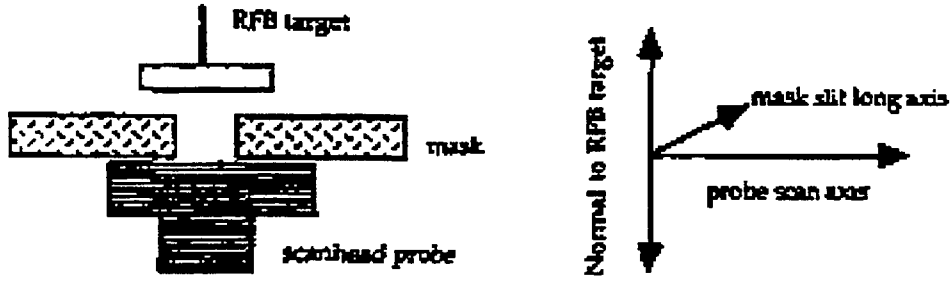


Figure 5-11
SUGGESTED ORIENTATION OF PROBE, MASK SLIT, AND RFB TARGET

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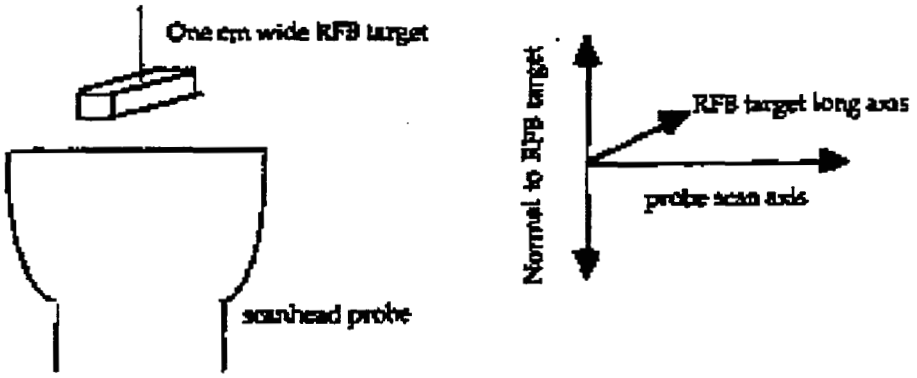


Figure 5-12
SUGGESTED ORIENTATION OF PROBE, MASK SLIT, AND 1 CM RFB TARGET

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Appendix A
STATISTICAL CONSIDERATIONS

A.1 BACKGROUND

Statistical methods can be very helpful in allowing for the determination of the most probable value or values of a quantity from a limited group of data. That is, given an experiment and the resulting data, it is possible to assess which value is the most likely to occur if the experiment is repeated. Furthermore, the probable error of one observation and the uncertainty in the best estimate obtained also can be determined.

However, a statistical evaluation cannot improve the accuracy of a measurement. The laws of probability used by statistics operate only on random errors and not on systematic errors. The systematic errors must be small compared to the random errors if the results of the statistical evaluation are to be meaningful.

The need to estimate population parameters from sample data stems from the fact that it is too expensive and/or not feasible to enumerate complete populations to obtain the required information. Statistical estimation procedures provide the means to obtain estimates of population parameters with desired precision.

Statistics is concerned with the theory and methodology for drawing inferences that extend beyond the particular set of data examined. Sample data are observed (or measured) to make inferences or decisions about the populations from which the samples are drawn.

Two different types of estimates of population parameters are of interest: point estimates and interval estimates. A point estimate is a single number used as an estimate of an unknown population parameter, such as the mean. Although any single point estimate is intended to be the true value, it most likely will deviate from it to some extent. It is thus necessary to have some measure of the error that might be involved in using this point estimate.

An interval estimate of a population parameter is a statement of two values between which we have some confidence that the [point estimate of the] parameter lies. There may be a great deal of confidence or very little confidence that the population parameter is included in the range of the interval estimate, so it is necessary to attach some sort of probabilistic statement to the interval. The procedure used is confidence interval estimation and is an interval estimate of the [point estimate of the] population parameter.

A.1.1 Large Sample Size

When the sample size is large, the sampling distribution of the mean may be assumed to be normally (Gaussian) distributed, even if the population is not normally distributed. This results from the remarkable fact that for almost all types of population distributions, the sampling distribution is approximately normal for sufficiently large samples. This relationship between the shapes of the population distribution and the sampling distribution of the mean has been summarized in one of the most important theorems of statistical inference, called the Central Limit Theorem, which states: If a population distribution is non-normal, the sampling distribution of the mean may be considered to be approximately normal for large samples.

Let us now consider some notation. Let N_p denote the population size. This could represent the total number of **ultrasound systems** that are manufactured in a particular series. For this population, let:

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a. μ_p denote the population mean, and
b. σ_p denote the population standard deviation.

Now, let N_s denote the sample size, which is less than the population size, that is, $N_s < N_p$. For this sample size, let:

a. μ_s denote the sample mean, and
b. σ_s denote the sample standard deviation.

These mean and standard deviation quantities represent some quantifiable characteristics of **ultrasound systems**. From the sample mean and sample standard deviation, an estimate of the population mean and population standard deviation can be made (assuming the estimates are unbiased) to be:

$$\mu_p = \mu_s \qquad \text{(A1.1-1)}$$

$$\sigma_S = \sigma_p / \sqrt{N_S} \qquad \text{(A1.1-2)}$$

If $N_s > 30$, the interval of one sample standard deviation about the sample mean, that is $\mu_s \pm s_s$, comprises 68.27 percent of the total area under the distribution. Thus, we can be confident of finding the sample mean 68.27 percent of the time $\pm \sigma_s$, that is, within the interval σ_s on either side of the mean μ_s. This percentage is called the confidence limit, and the value $\mu_s + \sigma_s$ is called the upper 68.27 percent confidence limit.

In general, the confidence limits for the population means are given by:

$$\mu_S \pm z_C \sigma_S / \sqrt{N_S} \qquad \text{(A1.1-3)}$$

where, for a 95 percent confidence interval, the confidence coefficient $z_c = 1.96$. That is, for a sample size of N_s, the interval:

$$\mu_S \pm 1.96 \sigma_S / \sqrt{N_S} \qquad \text{(A.1.1-4)}$$

will include the true mean value, μ_p, 95 percent of the time.

A.1.2 Small Sample Size

The distinction between large and small sample sizes is important when the population standard deviation is unknown and therefore must be estimated from sample observations. For large sample sizes, the sample distribution is approximately normally distributed according to the Central Limit Theorem. Thus, the z_c statistic (Equation A.1.1-3) is normally distributed for large samples even if the population is not normally distributed. Even if the standard error of the mean is estimated from the sample standard deviation, the sampling distribution may be assumed to be a standard normal distribution for practical purposes.

For small sample sizes, the theoretically correct distribution is the t distribution. As noted in A1.1, the z_c statistic represents a known standard error because it is based on a known population standard deviation. For small sample sizes, the t statistic represents an estimated standard error because σ_s is an estimator of the population standard deviation:

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$$\sigma_s = \sqrt{\frac{\sum (x_i - \mu_s)^2}{N_s - 1}} \qquad \text{(A.1.2-1)}$$

and the number $N_s - 1$ in the formula is referred to as the number of degrees of freedom. The symbol x_i represents the individual values.

NOTE—The t distribution has been derived mathematically under the assumption of a normally distributed population. Just as is true of the standard normal distribution, the t distribution is symmetrical and has a mean of zero. However, the standard deviation of the t distribution is greater than that of the normal distribution, but approaches the latter figure as the number of degrees of freedom, and therefore the sample size, becomes large. As a rule of thumb, for a sample size of more than 30, the standard normal distribution may appropriately be used as an approximation to the t distribution.

In general, confidence intervals for population means can be represented by:

$$\mu_s \pm t_c \sigma_s / \sqrt{N_s} \qquad \text{(A.1.2-2)}$$

where the values $+t_c$, called critical values or confidence coefficients, depend on the level of confidence desired and the sample size. For 95 percent confidence limits, Table A-1 provides the $t_{0.95}$ value as a function of the degrees of freedom (df), that is $N_s - 1$, and sample size (N_s).

Table A-1

df	N_s	$t_{0.95}$	df	N_s	$t_{0.95}$
1	2	12.71	18	19	2.10
2	3	4.30	19	20	2.09
3	4	3.18	20	21	2.09
4	5	2.78	21	22	2.08
5	6	2.57	22	23	2.07
6	7	2.45	23	24	2.07
7	8	2.36	24	25	2.06
8	9	2.31	25	26	2.06
9	10	2.26	26	27	2.06
10	11	2.23	27	28	2.05
11	12	2.20	28	29	2.05
12	13	2.18	29	30	2.04
13	14	2.16	30	31	2.04
14	15	2.14	40	41	2.02
15	16	2.13	60	61	2.00
16	17	2.12	120	121	1.98
17	18	2.11	infinite		1.96

NOTE—$t_{0.95}$ values (95% confidence limits) as a function of degrees of freedom (df = N_s - 1) when N_s is the sample size

A.2 IMPLEMENTATION

Acoustic quantities will be characterized and reported for a mean value +95 percent confidence interval, and the number of samples used to obtain the mean value. The confidence interval is based on the total uncertainty in the measurement process.

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Two sources of error are considered in reporting the uncertainty of the quantity measured, viz., the uncertainty of the measurement system and the uncertainty of the diagnostic **ultrasound systems**. The uncertainty of the measurement system is assessed by a calibration procedure, which is traceable either to the US National Institute of Standards and Technology's Standard Reference Material 1855 (Ultrasonic Power Transducer Standard) or to the UK National Physical Laboratory's ultrasonic pressure standard. The uncertainty of the diagnostic **ultrasound systems** is assessed by measuring the appropriate labeling quantities of an adequate number of systems of the same series with the calibrated measurement system.

A.2.1 Measurement System Uncertainty—Ultrasonic Power

The measurement of ultrasound **power** is performed with a force balance, which shall be calibrated with respect to a known **power** source traceable to the National Institute of Standards and Technology NIST) Ultrasound Power Transducer Standard. This reference source has a known output (denoted as $\bar{\mu}$) and a source uncertainty (denoted as E_s), viz., a 95 percent confidence interval that is expressed as a percentage relative to $\bar{\mu}$.

A minimum of ten independent measurements of **power** output of the US National Bureau of Standards' Ultrasonic Power Transducer Standard (or known **power** source traceability to the NIST Ultrasonic Power Transducer Standard) shall be performed at a minimum of two frequencies within the **bandwidth** of the diagnostic ultrasound system to be calibrated. Independence is defined operationally to mean that the entire setup, measurement, and shut down procedures be used each and every time the measurement is performed. This requires a complete shut down of the measurement system in accordance with those adopted procedures for end-of-day shut down and start up of the measurement system in accordance with those adopted procedures at the start of the work day between each measurement.

The mean, μ_s, and standard deviation, σ_s, are then calculated for the (at least ten) values of the applicable ultrasonic quantity.

For the case when the ultrasonic quantity is **power**, error E_1 is calculated as the percentage deviation between the measured mean μ_s of N_s samples, and the presumed known **power** $\bar{\mu}$, as:

$$E_1 = \frac{\bar{\mu}}{\mu_s} \times 100 \qquad \text{(A.2.1-1)}$$

This represents the percentage correction multiplier that must be used for each measurement to be performed using this system.

For example, Table A-2 lists ten independent measurements of a known **power** source traceable to NIST. The known ultrasound **power** is 1.0 W and the source uncertainty, provided by NIST, is 4 percent. From Table A-2, the mean and standard deviation (from A.1.2-1) are 1.024 W and 86 mW, respectively. The percentage correction multiplier, E_1, which should be applied to every **power** measurement made with the measurement system, is (1.000/1.024) ×100 = 97.7 percent. In other words, each **power** measurement should be multiplied by 0.977 to correct for the bias in the measurement system.

Since the variation of these measurements is a function of the sample size, the uncertainty of the 10 measurements, in Table A-2, as represented by the standard deviation value, will not be used as represented here. Rather, the measurement system uncertainty will be incorporated into the total uncertainty after evaluating a set of diagnostic ultrasound systems.

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Table A-2

Actual Measurement	Corrected Measurement
0.95	0.928
0.94	0.918
1.02	0.996
0.90	0.879
1.08	1.055
1.12	1.094
1.11	1.084
1.09	1.064
0.93	0.908
1.10	1.074
mean = 1.024	mean = 1.000
S.D. = 0.086	S.D. = 0.084
$E_2 = (1.96)(0.084)(100)/(1.000\sqrt{10}) = 5.2$ percent	

NOTE—Example for determining the error E_2 for repeated measurements (see eq. A2.1-3)

Error E_2 represents the uncertainty of the measurement system. It includes random errors in the force balance system and random errors in the transducer positioning system. E_2, which is stated as a percentage in terms of a 95 percent confidence interval, is given for a single measurement by:

$$E_2 = \frac{1.96\sigma_s \times 100}{\mu_s} \qquad \text{(A.2.1-2)}$$

When the system is used to make m repeated measurements of the same source output, the uncertainty can be reduced for the mean of m repeated measurements such that:

$$E_2 = \frac{1.96\sigma_s \times 100}{\mu_s\sqrt{m}} \qquad \text{(A.2.1-3)}$$

The error E_3 denotes the source uncertainty, as given by NIST for its source, that is 4 percent as stated above. Therefore, the overall measurement system uncertainty is given by:

$$\text{Overall measurement uncertainty} = \sqrt{E_2^2 + E_3^2} \qquad \text{(A.2.1-4)}$$

If you were to evaluate the overall measurement uncertainty of the known **power** source, then:

$$E_2 = (1.96)(0.084)(100)/(1.000\sqrt{10}) = 5.2 \text{ percent}$$

$$E_3 = 4 \text{ percent, and}$$

$$\sqrt{E_2^2 + E_3^2} = 6.6 \text{ percent}$$

This value is not reported but may be useful for in-house routine evaluation of the measurement system.

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A.2.2 Measurement System Uncertainty—Ultrasonic Pressure

The same procedure shall be followed as that for determining the measurement system uncertainty for **ultrasonic power**. In this case, a minimum of ten independent measurements of a UK National Physical Laboratory's calibrated hydrophone for known ultrasonic pressure shall be performed at a minimum of two frequencies within the **bandwidth** of the diagnostic ultrasound system to be calibrated.

A.2.3 Diagnostic Ultrasound Systems Uncertainty

The number of diagnostic ultrasound systems of a particular equipment model that need to be measured with the calibrated measurement system shall not be specified. In general, the numerical value of uncertainty of any quantity measured will be larger when fewer systems are measured.

The number of systems measured is denoted as N_s, the sample size. For whichever quantity is being determined, the mean, μ_s, and standard deviation, σ_s, are calculated from the N_s values. The 95 percent confidence limits are then calculated from A.1.2-2, using $t_c = t_{0.95}$ for this measurement set from Table A-1. The percentage error E_4 of this measurement set is calculated as:

$$E_4 = \frac{t_{0.95}\sigma_s/\sqrt{N_s}}{\mu_s} \times 100 \qquad \text{(A.2.3-1)}$$

A.2.4 How to Specify Mean and Uncertainty of Ultrasonic Power

The **ultrasonic power** of five ultrasound transducers ($N_s = 5$) is measured by the calibrated system to be 65, 98, 112, 85, and 75 mW (after correction by the E_1 term), yielding an overall mean of 87.0 mW and an overall standard deviation of 18.56 mW (see Example A-1). In this example, only one measurement each is made for each of the five transducers (m = 1 in A.2.1-3).

To determine the 95 percent confidence limits, note that for five measurements (four degrees of freedom), the confidence coefficient from Table A-1, $t_{0.95}$, is 2.78. Example A-1 summarizes the results. Error E_2 = 41.81 percent, Error E_3 (a given) = 3 percent, and Error E_4 = 26.52 percent. The total uncertainty (U) of the measurement is:

$$U = \sqrt{E_2^{\,2} + E_3^{\,2} + E_4^{\,2}} \qquad \text{(A.2.4-1)}$$

which for this example yields 49.61 percent. In terms of units of mW for this example, the total uncertainty of the measurement is 43.2 mW. The **ultrasonic power** of the transducer will be reported as:

Ultrasonic Power = 87.0 + 43.2 mW (5) (A.2.4-2)

where the number 5 in parenthesis represents the number of transducers measured.

Example A-2 includes two additional, independent measurements for each of the five ultrasonic transducers reported in Example A-1. In general, more than one measurement would be made for each transducer. In this case, the total uncertainty of the measurement is 24.0 percent.

Example A-3 includes seven additional, independently repeated measurements for each of the five transducers reported in Example A-2. In this example, the individual transducer means for the five transducers were approximately equal to those of Example A-2. For example, for transducer A in Example A-3, the individual transducer mean is 80.70 mW, whereas for that in Example A-2, it is 80.67 mW. Likewise, the overall means of the means were approximately equal at 87.5 mW for both Examples A-2 and A-3.

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The only initial difference between these examples is the number of independently repeated measurements for each transducer, viz., Example A-2, m = 3, and Example A-3, m = 10. By increasing the number of independent, repeated measurements, the total uncertainty of the measurement decreases from 24.0 to 18.3 percent.

To show the effect of the number of transducers evaluated, Examples A-3, A-4, and A-5 represent, respectively, 5, 4, and 3 diagnostic ultrasound systems. The same data were used for these three examples, with the exception that in Example A-4, transducer E was deleted and in Example A-5, transducer D also was deleted. The overall mean of the means for these three examples remained relatively constant. The overall standard deviations tended to increase as the number of transducers (hence the number of measurements) decreased. Error E_2 tended to increase slightly as the number of transducers decreased. This increase resulted from the increasing overall standard deviation. Error E_4 increased markedly as the number of transducers decreased. This increase was due to two competing effects, the increasing value of the confidence coefficient as N_s decreased in the numerator and the decreasing square root of N_s in the denominator. There was also the influence of the increasing overall standard deviation in the numerator as N_s decreased.

Example A-1

N = 5 and m = 1

	A	B	C	D	E
	65.00	98.00	112.00	85.00	75.00
Individual transducer means:	65.00	98.00	112.00	85.00	75.00

Overall Mean of Means:	87.00
Overall Standard Deviation:	18.56
E2 = (1.96 x 18.56)/(87.00 x 1) =	41.81 %
E3 =	3.00 %
E4 = (2.78 x 18.56)/(87.00 x 2.236) =	26.52 %
U =	49.61 %

Ultrasonic Power = 87.0 + 43.2 mW (5)

NOTE–This example consists of m rows and N columns, where N is the number of transducers measured and m is the number of repeated measurements for each of the N transducers

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Example A-2

N = 5 and m = 3

	A	B	C	D	E
	65.00	98.00	112.00	85.00	75.00
	83.00	73.00	99.00	101.00	95.00
	94.00	77.00	85.00	87.00	84.00
Individual Transducer Means	80.67	82.67	98.67	91.00	84.67
Individual Transducer Standard Dev.	11.95	10.95	11.03	7.12	8.18

Overall Mean of Means:	87.53
Overall Standard Deviation:	12.40
E2 = (1.96 x 12.40)/(87.53 x 1.732) =	16.03 %
E3 =	3.00 %
E4 = (2.78 x 12.40)/(87.53 x 2.236) =	17.61 %
U =	24.00 %

Ultrasonic Power = 87.5 + 21.0 mW (5)

NOTE— This example consists of m rows and N columns, where N is the number of transducers measured and m is the number of repeated measurements for each of the N transducers.

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Example A-3

N = 5 and m = 10

	A	B	C	D	E
	65.00	98.00	112.00	85.00	75.00
	83.00	73.00	99.00	101.00	95.00
	94.00	77.00	85.00	87.00	84.00
	85.00	91.00	98.00	75.00	84.00
	66.00	74.00	106.00	88.00	80.00
	99.00	88.00	103.00	95.00	91.00
	74.00	83.00	78.00	105.00	86.00
	78.00	79.00	89.00	93.00	95.00
	80.00	89.00	111.00	86.00	88.00
	83.00	75.00	105.00	95.00	68.00
Individual Transducer Means	80.70	82.70	98.60	91.00	84.60
Individual Transducer Standard Dev.	10.28	8.04	10.73	8.21	8.13

Overall Mean of Means:	87.52
Overall Standard Deviation:	11.36
E2 = (1.96 x 11.93)/(87.52 x 3.162) =	8.05 %
E3 =	3.00 %
E4 = (2.78 x 11.36)/(87.52 x 2.236) =	16.14 %
U =	18.28 %

Ultrasonic Power = 87.5 + 16.0 mW (5)

NOTE—This example consists of m rows and N columns, where N is the number of transducers measured and m is the number of repeated measurements for each of the N transducers.

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Example A-4

N = 4 and m = 10

	A	B	C	D
	65.00	98.00	112.00	85.00
	83.00	73.00	99.00	101.00
	94.00	77.00	85.00	87.00
	85.00	91.00	98.00	75.00
	66.00	74.00	106.00	88.00
	99.00	88.00	103.00	95.00
	74.00	83.00	78.00	105.00
	78.00	79.00	89.00	93.00
	80.00	89.00	111.00	86.00
	83.00	75.00	105.00	95.00
Individual Transducer Means	80.70	82.70	98.60	91.00
Individual Transducer Standard Dev.	10.28	8.04	10.73	8.21

Overall Mean of Means: 88.25
Overall Standard Deviation: 11.93

E2 = (1.96 x 11.93)/(88.25 x 3.162) = 8.38 %
E3 = 3.00 %
E4 = (3.18 x 11.93)/(88.25 x 2.0) = 21.49 %
U = 23.26 %

Ultrasonic Power = 88.25 + 20.5 mW (4)

NOTE—This example consists of m rows and N columns, where N is the number of transducers measured and m is the number of repeated measurements for each of the N transducers.

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Example A-5

N = 3 and m = 10

	A	B	C
	65.00	98.00	112.00
	83.00	73.00	99.00
	94.00	77.00	85.00
	85.00	91.00	98.00
	66.00	74.00	106.00
	99.00	88.00	103.00
	74.00	83.00	78.00
	78.00	79.00	89.00
	80.00	89.00	111.00
	83.00	75.00	105.00
Individual Transducer Means	80.70	82.70	98.60
Individual Transducer Standard Dev.	10.28	8.04	10.73

Overall Mean of Means:	87.33
Overall Standard Deviation:	12.83
E2 = (1.96 x 12.83)/(87.33 x 3.162) =	9.11 %
E3 =	3.00 %
E4 = (4.30 x 12.83)/(87.33 x 1.732) =	36.47 %
U =	37.71 %

Ultrasonic Power = 87.33 + 32.8 mW (3)

NOTE—This example consists of m rows and N columns, where N is the number of transducers measured and m is the number of repeated measurements for each of the N transducers.

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Appendix B
NONLINEAR EFFECTS

B.1 NONLINEAR WAVEFORM DISTORTION

The observed behavior of ultrasonic pressure **waveforms** in water generally cannot be explained on the basis of linear acoustics. For example, Figure B-1 shows measurements of pressure **waveforms** at three frequencies. Each measurement was made at the **far field transition length** distance, $d^2/4\lambda$, where d is the diameter of the circular unfocused transducer and λ is acoustic **wavelength**. The **ultrasonic power** emitted by the transducer is 800 mW in each case, but the **waveforms** indicate a progressive distortion from a sinusoid shape as frequency is increased. As frequency and distance increase, the pressure **waveforms** become asymmetric so that the compressional half-cycles (at the bottom of Figure B-1) evolve into sharp peaks and the (top) rarefactional half-cycles become more shallow, rounded, and extended in time. These distortions are a natural consequence of the nonlinear propagation of pressure waves in water under these conditions. Finite amplitude or nonlinear effects require special care and adequate instrumentation in ultrasonic output measurement.

As evident from Figure B-1, the compressional and rarefaction half-cycles must each be accounted for separately as measurement quantities. The notations p_c for **peak compressional pressure** and p_r for **peak rarefaction pressure**, are used rather than the designations p_+ and p_-, respectively. The reason this notation is used is that the polarity shown on a video display of the compressional half-cycles for a display may be either positive or negative, depending on the internal lead attachments of the hydrophone and/or a possible 180° inversion by the associated amplifier (Harris, 1988). For example, the **waveforms** in Figure B-1 appear inverted.

A simplified explanation of nonlinear effects is that as a pressure **waveform** propagates through water, compressional and rarefactional pressure travel at different effective speeds and phases. Ultrasonic **waveform** distortions increase with distance from the transducer, strength of focusing gain, and frequency, as well as transducer drive level, as explained more fully in the next section. More information about nonlinear effects can be found in Carstensen and Muir (1986) and Bacon (1984).

The asymmetric pressure **waveforms** associated with nonlinear effects contain harmonic frequencies that exceed the radiating transducer's bandpass and **center frequencies**; consequently, a wide **bandwidth** hydrophone system meeting the minimum requirements of Section 3.3.2 is necessary to reproduce faithfully the pressure **waveform**. These harmonics, observed through a spectrum analyzer or spectral analysis of the hydrophone voltage **waveform**, can be used as indicators of the severity of nonlinearity. A sinusoidal pressure wave undergoing maximum finite amplitude distortion eventually evolves into a sawtooth-shaped **waveform** under idealized conditions neglecting diffraction. For this sawtooth, harmonic frequency amplitudes are proportional to 1/m where m is the harmonic (integer) multiple of the **center frequency** (Blackstock, 1965). This result is a simplification of reality in which diffraction and focusing modify the harmonic relationships. Inadequate hydrophone **bandwidth** may only pass the fundamental frequency and only a few harmonics, resulting in an underestimation of actual pressure levels.

Because of the redistribution of frequencies in transducer beams affected by nonlinearities, spatial beam characteristics also may change. For example, for severe nonlinearities, narrowing of the beamwidth can occur. The locations of the peak values of pressure, p_c and p_r, change in different ways from the linear range spatial peak location according to drive level applied and the focusing configuration (Duck and Starritt, 1986). These deviations from linear conditions require special care in ultrasonic output measurement.

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Because of nonlinear effects, peak pressure values cannot be used to accurately estimate **temporal average intensity**. Other **waveform** features are more appropriate for **hydrophone calibration** (see Sections 4.6 and 4.8 and Corbett, 1988). Nonlinear **waveform** distortion and its significance in altering conditions for onset of cavitation is a topic of current research (Ayme' et al., 1987); see Appendix F.

B.2 NONLINEARITY PROPAGATION PARAMETER

The degree of nonlinearity of a **waveform** can be evaluated by the **nonlinearity propagation parameter**, σ_m. For Figure B-1, for example, the cases shown represent a range of σ_m from 0.18 to 0.62.

For the **far field** of unfocused transducers, (Bacon, 1984), σ_m is:

$$\sigma_m = \frac{\beta \omega r_o p_o}{\rho c^3} \sinh^{-1}(z/r_o) \qquad \text{(B.2-1)}$$

where β is the nonlinearity parameter ($\beta = 3.5$ for pure water at 20°C), ω is the angular frequency, $\omega = 2\pi f_c$, z is the distance from the face of the transducer, ρ is the density and c is the sound speed of the undisturbed medium (water, for example), p_o is the source pressure at the face of the transducer, and r_o is the Rayleigh length, $r_o = \pi d^2/4\lambda$.

For focused transducers, (IEC, 1991b; Bacon, 1984), σ_m is defined as:

$$\sigma_m = \frac{\beta \omega z p_m}{\rho c^3} \frac{1}{\sqrt{F_g - 1}} \ln\left[\sqrt{F_g - 1} + \sqrt{F_g}\right] \qquad \text{(B.2-2)}$$

where p_m is the mean peak cycle **acoustic pressure** at the point in the acoustic field corresponding to the spatial peak temporal peak **acoustic pressure** at axial distance z, and F_g is 0.69 times the ratio of the geometrical area of the ultrasonic transducer to the –6 dB beam area at z.

NOTE—The equation given above is applicable to ultrasonic fields in which $F_g > 2.1$.

B.3 NONLINEAR REGIONS

As mentioned above, the propagation of ultrasound in water at the **acoustic pressures** and frequencies frequently encountered in ultrasonic field is not a linear process, and the shape of the acoustic pulse **waveform** often approximates a sawtooth. In diffractive fields, enhanced differences exist between the peak positive **acoustic pressure** and the peak negative **acoustic pressure**. To determine the significance of the distortion in the characterization of an ultrasonic field, the degree of nonlinear propagation can be predicted by calculation of the nonlinear propagation parameter, σ_m.

The following regimes may be defined:

a. $\sigma_m < 0.5$: Little nonlinear distortion has occurred. The amplitude at the **center frequency** differs by less than 5 percent from the value in the absence of nonlinear effects.

b. $0.5 < \sigma_m < 1.5$: Considerable nonlinear distortion has occurred. A broadband hydrophone should be used with a sensitivity which varies by less than ±3dB over the frequency range up to three octaves above the **center frequency**. The amplitude in a one-half octave band centered at the **center frequency** would differ from its value in the absence of nonlinear effects by between 5 and 25 percent.

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c. $\sigma_m > 1.5$: Considerable nonlinear distortion and also loss in energy from the wave due to shock propagation has occurred. A broadband hydrophone should be used as in (2) above. The amplitude in a one-half octave band centered at the **center frequency** would differ by more than 25 percent from the value in the absence of nonlinear effects.

These regions and the σ_m parameter provide guidelines for estimating the degree of distortion. For transient wideband acoustic pulses from diagnostic equipment, the application of these guidelines must be viewed with caution. Differences in pressures and **intensity** measurements from linear expectations may be significant even for $\sigma_m < 0.5$ if inadequate instrumentation is used. For situations in which ultrasonic parameters can be controlled, such as calibration, these guidelines maybe helpful in identifying the variables affecting nonlinear effects and the amount by which they might be changed in order to reduce distortion.

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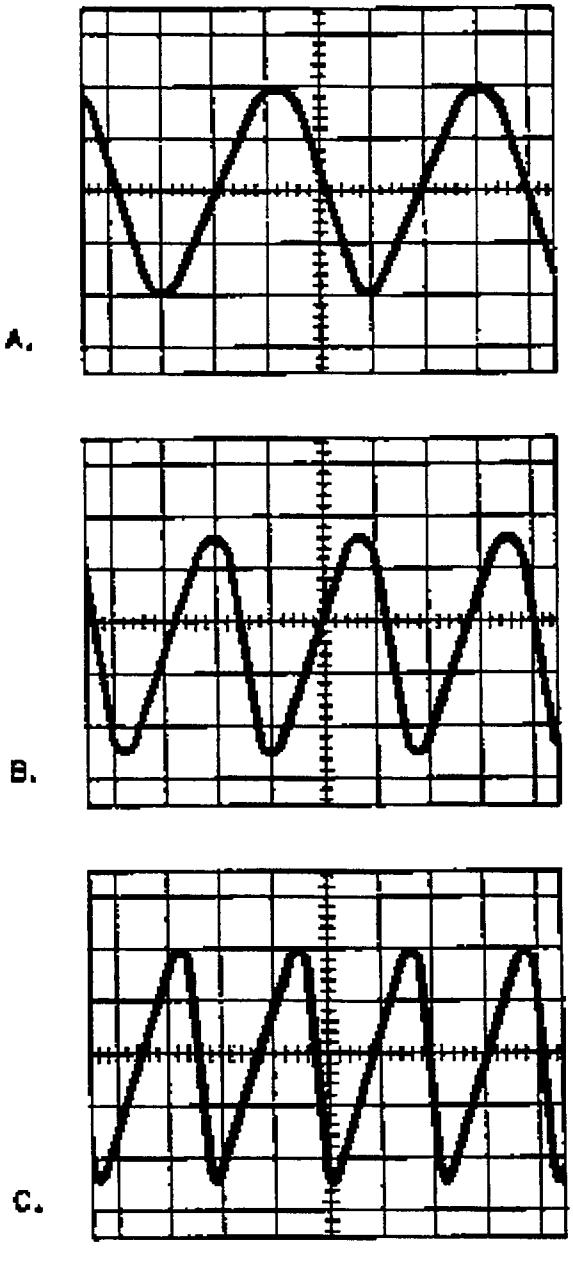


Figure B-1
HYDROPHONE MEASUREMENTS OF PRESSURE WAVEFORMS FROM AN UNFOCUSED SOURCE EMITTING 800 MW OF ULTRASONIC POWER

Scales: 0.02 V/div., 0.1 ms/div.

a. Measurement distance = 10.8 cm, **center frequency** = 2.6 MHz, $\sigma_m = 0.30$
b. Measurement distance = 15.2 cm, **center frequency** = 3.7 MHz, $\sigma_m = 0.60$
c. Measurement distance = 19.5 cm, **center frequency** = 4.8 MHz, $\sigma_m = 1.0$

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Appendix C
DIRECTIVITY OF HYDROPHONE

Ideally, a hydrophone should sample an acoustic field without spatially averaging it significantly. Because of the wide range of measurement situations, commercially available probes cannot always meet this ideal. Spatial averaging effects result when the effective size of the hydrophone's active element is too large. The effective size can be found experimentally from a measurement of the hydrophone's directional response, or directivity pattern.

To perform a directional response measurement, the hydrophone is positioned in the **far field** of a single element circular ultrasonic transducer operated by using tone burst pulses of at least 15 cycles at the approximate frequency for which the directional response is required. (This frequency is normally the **center frequency** of the diagnostic source transducer to be characterized.) The hydrophone is aligned for maximum received signal first by translating it normally to the **beam axis** (i.e., z axis). Then, while keeping the hydrophone centered on this point, it is rotated about the two axes passing through the plane of the hydrophone's active element.

Measurements of the received signal as a function of angular rotation of the hydrophone are made using one of the two rotation axes that pass through the plane of the active element (i.e., the x and y axes). The directional response is determined by dividing the received signal at a particular angle by the maximum received signal.

The **effective hydrophone radius** a_e in mm of the active element is determined by inserting the measured half angle of the directivity function at the –3 dB and –6 dB points into the theoretical directivity function of a uniform, circular receiver and calculating the two values a_e. For circular hydrophone apertures of radius a_e, incident waves of **wavelength**, λ, and measured half angle, δ, the pressure directivity function is:

$$\frac{2J_1[(2\pi a_e/\lambda)\mathrm{Sin}\delta]}{(2\pi a_e/\lambda)\mathrm{Sin}\delta} = \begin{cases} \frac{1}{\sqrt{2}} & \text{for } -3 \text{ dB} \\ \frac{1}{2} & \text{for } -6 \text{ dB} \end{cases} \qquad \text{(C-1)}$$

where J_1 is a first order Bessel function of the first kind. If δ_3 and δ_6 are the measured half angles at the -3 dB and -6 dB points, respectively, then the corresponding effective radii, a_{e3} and a_{e6}, are:

$$a_{e3} = \frac{1.62\lambda}{2\pi\mathrm{Sin}\delta_3} \text{ and } a_{e6} = \frac{2.22\lambda}{2\pi\mathrm{Sin}\delta_6} \qquad \text{(C-2)}$$

The **effective hydrophone radius** a_e is determined from the arithmetic mean of a_{e3} and a_{e6}.

NOTE—If in practice the –6 dB point occurs at an angle greater than 30°, then a_{e3} may be taken as the **effective hydrophone radius**.

In the case of a hydrophone that is constructed such that it has a noncircular active element, it is still possible to use this procedure to determine its approximate effective dimension in any specified direction. In this case, the rotational axis used for the directional response measurements would be normal to the direction of interest.

Alternatively, for rectangular hydrophones with sides g = b or c, a similar procedure can be adopted by using the theoretical directivity function of a uniform, rectangular receiver. A linear scan is made along

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each of the coordinate axes aligned parallel to the edges of the hydrophone. Effective aperture sizes $g_e = b_e$ or c_e can be determined by the appropriate relationships below. When:

$$\frac{\sin(\pi g_e \mathrm{Sin}\delta/\lambda)}{(\pi g_e \mathrm{Sin}\delta/\lambda)} = \begin{cases} \frac{1}{\sqrt{2}} & \text{for } -3 \text{ dB} \\ \frac{1}{2} & \text{for } -6 \text{ dB} \end{cases} \quad \text{(C-3)}$$

then, $$g_{e3} = \frac{0.443\lambda}{\mathrm{Sin}\delta_3} \quad \text{(C-4)}$$

and, $$g_{e6} = \frac{0.603\lambda}{\mathrm{Sin}\delta_6} \quad \text{(C-5)}$$

Equations 3.3.3-1 and 3.3.3-2 in Section 3 are used in choosing the **effective hydrophone diameter**, d_e. Table C-1 gives d_e dimensions (in mm) for z/d_e ratios of from 2 to 10 and **center frequencies** from 1 to 10 MHz.

Table C-1
EFFECTIVE HYDROPHONE DIAMETER VALUES FROM EQUATION 3.3.3-1

		d_e in mm				
Frequency (Mhz)	**z/d_e =**	**2**	**4**	**6**	**8**	**10**
1.0		1.5	3.0	4.5	6.0	7.5
2.5		0.60	1.2	1.8	2.4	3.0
3.5		0.43	0.86	1.3	1.7	2.1
5.0		0.3	0.6	0.9	1.2	1.5
7.5		0.2	0.4	0.6	0.8	1.0
10		0.15	0.30	0.45	0.60	0.75

NOTE—A less conventional but still useful approach for finding directional response characteristics of hydrophones is based on broadband pulse rather than tone burst measurements (Harris and Shombert, 1985). In this method, a pulse spectrum obtained from a hydrophone oriented at two different angles with respect to the **beam axis** is used to calculate an effective radius.

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Appendix D
ACOUSTICAL OUTPUT QUANTITIES IN WATER AND IN TISSUE MODELS; DERATED VALUES

In this standard, it is specified that W, I_{SPTA}, I_{SPPA}, and p_r are to be measured in water. Rationale for this is presented in Appendix K. It is also required that calculations and procedural steps be carried out, leading to derated quantities, such as $p_{r.3}$, $I_{SPPA.3}$, and $I_{SPTA.3}$. (The **ultrasonic power**, W, is considered to be a property of the source which is unaffected by derating.) Derating procedures and calculations are discussed below.

D.1 TISSUE MODELS

In clinical practice, it would be desirable to know what intensities actually exist *in situ*, i.e., at points of interest in the patient's body during an ultrasound examination. Since it is not feasible to measure *in situ* values, they must be estimated on the basis of the best available information. The general process of estimating these values is called **derating** and the estimates are called derated values.

Such estimates are necessarily rough and uncertain because of the wide variations in attenuation of the acoustic beam that occur in different clinical situations. Adding to the problem is the fact that acoustical measurements in water may be influenced greatly by nonlinear propagation, while effects of nonlinearity in tissue are uncertain.

In one class of models for estimating *in situ* values, the body tissue is assumed to be homogeneous with an attenuation coefficient equal to an average of values measured in "soft tissue" (e.g., liver, spleen, brain) in laboratory experiments. (These homogeneous-tissue models are simple conceptually although—as will be seen—they present some difficulties in implementation.) One supposes that a source transducer transmits an ultrasound beam of frequency f in the z direction into either water or tissue, the output **power** being the same for both situations. A **derating factor** f at any point in the medium is then defined as follows:

$$\textbf{derated intensity} = \phi \times \textbf{intensity} \text{ in water} \qquad \text{(D.1-1)}$$

For the **peak rarefactional pressure**, p_r, the corresponding relationship is:

$$\textbf{derated pressure} = \phi^{0.5} \times p_r \text{ in water} \qquad \text{(D.1-2)}$$

The following equation has been used (CDRH, 1985) to calculate the factor f for a specific homogeneous-tissue model:

$$\phi = e^{-0.23 \times 0.3 \times f \times z} = e^{-0.069fz} \qquad \text{(D.1-3)}$$

where 0.23 is the conversion factor from decibels to nepers, 0.3 is the assumed tissue attenuation coefficient of 0.3 dB/cm–MHz, f is the ultrasonic frequency in MHz and z is the distance (in cm) of propagation through the attenuating medium. Suppose, for example, that f is 3 MHz and that an **intensity** of 120 mW/cm^2 is produced in water at a propagation distance z of 5 cm. From Equation D.1-3 we find that ϕ is 0.355; hence (by D.1-1) the corresponding **derated intensity** is:

$$0.355 \times 120 = 43 \text{ mW/cm}^2. \qquad \text{(D.1-4)}$$

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Even for a homogeneous-medium soft-tissue model, possibilities for error exist because of uncertainties in the attenuation coefficient for tissue. Another expression which has been used for ϕ, based on the value of the attenuation coefficient of 0.435 dB/cm–MHz (NCRP, 1983), is:

$$\phi = e^{-0.1fz} \qquad \text{(D.1-5)}$$

Here, f and z have the same meanings as in D.1-3. As expected, for given values of f and z, D.1-5 leads to smaller values of f (and, hence, smaller values of the *in situ* **intensity** for a given value of the **intensity** in water) than does D.1-3, that is, 27 mW/cm^2 under the same conditions as that of D.1-4.

Of course, tissue is not really homogeneous; an ultrasound beam passes through media of differing acoustical properties as it propagates through the human body. Primary features of a given type of clinical situation can be taken into account by using a model specific to the situation.

For fetal scanning, a "worst-case" model has been proposed (NCRP, 1983; Carson, 1988) in which the medium between the source and the fetus consists of several parallel layers. One of the layers is composed of liquid (urine in the bladder) in which the acoustic attenuation is assumed negligible; the thickness of this layer varies from patient to patient. The other layers cause a total attenuation that does not vary greatly between patients and, for simplicity, is assumed to be the same for all. For different patients, the **focal length** used will depend on the thickness (say, L) of the liquid layer but the total attenuation is assumed independent of L. For this model the factor ϕ does not vary with distance z and, instead of D.1-3 or D.1-5, we have:

$$\phi = e^{-0.23 \times 0.75 \times f} = e^{-0.17f} \qquad \text{(D.1-6)}$$

Equation D.1-6 has been proposed specifically for fetal scanning during the second trimester (Carson and Rubin, 1988). It may be noted that values of ϕ from D.1-6 are the same as those from D.1-5 when z = 1.7 cm. (This agrees with estimates of a minimum value for the total thickness of solid-tissue layers in recent studies by Carson and Rubin (1989)). For the same situation considered above, where the frequency is 3 MHz and the **intensity** in water at z = 5 cm is 120 mW/cm^2, one obtains 0.60 for ϕ and 72 mW/cm^2 for the **derated intensity**.

If the model proposed by D.1-6 were used, the labeling quantities could be designated by the subscript addition ".F7" (for an assumed fixed attenuation of 0.75 dB/MHz) as, for example, $I_{SPTA.F7}$.

In general, the acoustical field in the body is complicated and cannot be related to the field in water by any existing simple model. The velocity of sound and the density vary along all three coordinates; this causes refraction and reflection of the ultrasound beam and, consequently, changes in spatial patterns of the **acoustic pressure** and **intensity**. Shadowing and diffraction caused by structures produce further nonuniformity in the acoustic field.

Another important complication in relating acoustical parameters measured in water to the values these parameters have in a patient's body arises from the distortion associated with nonlinear propagation. As explained in Appendix B, nonlinear propagation affects the shape of the **waveform** and, correspondingly, its frequency content; the extent of the distortion depends on acoustical properties of the medium as well as on the **intensity** level of the ultrasound beam. Because most tissues are much more highly absorbing than water, **intensity** levels (for a given source level) are correspondingly lower, and the distortion is typically much less in tissue than water. Since the expressions for ϕ in D.1-3, D.1-5, and D.1-6 are based on the assumption of linearity, they do not apply when the water values are influenced by nonlinear propagation.

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In spite of the difficulties discussed above, it is useful to choose a model whose acoustical properties roughly approximate those of body tissues. Although crude, the model has been found to provide a meaningful basis for comparing different exposures at a particular biological site.

D.2 DETERMINATION OF DERATED QUANTITIES WHEN A HOMOGENEOUS-TISSUE MODEL IS USED

The procedures required for determining the derated quantities required for labeling depend on the tissue model selected. For a homogeneous-tissue model, the derating procedures are described in Section 5. The derating calculations for any model are based on D.1-1 and D.1-2; for the illustrative procedures described in Section 5, the **derating factor** f is given by D.1-3. The latter equation comes from an assumption that the amplitude attenuation coefficient is 0.3 dB/cm–MHz (equivalent to 0.0345 np/cm–MHz). The symbols $p_{r.3}$, $I_{SPTA.3}$, and $I_{SPPA.3}$ were chosen to serve as reminders of this assumption. Equations D.1-1, D.1-2, and D.1-3 (with f equated to the **center frequency**, f_c) are equivalent to the derating expressions specified in Sections 5.4.8, 5.4.10, 5.4.19, and 5.4.21.

A complication arises when using the homogeneous-tissue model since attenuation not only reduces the acoustic **intensity** and pressure, but also changes their spatial distributions. An example, obtained from computations, is shown in Fig. D-1. In these plots, the ordinates give the **intensity** (scaled to a maximum of unity) which, for definiteness, is chosen to be the **pulse average intensity**. The **intensity** is plotted versus distance for a pulsed focused beam along the axis of a spherical curved source of diameter 1 cm, frequency 5 MHz, and radius of curvature 4.2 cm. (These results are based on linear theory, such as that discussed for CW focused beams by Kossoff (1979).) It is assumed that the pulsing produces a spectral **intensity** distribution given by $\exp(-x^2/2)$, where x is equal to (f-5)/2. The solid (upper) curve applies when the propagation medium is water, in which the attenuation is assumed negligible. For the dotted (lower) curve the ordinate is the **derated intensity**, calculated with f given by D.1-3 (with $f=f_c$); since f_c is 5 MHz one obtains:

$$\phi = \exp^{-0.345z} \qquad \text{(D.2-1)}$$

For example, at z = 3.0 cm, the ordinate of the upper curve is 0.75, the factor d is 0.355 and the corresponding ordinate of the lower curve is 0.267.

In the upper curve, the peak occurs at z_m; this **intensity** peak is the **spatial peak pulse average intensity** I_{SPPA}. Comparing the lower curve with the upper one, it is seen that a peak occurs here also, the derated **spatial peak pulse average intensity** $I_{SPPA.3}$. However, the latter peak occurs at a value of z less than z_m. Furthermore, $I_{SPPA.3}$ is greater than I, the **derated intensity** $\phi I_{SPPA.3}$ at z_m. Specifically, a calculation shows that $I_{SPPA.3}/I$ is equal to (0.304/0.289), i.e., 1.05 in Figure D-1. Thus, if $I_{SPPA.3}$ were to be approximated as ϕI_{SPPA}, the value determined would be too small by 5 percent. (Even when the error is small, as in this example, the procedure in Section 5.4.8 should be followed.)

Figure D-1 applies to the field of a "piston-type" transducer, all of whose surface elements vibrate with equal amplitude and phase. In modern instruments, annular arrays are often used, whose elements are concentric rings which can be driven independently. Filipczynski and Etienne (1973) have discussed the acoustic field of a focused annular-array transducer for which the surface vibration amplitude decreases with distance from its center according to a Gaussian function.

In Figure D-2, the plots are similar to those in Figure D-1, but are for a focused pulsed annular-array transducer. Its radius of curvature is 6 cm and its **center frequency** is 5 MHz; driven in a pulsed mode, its spectral distribution is assumed to be Gaussian as for Figure D-1, but narrower, the quantity x being (f5)/1.25. Its ring elements are so driven that the amplitude at a distance r (in centimeters) from the center is proportional to $\exp-(r^2/0.16)$.

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Examining Figure D-2, we see that the lower curve, for the **derated intensity**, is very different from the upper one in that the peak is reduced and is very broad. Here, the ratio $I_{SPTA.3}/I$ is 1.19, larger than in Figure D-1; for this situation the procedure specified in Section 5.4.8 will clearly yield a more accurate determination of $I_{SPPA.3}$.

In general, weighted aperture transducers have extended depths-of-field which can exaggerate axial peak shifts under *in situ* conditions.

In still other situations, such as rectangular apertures, there may be multiple peaks along the axis, such that a peak which is of secondary magnitude in water becomes the primary peak after derating, Szabo et al. (1988). A form of the procedure in Section 5.4.8 is then required in order to locate the highest of the derated peaks.

D.3 CALCULATION OF DERATED QUANTITIES USING A FIXED-ATTENUATION MODEL

In the "worst-case" model, which has been proposed for applications to fetal scanning, the **derating factor** is given by D.1-6, i.e., by $e^{-0.17f}$. For fixed-attenuation models of this kind, the procedures for determining derated quantities are much simpler than for homogeneous-tissue models. This may be seen by considering Figures D-1 and D-2, which show water-values (upper curve) and derated values (lower curve) of the pulse-average **intensity** plotted versus position z. Since a z-dependent expression for f was used in calculations for the lower curves, the peaks occur at different positions than for the upper curves, as was noted earlier. However, for a fixed-attenuation model, f does not vary with z; hence the spatial peak of the derated quantity occurs at the same position as the spatial peak of the corresponding water value. For the specific model represented by D.1-6, and for the frequency (5 MHz) to which Fig. D-1 and Fig. D-2 apply, the **derating factor** is given by:

$$\phi = e^{-0.85} = 0.43 \qquad \text{(D.3-1)}$$

If a third curve were added to each of Figs. D-1 and D-2, showing the pulse-average **intensity** derated according to Eq. D.1-6, it would be identical to the upper curve except that all ordinates would be reduced by the factor 0.43. In particular, $I_{SPPA.F7}$ would be equal to 0.43 I_{SPPA} and the two peaks would occur at the same position in each figure. In addition, $I_{SPTA.F7}$ would be equal to 0.43 I_{SPTA} at the same frequency (5 MHz) and, again, the two peaks would occur at the same position. Since $\phi^{0.5}$ is 0.66 in this example, the derated compressional peak $p_{r.F7}$ is equal to 0.66 p_r.

Other simplifications in procedures when using a fixed-attenuation model come from the fact that the **operating conditions** for the derated labeling quantities are the same as those for the corresponding quantities measured in water.

It is seen from the examples in Figures D-1 and D-2 (and many others) that the derated quantities are lower than the corresponding water values. This reflects the fact that expected values of acoustical pressures and intensities in the patient's body, i.e., *in situ* values, are lower than the values measured in water. It should be realized, however, that the derated quantities are, by no means, to be considered as true *in situ* values. While the latter may often be closer to the (calculated) derated values than to the measured values in water, the difference may be small, and the opposite may sometimes be true. (The latter possibilities would be realized at the higher ranges of f and z if the derated quantities were calculated from D.1-3 or D.1-5, for clinical situations that are better represented by D.1-6. For example, suppose D.1-6 gives the correct result for an application where f is 5 MHz and z is 7 cm. For these conditions, ϕ is 0.30 from D.1-6, 0.089 from D.1-3, and 0.030 from D.1-5. Then the water values of **intensity** and **acoustic pressure** are 5.2 dB too high, while the derated value from D.1-3 is 5.3 dB too low and that from D.1-5 is 10 dB too low.) In general, the actual *in situ* levels will usually fall far outside the 95 percent confidence limits for either the measured or the derated quantities.

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It is believed that, to informed users, the availability of both the measured and the derated quantities will be found helpful.

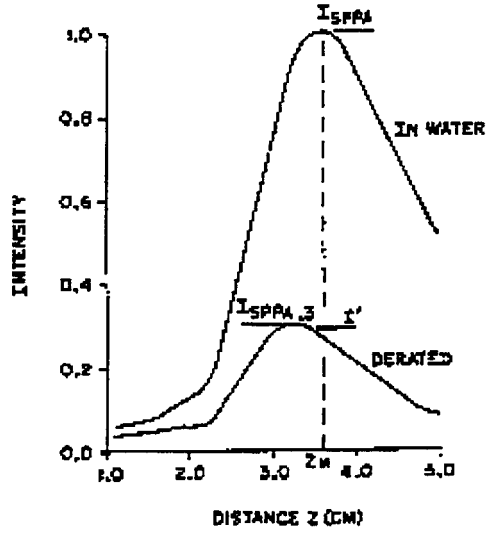


Figure D-1
PULSE-AVERAGE INTENSITY VERSUS DISTANCE FROM A SPHERICALLY FOCUSED PULSED TRANSDUCER

Center frequency 5 mhz; source diameter 1 cm; radius of curvature 4.2 cm.

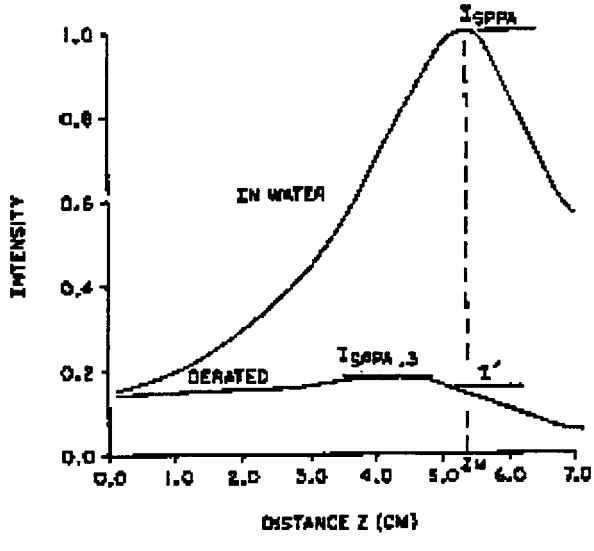


Figure D-2
PULSE-AVERAGE INTENSITY VERSUS DISTANCE FROM A GAUSSIAN FOCUSED PULSED TRANSDUCER

Center frequency 5 MHz; radius of curvature 6 cm.

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Appendix E
WATER DEGASSING PROCEDURE

Obtaining large volumes of degassed water involves the use of a centrifugal pump and a standard 2000 watt circulation heater. The pump and circulation heater are connected in series with the heater connected on the outward flow from the pump. The inward flow side of the pump is connected with very strong tubing to the lowest portion of the measurement tank. On the far side of the heater, a comparably strong tubing is connected to the topmost portion of the measurement tank just immediately below the normal water level. The length of the tube from the water tank to the inward flow side of the pump should be approximately six feet and the tube length returning the water from the heater to the tank also should be approximately six feet.

The measurement tank is filled with tap water that has passed through a deionization process by an ion exchange resin. With the measurement tank filled with water, the pump and heater are turned on. The water degassing process may take upwards of three hours from the initial filling of water. The degassing process occurs by virtue of the high speed, high-volume pump pulling the water from the measurement tank in such a way that the water within the tube between the measurement tank and the inflow to the pump is at an extremely low pressure. Within this tube, outgassing of water generally occurs. The water passes through the pump and through the heater and returns at the uppermost portion of the water level within the tank.

This arrangement allows for the control of the water temperature with the circulation heater. The continuous flow of water through the pump heater system maintains adequate degassing. Fresh water can be added to the system at any time. In general, the water should be completely replaced once a week.

The oxygen content of freshly degassed water should be approximately 1 ppm or less. This can be checked conveniently by using a calorimetric technique. As gas content increases, it is possible that microbubbles could form on the hydrophone and source surfaces, as well as radiation force targets, thus perturbing the ultrasonic field and measurements. Although little effect of increasing gas content on hydrophone measurements in a pulsed field has been reported (Harris, 1988), it still would be prudent to keep the dissolved gas concentration as low as practical (< 5–8 ppm O_2), and the use of wetting agents may be advisable as well. (Note that if for any reason **ultrasonic powers** of greater than 10 watts are being measured, the oxygen concentration should be kept below 4 ppm.)

One simple way to extend the time over which a water bath remains degassed is to place an air barrier on the water surface (e.g., kitchen wrap or hollow plastic spheres).

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Appendix F
RATIONALE FOR THE MEASUREMENT OF SELECTED PARAMETERS

In this standard, certain acoustic information is specified for measurement on diagnostic ultrasound equipment. This information consists of values for selected acoustic parameters, chosen for their relevance to performance and safety, or a combination of safety and performance. For example, the quantities frequency, **pulse duration**, and source diameter are important primarily for their relevance to achievable resolution, but also to expected achievable intensities in various anatomical locations. At the other extreme, "acoustic **intensity**" is most critical in determining penetration (i.e., the ability to obtain signals from deep-lying regions in a patient's body). The potential for adverse effects from the ultrasound also depends on the above parameters, as well as on others. In this section, each of the labeling parameters is taken up and its importance to safety and/or efficacy discussed.

F.1 ACOUSTIC POWER (W)

During an ultrasound examination, virtually all of the acoustic energy generated by the source is transmitted into the patient's body and is there converted into heat. Hence, the thermal energy produced in the patient's body during an exposure of duration t is equal to Wt. (If W is 0.1 watts and t is 20 seconds, the heat produced is 2 joules or 0.48 calories.) The temperature pattern produced will depend on how the heat is distributed, on blood perfusion, and on the thermal properties of the tissue.

F.2 SPATIAL PEAK TEMPORAL AVERAGE INTENSITY (I_{SPTA})

Knowing the water value of the **spatial peak temporal average intensity**, one can estimate the highest value of the **temporal average intensity** in tissue, i.e., the *in situ* I_{SPTA} (see Appendix D). This quantity is important to performance as well as safety because (1) it relates to performance since the time averaged acoustic **power** scattered by body structures of interest during an ultrasound examination is proportional to the local **intensity**. It is this scattered **power** that carries the desired diagnostic information; it must be high enough to yield a satisfactory signal/noise ratio; and (2) the *in situ* I_{SPTA} is important as a critical factor in determining whether bioeffects are produced. This is true whether the mechanism is thermal or nonthermal.

F.3 SPATIAL PEAK PULSE AVERAGE INTENSITY (I_{SPPA})

Knowing the water value of the **spatial peak pulse average intensity**, one can estimate the *in situ* I_{SPPA}. This quantity is important to performance as well as safety because (1) it relates to performance since the acoustic **power** scattered by a body structure of interest during a pulse is proportioned to the local I_{SPPA}. This **power** multiplied by the **pulse duration** gives the acoustic energy of an echo; and (2) its relevance to safety is primarily in its importance to non-thermal effects.

F.4 PEAK RAREFACTIONAL PRESSURE (p_r)

This quantity probably has essentially the same significance for performance as does the I_{SPPA}, but has been found to be much better than the latter as an indicator for cavitation (Ayme' et al, 1987). Comparison of I_{SPPA} and p_r can give some indication of the pulse shape. Furthermore, the units of pressure may be more familiar to many scientists involved in generation and bioeffects of cavitation.

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Associated quantities:

center frequency: Affects the resolution, the penetration depth, the absorption coefficient (and hence, the possibility of thermal bioeffects), and other aspects of performance and safety.

pulse duration: Affects the axial resolution and is proportional to the energy scattered in a pulse; it is important in determining the likelihood of cavitation.

entrance beam dimensions: Relevant to safety in that the **power** W divided by the entrance beam area gives the **spatial average temporal average intensity** in the entrance region.

focal length: Important for performance and safety as indication of position where I_{SPTA}, I_{SPPA}, and p_r apply.

focal depth and cross-sectional dimensions: Important to performance and safety as dimensions and locations of regions to which I_{SPTA}, I_{SPPA}, and p_r apply. In particular, the focal cross-sectional dimensions are critical quantities in recent statements and conclusions relative to safety. (AIUM, 1988.)

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Appendix G
DETERMINATION OF CONTROL SETTINGS RESULTING IN INTENSITY AND PRESSURE GLOBAL MAXIMA

Guidance is provided here for determining which diagnostic system **control settings** will result in **global maximum** values of **intensity** or pressure and where the maxima are likely to occur. Predictions of these maxima require a priori knowledge of the characteristics and operation of the system to be tested. More detailed information about the approach discussed here can be found in Szabo et al., 1988.

For any combination of switch settings that affects acoustic output, there are several parameters associated with each signal or unique **waveform** type (Doppler, **M-mode**, etc.): acoustic line location; axial focusing gain, FG; **pulse repetition frequency**, PRF; **pulse duration**, PD; an electroacoustic conversion constant, E_t; and the voltage applied to the transducer, V. The I_{SPPA} along an acoustic line or axis z can be expressed as:

$$I_{SPPA}(z) = FG_w(z)E_tV^2 \qquad \text{(G-1)}$$

where focusing gain in water, FG_w, is used here as the ratio of I_{SPTA} of one signal type at point z to average **intensity** (**ultrasonic power** divided by the area of the transducer) on the surface of the transducer. Focusing gain can be determined either by measurement or by simulation. The constant E_t is a measure of electroacoustic conversion and aperture weighting for the **waveform** type under examination. Because only the relative ranking of switch setting combinations is important, E_t does not have to be determined when comparing output levels for different combinations for the same transducer configuration.

To find the **control settings** producing **global maximum** value of I_{SPPA}, usually (unless E_t changes) the largest value of the product of V^2 and FG needs to be determined. Note that only the peak value of FG located at position $z = z_{pk}$ is used to determine maximum I_{SPPA} in Eq. H-1. As a rule of thumb, FG is inversely proportional to the geometrical **focal length**, so the smaller **focal lengths** usually correspond to the highest focusing gain (assuming the same aperture size).

If the maximum value of derated I_{SPPA} is sought, a different relationship is appropriate:

$$I_{SPPA}(z) = \left[FG_W(z)e^{-.23af_cz}\right] E_tV^2 \qquad \text{(G-2)}$$

where a is the derating attenuation in dB/(MHz–cm), and f_c is transducer **center frequency**. For example, for a = 0.3 dB/MHz–cm and f_c = 5 MHz, the location of the maximum derated I_{SPPA} will be lower in magnitude and will occur at a peak location which is closer to the transducer than the I_{SPPA} maximum in water.

Predicting the **global maxima** of I_{SPTA} is more involved because a number, N_s, of signal types (each designated by "j") and their timing are required:

$$I_{SPTA}(z) = \sum_{j=1}^{N_S} I_{SPPAj}\ PRF_j\ PD_j \qquad \text{(G-3)}$$

I_{SPPAj} can be determined for either water or a derated case from the previous equations. Note that the location of the I_{SPTA} maximum is usually different than the I_{SPPA} maximum because of its dependency on several signals and their timing.

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In summary, *a priori* knowledge of ultrasound system parameters can be used to predict which system switch setting combinations and corresponding locations produce the highest levels of **intensity**. Because linearity was assumed to hold for the equations (as well as an **intensity** proportional to pressure squared), the actual **global maxima** can differ from the predictions because of nonlinear effects (see Appendix B) and system variations. In practice, a number of the highest ranked switch setting combinations likely to produce maxima are used as the starting points to begin experimental searches for the actual **global maxima**.

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Appendix H
HYDROPHONE CALIBRATION BY PLANAR SCANNING TECHNIQUE

H.1 INTRODUCTION

The planar scanning **hydrophone calibration** technique involves scanning the **far field** of a source transducer with known **ultrasonic power** using the hydrophone to be calibrated (Jones et al, 1981; Herman and Harris, 1982; IEC, 1991a; Corbett, 1988). The **ultrasonic power** of the source transducer is measured with a radiation force balance (radiometer), as described in Section 3.6. This **ultrasonic power**, W_r, is equated to the **power**, W_h, found from the hydrophone scanning. W_h is a function of the **end-of-cable loaded sensitivity**, $M_L(f)$, so by setting $W_h = W_r$, $M_L(f)$ can be found.

Ideally, the **ultrasonic power**, W_r, of an ultrasound source placed in a water tank could be determined if the **acoustic pressure** and particle velocity were measured at every point on a large sphere enclosing the source transducer. Since such a measurement is impractical, several simplifying assumptions are made to reduce the effort involved. First, because a hydrophone is used to make each measurement at a point, only **acoustic pressure** is measured. If the hydrophone is placed in the **far field** of the source, then the particle velocity is nearly in phase with the **acoustic pressure**, and the instantaneous ultrasonic **intensity** is proportional to the square of the instantaneous **acoustic pressure**.

A second important simplification is to recognize that the source transducer has a well-behaved directivity so that significant energy passes through only a small region of the encompassing sphere. The size of this region for a given degree of error can be calculated for transducers of known directivity. A third simplification is that instead of measuring each point in the selected region, assumptions about beam geometry are made, and the result for the total region is estimated mathematically.

This Appendix is divided into five sections: a derivation of the calibration equation; a description of the source transducers to be used; a description of the acoustic field measurements to be performed with the hydrophone (beam profiles and time **waveforms**); a correction for water attenuation; and a description of simplified scanning geometries. In all cases, it will be assumed that the hydrophone to be calibrated meets the requirements set forth in Section 3.

H.2 DERIVATION OF CALIBRATION EQUATION

Calibration of the hydrophone is accomplished by recognizing that under specified conditions, the **ultrasonic power** from the source transducer is equal to a two-dimensional space integral of **intensity** computed from the hydrophone measurements on the source transducer. The **power** measured by using a hydrophone is equated to that measured using a force balance radiometer, to arrive at a value for the **end-of-cable loaded sensitivity** $M_L(f)$, of the hydrophone.

For cases in which the **acoustic pressure** and particle velocity in the acoustic field being measured are in phase, such as is approximately true in the **far field** of a source transducer, the **acoustic pressure** and velocity at a point P in space, are related as follows:

$$v\left(\tilde{P},t\right)=\frac{p\left(\tilde{P},t\right)}{\rho c} \qquad \text{(H.2-1)}$$

where v is the particle velocity (m/s), ρ is the density (kg/m^3), and c is the speed of sound (m/s) in the material through which the wave is propagating. The pressure units are Pascals (Pa).

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The **instantaneous intensity** is defined as the product of instantaneous **acoustic pressure** and particle velocity, in the direction of the particle velocity. Specifically, the instantaneous **intensity** $i(\tilde{P},t)$ in a plane-wave field is given by:

$$i(\tilde{P},t) = p(\tilde{P},t) \times v(\tilde{P},t) = \frac{p^2(\tilde{P},t)}{\rho c} \qquad \text{(H.2-2)}$$

The **temporal average intensity** $I_{TA}(\tilde{P})$, in the plane-wave field is defined as follows:

$$I_{TA}(\tilde{P}) = \frac{1}{T}\int_0^T i(\tilde{P},t)dt = \frac{1}{T}\int_0^T \frac{p^2(\tilde{P},t)}{\rho\delta\tau c}dt \qquad [W/cm^2] \qquad \text{(H.2-3)}$$

where T is a time interval over which $p(\tilde{P},t)$ repeats itself. For a CW source, T is any integral multiple of (1/f); for a repetitively pulsed source, T is any integral multiple of (1/PRF). Using the expression for the **end-of-cable loaded sensitivity** of the hydrophone, $M_L(f)$(V/Pa), the **temporal average intensity** becomes:

$$I_{TA}(\tilde{P}) = \frac{1}{\rho c M_L{}^2(f_c)} h(\tilde{P}) \qquad [W/cm^2] \qquad \text{(H.2.4)}$$

where

$$h(\tilde{P}) = \frac{1}{T}\int_0^T V^2(\tilde{P},t)dt \qquad [Volts^2] \qquad \text{(H.2-5)}$$

and V, the hydrophone output voltage (volts), is a narrow band signal with **center frequency** f_c. Note that $h(\tilde{P})$ is equivalent to a mean squared voltage at point $\tilde{P}$. Since $I_{TA}(\tilde{P})$ is the time-averaged **power** passing outward from the source per unit area, the total time-averaged **power** W_h is found by the integral over the surface S normal to the **beam axis** of the source, in the **far field**, containing the **intensity** flux:

$$W_h = \iint_S I_{TA}(\tilde{P})\,ds = \frac{1}{\rho c M_L{}^2(f_c)} H_S[h(\tilde{P})] \qquad [Watts] \qquad \text{(H.2-6)}$$

where

$$H_S[h(\tilde{P})] = \iint_S h(\tilde{P})ds \qquad [Volts^2 - m^2] \qquad \text{(H.2-7)}$$

The **power** W_h is equated to the **ultrasonic power** W_r of the same source transducer, as measured on a force balance and corrected for water attenuation for the planar scanning path length:

$$W_r = W_h \qquad \text{(H.2-8)}$$

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$$= \frac{H_S\left[h(\tilde{P})\right]}{\rho c M_L^{\,2}(f_c)} \quad \text{[Watts]} \qquad \text{(H.2-9)}$$

Solving for $M_L^{\,2}(f_c)$:

$$M_L(f_c) = \left[\frac{H_S\left[h(\tilde{P})\right]}{W_r \rho c}\right]^{1/2} \quad \text{[Volts/Pascal]} \qquad \text{(H.2-10)}$$

H.3 POWER MEASUREMENTS ON SOURCE TRANSDUCER

For planar scanning, a source transducer whose **ultrasonic power** output has been calibrated at one or more frequencies is required. A pure, stable sinusoidal excitation source is recommended to drive the source transducer in a tone burst mode. If the source transducer has been calibrated under continuous wave excitation, then the pulsed or tone burst source must be adjusted to give the same amplitude drive level as in the continuous wave case. When a source transducer of the type provided by NIST (Fick et al., 1984) is used, the source should be placed in water at an angle to any planar reflectors (or hydrophones) or any tank walls, and the CW excitation should be adjusted to the calibrated level. The peak RF excitation voltage level is noted, so that when the signal source is operated in a tone burst mode, its level is adjusted to be equivalent.

The source transducer and receiving hydrophone are placed in a water tank and the source is driven with a narrow-band, quasi-CW (10–15 cycle) burst at the calibration frequency of interest, at a repetition frequency such that T = 1/PRF is greater than twice the propagation time to the hydrophone receiver. The source also may be driven in a CW mode for the calibration. Precautions must be taken to avoid standing wave effects, especially when using membrane hydrophones in CW fields. There should be no distortion in the signal driving the source transducer (see, e.g., Fick et al., 1984). If possible the frequency spectrum of the transmitted burst should be checked by locating the hydrophone within 1–2 cm from the source and observing the output of the hydrophone on a spectrum analyzer. Harmonics must be at least 40 dB below the fundamental.

The **ultrasonic power** (W_r) of the source transducer is measured on a calibrated force balance. (See Section 4.4.3 for calibration of the force balance.) The pulser **waveform**, voltage, and PRF must remain exactly as configured above. For the NIST calibrated CW source, W_r is determined from the calibration of the source.

H.4 RECORDING OF TIME WAVEFORMS AND BEAM PROFILES

The calibrated source transducer and hydrophone are placed in the water tank. Prior to the planar scan, the source and hydrophone must be aligned and cleaned as described in Section 4.5.2. The scanning system and positioning device required to translate the hydrophone in the acoustic field must conform to that described in Section 3.5.3.

The **waveform** generated by the hydrophone must be recorded using an oscilloscope or digitizing system as specified in Section 3.5.4. To display a stationary pulsed time **waveform** on the oscilloscope, a trigger synchronous with the excitation of the source transducer must be provided.

After the source transducer and hydrophone have been aligned, $H_S\left[h(\tilde{P})\right]$ is evaluated by scanning over all points on the scan surface above the noise floor. All measurements to obtain beam profiles $h(\tilde{P})$ are performed at or beyond an axial distance of $S/\pi\lambda$ for a non-focused source, where S is the area of the

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active element and λ is the **wavelength** in water. The scanning plane is first **scanned** in a raster pattern to locate the point of maximum $h(\vec{P})$. The scan plane is then **scanned** either in a two-dimensional raster pattern, or using a simpler pattern consistent with the source geometry. For rectangular transducers, this simpler pattern consists of two orthogonal directions passing through the **beam axis**, and parallel to the sides of the source. For circular transducers, beam profiles can be taken along at least two orthogonal diameters. See discussion on "Simplified Scanning Geometries" later in this Appendix for further details.

Beam profiles are generated by evaluating $h(\vec{P})$ at each point in the acoustic field along the **scan line**. This integral can be evaluated in the most straightforward manner by digitizing the time **waveform** recorded by the hydrophone and performing a numerical integration using the trapezoidal rule as described at the end of this Appendix.

H.5 CORRECTION FOR WATER ATTENUATION

In practice, W_r, the **ultrasonic power** radiated by the source, must be corrected for the attenuation of the water over the separation distance R between the surface S and the source transducer. This correction is stated as:

$$W_r = W_r' e^{-2\alpha R} \qquad \text{(H.5-1)}$$

where W_r' is the unattenuated **ultrasonic power** (i.e., the **power** at the transducer face), and α is the pressure attenuation coefficient for water. α is a function of frequency and temperature, as shown in Figure H.1 (see Herman and Harris, 1982). At 24°C, $\alpha = 2.2 \times 10^{-4} f^2$ $cm^{-1}MHz^{-2}$, where f is the frequency in MHz.

H.6 SIMPLIFIED SCANNING GEOMETRIES

In general, the surface integral in Equation H.2.1-7 is evaluated using a two dimensional raster scan. However, if the source transducer has either circular or rectangular geometry, it is possible to use a simplified scanning pattern by making assumptions about beam symmetry.

H.6.1 Circular Source

For cylindrically symmetric sources, either a scan along an arc (spherical scanning) or a line (cylindrical scanning) can be used. For spherical scanning, arcs are used to estimate **power** flux through a spherical cap surface. For cylindrical scanning, **scan lines** are used in the same way for estimating flux through a disc surface in a plane parallel to the surface of the source transducer.

A source transducer with cylindrical symmetry and a spherical scanning geometry for a hydrophone are shown in Figure H-2. Spherical scanning consists of individual scans at a constant radial distance, R, from the center of the source transducer. In each scan, starting from a point, P_s, the hydrophone is moved in small angular increments over θ to an end point P_e, and the hydrophone mean square voltage is recorded at each point, defining a data array, h(R,θ). This array can be recognized as the beam profile of the source transducer at a constant radius R and at a constant angle $\phi = \phi_0$. Two or more scans at different angles φ (0 and 90 degrees, etc.) are used to estimate the **power** passing through a spherical cap generated by rotating the scan arc to form a surface of revolution. For each scan:

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$$M_L(f) = \left[\frac{\pi R^2}{\rho c W_r} \int_{\theta_{min}}^{\theta_{max}} \{h(R,\theta) - NF\} \sin\theta \, d\theta \right]^{\frac{1}{2}} \qquad \text{(H.6.1-1)}$$

where the extreme scan angles, θ_{min} and θ_{max}, are chosen to be where the hydrophone signal is in the noise floor, when NF is the mean square value of the noise floor. The results of several scans, as calculated by Eq. H.6.1-1, are averaged together to improve accuracy. Significant errors can occur if less than two orthogonal scans are made. The mean square value of the noise floor must be subtracted from each data point in the $h(R,\theta)$ array.

For cylindrical scanning, with reference to Figure H-2, the hydrophone is **scanned** along a straight line chord between the same end points as in the spherical case, at a constant distance Z_o from the plane of the source transducer. Here, the end points P_s and P_e can be expressed in terms of radial distance r, $Z = Z_o$, and $\phi = \phi_o$. The $M_L(f)$ equation for this scanning geometry is:

$$M_L(f) = \left[\frac{\pi}{\rho c W_r} \int_{r_{min}}^{r_{max}} \{h(r) - NF\} |r| dr \right]^{\frac{1}{2}} \qquad \text{(H.6.1-2)}$$

As before, several scans at different angles, ϕ, must be averaged together. A BASIC computer program using the trapezoidal rule for calculating $M_L(f)$ is given below.

H.6.2 Rectangular Source

For rectangular source transducers, the simplified expression for $M_L(f)$ is:

$$M_L(f) = \left[\frac{1}{\rho c W_r h(0,0)} \int_{x_{min}}^{x_{max}} h(x,0) dx \int_{y_{min}}^{y_{max}} h(0,y) dy \right]^{\frac{1}{2}} \qquad \text{(H.6.2-1)}$$

where the **beam axis** passes through the points x = y = 0, and where it is assumed that $h(x,y) = h(x,0)h(0,y)/h(0,0)$. This assumption comes from the fact that the theoretical directivity of a rectangular piston radiator has the form $[\sin(x)/x] \times [\sin(y)/y]$; that is, the product of two sinc functions. h(x,0) and h(0,y) are the beam profiles of the rectangular source along the x and y axes, respectively.

H.7 NUMERICAL EVALUATION OF INTEGRALS

A sample evaluation of $M_L(f)$ for cylindrical scanning of a circular source (Equation H.6.1-2) is given below:

The first operation involves generating an array of points, h(r), along four or more radii in the scan plane. h(r) at any given location is defined by H.2.1-5 as:

$$h(r) = \frac{1}{T} \int_0^T v^2(r,t) dt \qquad [\text{Volts}^2] \qquad \text{(H.7-1)}$$

where v(r,t) is the voltage **waveform** recorded by the hydrophone at location r as shown in Figure I-2. Equation H.7-1 can be evaluated numerically using the trapezoidal rule as follows:

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$$h(r) = \frac{1}{\Delta t * N}\sum_{i=2}^{N}\left[\frac{v_r^2(i) + v_r^2(i-1)}{2}\right]\Delta t$$
$$= \frac{1}{2N}\left[v_r^2(1) + v_r^2(N)\right] + \frac{1}{N}\sum_{i=2}^{N-1} v_r^2(i) \qquad \text{(H.7-2)}$$

where $T = N^*\Delta t$, Δt being the sampling interval, and $v_r(i)$ is the i_{th} point of an N-point array consisting of the time **waveform** as sampled by the hydrophone and **waveform** recorder at location r.

A BASIC program to evaluate Equation H.7-2 for a 1000 point array is given below:

```
10 HR = 0
20 N = 1000
30 For I = 2 to N-1
40 HR = HR + VR(I)^2
50 NEXT I
60 HR = (HR + 0.5*(VR(1)^2 + VR(N)^2))/N
70 END
```

where HR is the value of h(r) in Equation H.7-2 for the location r and VR(*) is the array containing the voltage **waveform**.

This process is completed at every point along a radius to generate an array of points h(r), which defines the beam profile. h(r) is evaluated along at least four radii and averaged.

Equation H.6.1-2 is then evaluated using the trapezoidal rule as follows:

$$M_L(f) = \left[\frac{2\pi(\Delta r)^2}{\rho c W_r}\sum_{i=1}^{N}\frac{ih(r_i) + (i-1)h(r_{i-1})}{2}\right]^{1/2}$$
$$= \left[\frac{2\pi(\Delta r)^2}{\rho c W_r}\left[\frac{1}{2}Nh(r_N) + \sum_{i=1}^{N-1} ih(r_i)\right]\right]^{1/2} \qquad \text{(H.7-3)}$$

where Δr is the distance between sample points along the beam profile, $r_i = i * \Delta r$ and $h(r_i)$ is the value of Equation H.7-2 evaluated at the point r_i. r_o is the point intersecting the **beam axis** and i=N is the value of i for which $h(r_N)$ first reaches the noise floor.

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A BASIC program to evaluate $M_L(f)$ in Equation H.7-3 is as follows:

```
10  ML = 0
20  FOR I = 1 TO N-1
30  ML = ML + I*H(I)
40  NEXT I
50  ML = ML + (N/2) * H(N)
60  ML = (ML * 2 * PI * (delta r)^2)/(rho * C * WR)
70  ML = ML^0.5
80  END
```

where $H(I) = h(r_i)$ from Equation H.7-2.

NOTE—H(1) is the first point sampled on the beam profile at distance r_{min} of the **beam axis**.

More information regarding the evaluation of the above formulas can be found in Harris, 1985.

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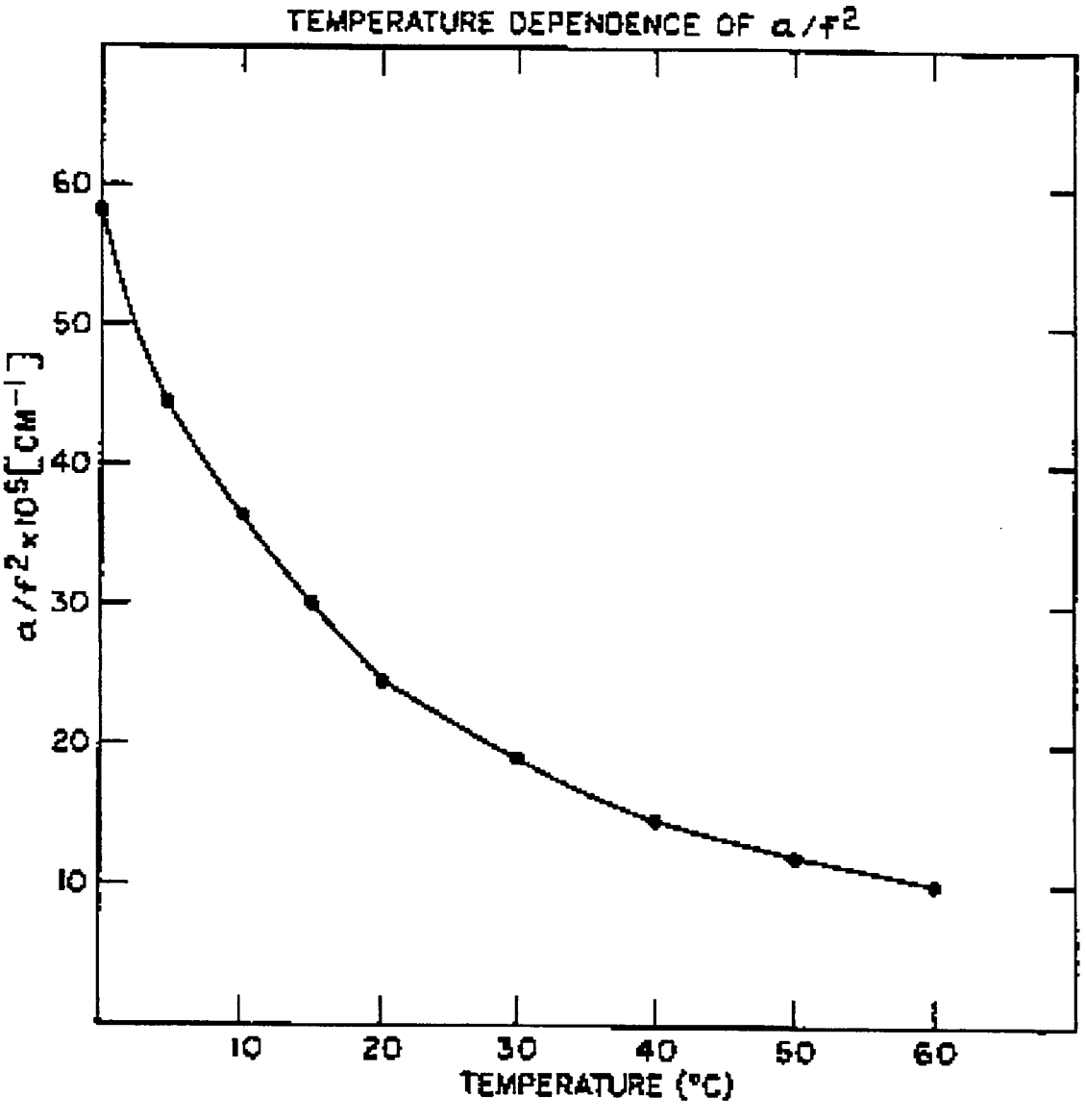


Figure H-1
TEMPERATURE DEPENDENCE OF THE ATTENUATION OF ULTRASOUND IN WATER, NORMALIZED TO f^2

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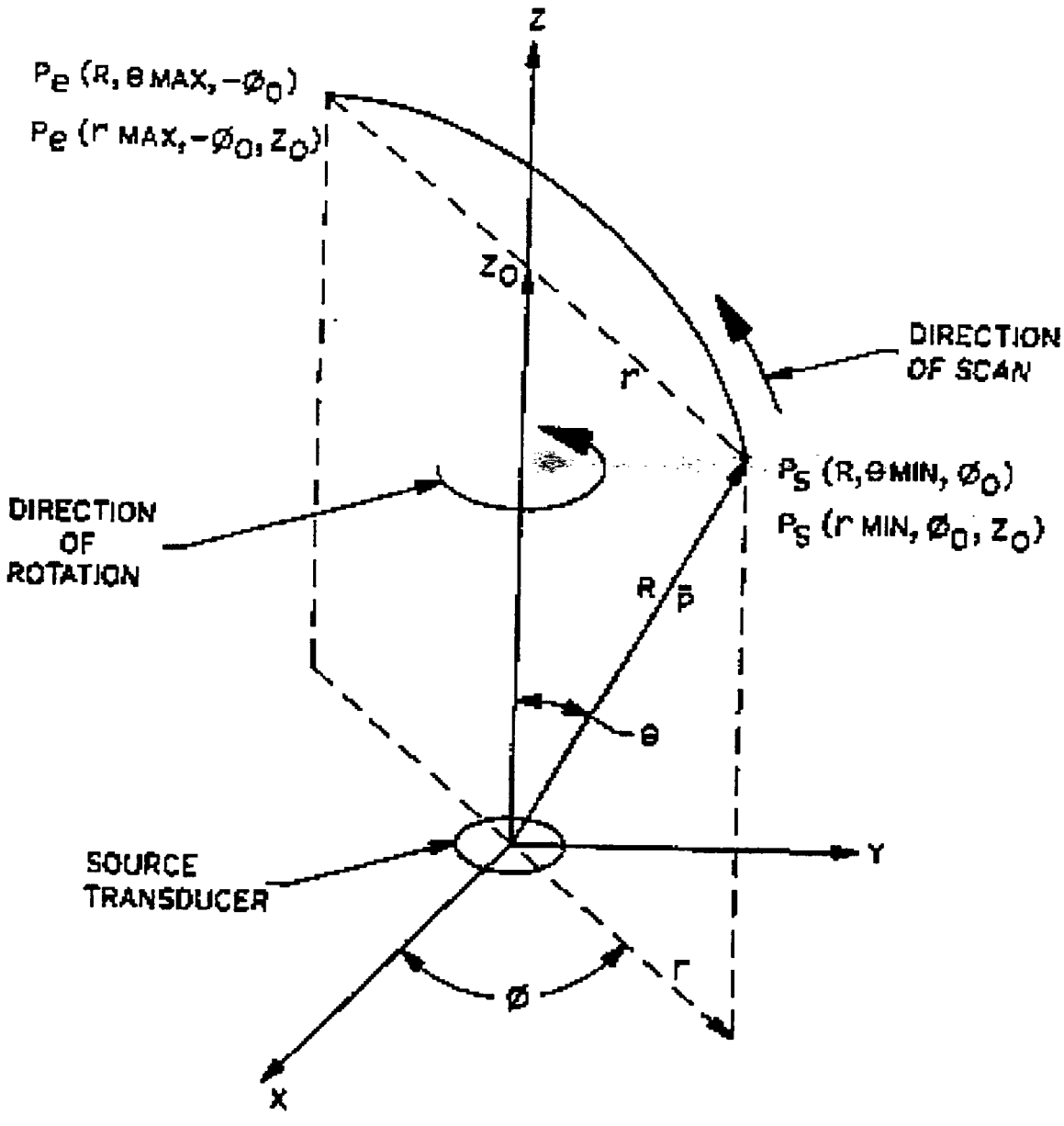


Figure H-2
SOURCE TRANSDUCER WITH CYLINDRICAL SYMMETRY AND A SPHERICAL SCANNING GEOMETRY FOR A HYDROPHONE

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Appendix I
CONSISTENCY CHECKS

As a check of the validity of the I_{SPTA} and I_{SPPA} values obtained from the hydrophone measurements, the following calculations can be made. These check calculations apply only to **discrete operating modes**, i.e., A-mode, **M-mode**, Doppler, or real-time imaging, and to simple combinations of real-time imaging and one of these three **non-autoscan** modes. If the measured values differ substantially from these calculations, the procedures, measurements, and calculations should be reviewed. (For more complicated **combined operating mode** cases, generalized check relationships can be found in Szabo et al., 1988.)

I.1 CHECK FOR I_{SPTA}

Scan Type	Check Calculation
Non-autoscan	$I_{SPTA} = 1.5\ (W)/(A)$
Autoscan with steerable A-mode, **M-mode**, or Doppler-mode	$I_{SPTA} = 1.5(W)(L)/(A)(M)$
Autoscan without steerable A-mode, **M-mode**, or Doppler-mode	$I_{SPTA} = [1.5(W)(SRF)/(A)(PRF)] \times [1 + (D_x)(M)/(SD)]$

where A, D_x, and SD are determined at the measurement distance R (see Figure I-1). If $(D_x)(M)(SD) >> 1$, then the above inequality becomes:

$$I_{SPTA} < 1.5(W)(D_X)/(A)(SD) \qquad (I\text{-}1)$$

where PRF has been taken to be the product of M and SRF.

I.2 CHECK FOR I_{SPPA}

$$I_{SPPA} < 1.5(W)/(A)(PD)(PRF) \qquad (I\text{-}2)$$

Symbols

W = **ultrasonic power**, mW.
A = **beam cross-sectional area** (-6 dB) for a single pulse (i.e., image line), cm^2 (see Figure 5-6).
L = number of acoustic pulses per image line at the location of the steerable A-mode, **M-mode**, and Doppler-mode line.
M = total number of acoustic pulses per image.
SRF = **scan repetition frequency**, images per second.
PRF = **pulse repetition frequency**, Hertz.
D_x = beam width (-6 dB) for a single pulse (i.e., image line), measured along a line normal to the **beam axis** and in the image plane, cm (see Figure I-1).
SD = width of scan in image plane; for sector scanners, SD = R (see Figure I-1).
PD = **pulse duration**, seconds.

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I.3 DISCUSSION

The rational for performing these simple checks is to identify gross procedural, measurement, or calculation inconsistencies. For example, if there were a significant error in hydrophone sensitivity at the time of measurement due to improper calibration or temporal instability, then the 1.5 W/A relationship should reveal this problem, assuming two things: (1) W is measured with a radiation force balance or obtained from a **reference source** calibration, and (2) measurement errors in determining W do not offset the error in hydrophone sensitivity. The offsetting situation in assumption (2) is unlikely. However, with respect to assumption (1), if W is found via planar scanning, then the I_{SPTA} = 1.5 W/A check value is less likely to uncover the error.

The **non-autoscan** check value for I_{SPTA} of 1.5 W/A is based on a roughly bell-shaped (Gaussian) **intensity** distribution and the other check values for I_{SPTA} and I_{SPPA} follow from this (actual values for several hypothetical and theoretical distributions are: Gaussian—1.39 W/A; Conical—1.69 W/A; $Sinc^2$—1.14 W/A; $Bessinc^2$ —1.23 W/A). While obviously not exact, these are reasonable approximations to use and if deviations of greater than roughly a factor of three are found (except for the I_{SPTA} inequality), then it should be verified that the difference is due to beam shapes rather than, for example, improper **hydrophone calibration**. That is, if the actual beam shape (obtained from a **pulse intensity integral** plot) were found to be quite "peaked," then 1.5 W/A could be much lower than the measured **non-autoscan** I_{SPTA}, and, conversely, if the actual beam shape (obtained from a **pulse intensity integral** plot) were "flat," then 1.5 W/A would be higher than the measured value. It also should be noted that when finite amplitude distortion is present in the pulse **waveform**, plotting the temporal peak hydrophone voltage instead of the **pulse intensity integral** can result in the area A being too small. This in turn can cause the check value to be higher than the measured value.

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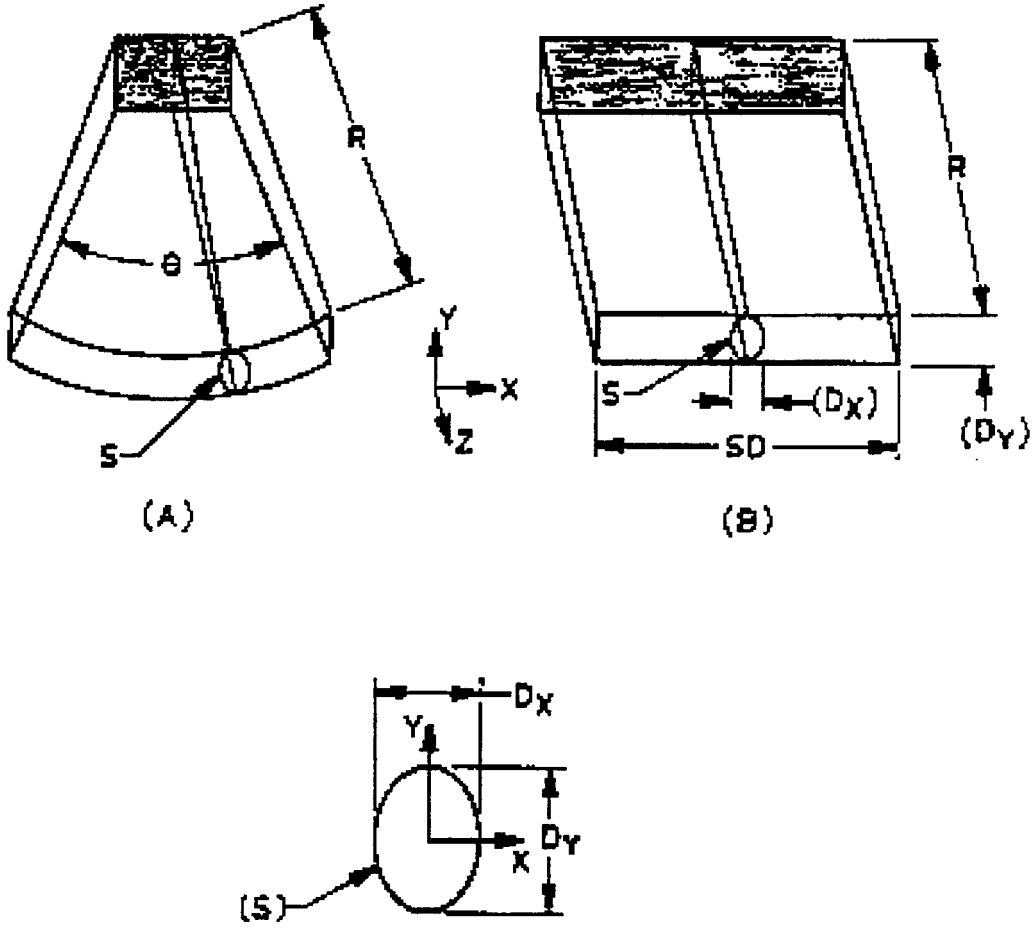


Figure I-1
DEPICTION OF MOVING BEAM GEOMETRY FOR (a) SECTOR IMAGE FORMAT AND (b) RECTILINEAR IMAGE FORMAT

The shaded regions represent the radiating surface of the source **transducer assembly**. The x-y plane is the measurement (e.g., focal) plane and the x-z plane is the image plane. The beam surface s, shown for one image line, has area A.

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Appendix J
MEASUREMENT OF I_{SPTA} FOR A COMBINED OPERATING MODE

To supplement Section 5, information is provided here for measurement of I_{SPTA} for a **combined operating mode**. If there are N_s types of **waveforms**, each associated with a **discrete operating mode**, then:

$$I_{SPTA} = \sum_{j=1}^{N_S} I_{SPPA_j} \; PRF_{mj} \; PD_j \; BOC_j = \sum_{j=1}^{N_S} I_{SPTA_j} \qquad \text{(J-1)}$$

where I_{SPPAj} is the I_{SPPA} of the jth signal, PRF_{mj} and PD_j are the local PRF or pulse density (the number of times a certain type of pulse passes along a line m through a point in space per second) and **pulse duration** of signal j, and BOC_j is the beam overlap correction factor of signal j.

The measurement consists of finding the signal which is the suspected dominant contributor to the overall I_{SPTA} and placing the hydrophone at the location of maximum I_{SPPAj}. For example, for a sector and M **combined mode** or a sector and Doppler **combined mode**, the **M-mode** and Doppler signals are principal contributors along one **scan line** direction.

If another **waveform** type is found on adjacent image lines, the contributions of all the lines to the measurement point may be seen on an oscilloscope by using a start of frame sync. Here, the display consists of a series of pulses (from the contribution of adjacent lines) that rise in amplitude to a maximum at the measurement point and decrease afterward. The individual line contributions usually can be obtained by synchronizing to the line and calculating the I_{SPPA}. If I_{SPPAj1} designates the maximum I_{SPPA} on hydrophone measurement line m, then the beam overlap factor for signal type j can be found by summing the I_{SPPAj}s of adjacent lines:

$$BOC_j = \sum_{n=1}^{N} \frac{I_{SPPA_{jn}}}{I_{SPPA_{j1}}} \qquad \text{(J-2)}$$

where n is a relative line index for lines offering significant contributions to the total ($\geq$ 10% of total).

In summary, if the signal type j is in one direction only, $BOC_j = 1$, otherwise the I_{SPPAj} is found from $I_{SPPAj} = BOC_j$, I_{SPPAj} obtained from J-2. If the dominant signal is spread over adjacent lines, the hydrophone can be moved along the line of interest until a true I_{SPTA} **global maximum** is located. As an alternative, an estimate of the beam overlap factor might be appropriate (CDRH, 1985).

As an example, data in Table J-1 is shown for a case with four signal modes. The overall result from J-1 is $I_{SPTA} = 252$ mW/cm^2. Note the method of assembling the data for the calculation is similar in form for both the water and derated in situ calculations. More information can be found in Szabo et.al., 1988.

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Table J-1
WATER VALUES AT I_{SPTA} MAXIMUM FOR A 2.5 MHZ PHASED ARRAY

Signal type	I_{SPPA} (W/cm^2)	PRF_{mj} (per sec)	PD_j (μs)	BOC_j
1	100	25	3.0	1.4
2	75	1000	3.0	1.0
3	150	350	0.3	1.0
4	150	10	0.3	1.4

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Appendix K
RATIONALE FOR MEASUREMENTS IN WATER

In this standard, it is specified that measurements are to be made on equipment operated under normal conditions, in water under free-field conditions. The choice of water as the measurement medium is based partly on its convenience. Water is available in large quantities; it can be distilled, filtered, and degassed if this is desired. Also, water's basic physical and chemical properties have been determined and can readily be found in handbooks or other literature.

Just as important is the consideration that although other models may be developed in the future, water is the best one presently available for clinical situations, at least for worst-case conditions. Thus, the specific acoustic impedance and speed of ultrasound propagation in water closely approximate those of soft body tissues and fluids that are of primary significance in diagnostic ultrasound. Furthermore, its attenuation coefficient, while much lower than those of liver, brain, and other soft body tissues, is representative of some of the important body fluids. As ultrasound passes into the body, much of its path can be through media, such as urine and amniotic fluid, in which the attenuation is low. Hence, if measurements were made in much more highly attenuating material, such as a liver-equivalent gel, they would not represent the highest possible **acoustic pressures** and intensities that might be encountered in the body.

It should be realized that **waveform** distortion caused by nonlinear propagation occurs to a greater extent in water than in most soft tissues. While the nonlinearity parameter in water is slightly less than in most soft tissues and considerably less than in fat, the increase in peak positive pressure (and the rise time of the pressure) due to nonlinear propagation is greater in water than in these tissues. This is because of the very low ultrasonic attenuation in water of the high-frequency harmonics associated with the positive pressure increase.

Overall, these properties of water relative to tissue make measurements of **acoustic pressures** and intensities in water represent a worst case, i.e., they yield significantly higher values than would measurements in body components other than least viscous body fluids.

Room temperature (24°C) is chosen for measurement convenience and reproducibility. However, the slightly low speed of sound in water at this temperature (1490 m/s) causes the transmitted beam to be focused beyond where it would be in a soft tissue with a speed of sound equal to the assumed average value of 1540 m/s.

Equipment is to be operated under conditions as similar as possible to those applied during clinical use. Free-field conditions are specified as being the most meaningful and the most readily reproduced in different laboratories.

There can be problems associated with measuring and reporting free-field measurements in water under normal **operating conditions**. While this standard requires that approach, or a demonstrated equivalence to it, it may be useful to be aware of the problems and the alternative methods that were considered in the drafting of this standard. Since ultrasound is attenuated less in water than in soft tissues, **acoustic pressures** and intensities measured in water are higher (sometimes, much higher) than would be produced by the same equipment *in situ*, i.e., in a patient's body. This will lead to confusion if, when acoustic output values are cited, the distinction is not made between measured "water values" and estimated *in situ* values. Particularly troublesome is the already mentioned fact that the **waveform** can be severely distorted when the attenuation is low. Increased demands are then made on the measurement technique because of the high-frequency content in the spectrum. Also, it may then be difficult to proceed from measurements in water to estimates of the **acoustic pressures** and intensities that would be

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produced *in situ* by the same equipment. Various proposals have been made for reducing these problems. Some of these are discussed briefly below. For a more extended discussion, see Carson, 1988.

a. Reduction of the transmitter voltage while measurements are carried out to reduce the acoustic output of the source so propagation occurs in water with distortion reduced or eliminated. Estimates would then be made of *in situ* **acoustic pressures** and intensities expected with the transmitter operating normally. (For an example of calculations that might be involved, taking into account nonlinear propagation in the tissue, see Bacon, 1987.) In pulsed-mode operation, this method applies only on the condition (not always satisfied) that the transient response of the source transducer to the reduced voltage is the same (except for amplitude) as it is to the voltage applied normally.

b. Attenuation of the transmitted **waveform** to a level that will propagate linearly by reflection of the beam from a flat plate of slightly lower impedance than the water (Kossoff and Carpenter, 1984). The method is promising but requires development and testing.

c. Development of a standard medium or "phantom" to measure that mimics attenuation properties of the body. Among the latter properties to be mimicked are the frequency dependence of the attenuation and the spatial variations, which exist in different critical and worst-case situations.

d. The predecessor to this standard recommended intentional attenuative filtering of the high-frequency components resulting from nonlinear propagation. The approach is not included here because of the significant loss in recorded **power**.

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