AAPM REPORT No. 8

PULSE ECHO ULTRASOUND IMAGING SYSTEMS: PERFORMANCE TESTS AND CRITERIA

Published for the American Association of Physicists in Medicine
by the American Institute of Physics

AAPM REPORT #8

PULSE ECHO ULTRASOUND IMAGING SYSTEMS:

PERFORMANCE TESTS AND CRITERIA

GENERAL MEDICAL PHYSICS COMMITTEE
ULTRASOUND TASK GROUP

November, 1980

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CONTENTS

		Page
1.	INTRODUCTION, NEED AND OBJECTIVES	1
2.	SCOPE	5
3.	DEFINITIONS	5
4.	MANUALS AND RELATED DOCUMENTS	9
5.	IMAGING PERFORMANCE -- MANUFACTURER AND USER SPECIFICATIONS AND EXPECTED LEVELS	9
	5.1 ULTRASONIC FREQUENCY AND BANDWIDTH	9
	5.2 SYSTEM SENSITIVITY CONTROLS	9
	5.2.1 RANGE INDEPENDENT	9
	5.2.2 RANGE DEPENDENT	10
	5.3 SYSTEM SIGNAL TO NOISE RATIO, RELATIVE SENSITIVITY OF THE DISPLAY MODES AND UNIFORMITY OF SEQUENTIAL ARRAYS	10
	5.3.1 SYSTEM SIGNAL TO NOISE RATIO USING REFERENCE PLANAR REFLECTOR	10
	5.3.2 BASELINE DATA FOR FUTURE QUALITY ASSURANCE TESTS	10
	5.3.3 SIGNAL TO NOISE RATION IN SYSTEMS WITH A LIMITED RANGE OF SENSITIVITY CONTROL	10
	5.3.4 USE OF VOLUMETRIC SCATTERERS IMBEDDED WITHIN TISSUE EQUIVALENT MATERIAL	11
	5.3.5 RELATIVE SENSITIVITY OF VARIOUS DISPLAY MODES	11
	5.3.6 UNIFORMITY OF PARALLEL BEAM LINEAR ARRAYS	12
	5.4 GEOMETRICAL RESOLUTION	12
	5.4.1 AXIAL RESOLUTION	12
	5.4.2 LATERAL RESOLUTION	13
	5.5 DISPLAY OF CHARACTERISTICS OF RELATIVE SIGNAL AMPLITUDE	14

5.6 GEOMETRICAL ACCURACY IN IMAGE PLANE 15

5.6.1 RANGE MARKER CALIBRATION 15

5.6.2 IMAGE DISTORTION 15

5.6.3 B-MODE REGISTRATION ACCURACY 16

5.6.4 ALIGNMENT OF THE ACOUSTIC AXIS WITH THE AXIS OF THE TRANSDUCER ASSEMBLY 16

5.6.5 ACCURACY OF M MODE TIME MARKERS 16

5.7 DELINEATION OF SCAN PLANE 16

5.7.1 SCANNING ARM RIGIDITY AND ACCURACY 16

5.7.2 TRANSDUCER FACE FORMAL TO SCAN PLANE 17

6. PERFORMANCE AFFECTING SAFETY MARGINS 17

6.1 ELECTRICAL SAFETY 17

6.2 ULTRASONIC EMISSIONS 18

6.2.1 ACOUSTIC OUTPUT LABELING 18

6.2.2 TRANSDUCER ASSEMBLING LABELING REQUIREMENTS 19

6.2.3 ADDITIONAL LABELING REQUIREMENTS FOR AUTOMATIC SCANNING INSTRUMENTS 19

7. TEST METHODS - IMAGING PERFORMANCE 20

7.05 GENERAL TEST MATERIALS 20

7.1 ULTRASONIC FREQUENCY, FRACTIONAL BANDWIDTH 23

7.1.1 SYSTEM INDEPENDENT FREQUENCY TESTS 24

7.1.2 ZERO CROSSING FREQUENCY 25

7.1.3 SPECTRUM ANALYZER 26

7.2 SYSTEM SENSITIVITY CONTROLS 26

7.2.1 RANGE INDEPENDENT SYSTEM SENSITIVITY CONTROLS 26

7.2.1.1 SYSTEMS WITH ELECTRICAL ACCESS 27

7.2.1.2 ACOUSTIC CALIBRATION 37

7.2.2 RANGE DEPENDENT 39

7.3 SYSTEM SIGNAL TO NOISE RATIO, RELATIVE SENSITIVITY OF THE DISPLAY MODES AND UNIFORMITY OF SEQUENTIAL ARRAYS 41

7.3.1 SYSTEM SIGNAL TO NOISE RATIO USING REFERENCE PLANAR REFLECTOR 41

7.3.2 BASELINE DATA FOR FUTURE QUALITY ASSURANCE CHECKS 43

7.3.3 TESTS FOR SYSTEM SIGNAL TO NOISE RATIO USING ACOUSTIC ATTENUATION OF THE ECHO FROM A PLANAR TARGET 43

7.3.4 USE OF VOLUMETRIC SCATTERERS IMBEDDED WITHIN TISSUE EQUIVALENT MATERIAL 46

7.3.5 RELATIVE SENSITIVITY OF VARIOUS DISPLAY MODES 48

7.3.6 UNIFORMITY OF REAL-TIME, PARALLEL BEAM LINEAR ARRAYS 49

7.4 GEOMETRICAL RESOLUTION 49

7.4.1 AXIAL OR RANGE RESOLUTION 49

7.4.2 LATERAL RESOLUTION 53

7.5 DISPLAY CHARACTERISTICS OFRELATIVE SIGNAL AMPLITUDE 54

7.5.1 A MODE 54

7.5.2 GRAY SCALE 56

7.6 GEOMETRICAL ACCURACY IN IMAGE PLANE 60

7.6.1 RANGE MARKER CALIBRATION 60

7.6.2 IMAGE DISTORTION 61

7.6.3 COMPOUND REGISTRATION ACCURACY 62

7.6.4 ALIGHMENT OF ACOUSTIC AXIS AND THE AXIS OF THE TRANSDUCER ASSEMBLY 65

7.6.5 CALIBRATION OF M MODE TIME MARKERS 65

7.7 DELINEATION OF SCAN PLANE 66

7.7.1 SCANNING ARM RIGIDITY 66

7.7.2 TRANSDUCER FACE NORMAL To SCAN PLANE 67

8. ELECTRICAL SAFETY, ULTRASONIC EMISSIONS 67

8.1 ELECTRICAL SAFETY TESTS 67

8.2 ULTRASONIC EMISSIONS 67

9. ACKNOWLEDGEMENTS 68

10. REFERENCES 69

11. APPENDIX 72

1. INTRODUCTION, NEED AND OBJECTIVES

1.1 Several acceptable documents on quality control of pulse-echo diagnostic ultrasound systems exist, and improvements in these techniques are being made rapidly. However, these quality control procedures are of value primarily in following the performance of a given system as a function of time to detect, document, and in some cases quantify system malfunctions. With these tests many of the most critical aspects of system performance are not determined with enough general validity to indicate whether the system is performing adequately in absolute terms or even to allow meaningful comparison of two different models of ultrasound systems. Quality control tests of many performance features also are not sensitive enough to differentiate between mediocre and very good, state of the art systems; they are consistently of value on those performance features only in identifying systems which obviously are very bad. Although many narrower or less detailed standards exist or are becoming available, [1-8] what has not been available is a set of higher level performance tests with the following characteristics: testing of a sufficiently wide range of features; general enough validity for comparison of different models of units; provision of quantitative results; and availability of expected values for interpretation of results. Such a set or sets of tests would be useful in evaluation of new systems to add an objective measure of performance for decisions involving cost, safety and performance trade-offs. They should be most useful in specification and acceptance testing of new equipment as well as in determining when system performance has degraded or become outdated enough to necessitate replacement of major system components or the entire system.

This document describes performance tests applicable to acceptance testing and other high level performance testing of pulse-echo ultrasound imaging systems. The objectives are: to identify system functional capabilities which should be assessed when evaluating ultrasound equipment; to provide the best available information on performance levels of state of the art equipment; and to describe techniques for carrying out high level performance tests of ultrasound equipment. Emphasis is given to the presentation of alternative test methods where appropriate. This is because it is highly debatable whether a single, very specific set of high level performance tests is nearing practical availability considering the large variety of pulse echo ultrasound systems in existence. The somewhat more general approach taken in this document is considered to be the best that can be done at the present time. Thus, this document is not intended to be a step-by-step protocol for acceptance testing, but one which identifies and provides instruction in several of the best available tests for evaluation of ultrasound imaging systems in situations such as acceptance testing.

1.2 The document is intended for use by hospital physicists and engineers, and those physicians and ultrasound technologists with skills and interest in exacting test methods and appropriate specifications. The performance parameters and test methods outlined in this document should also be of value to manufacturers of pulse echo imaging equipment when developing equipment specifications and performance characteristics for users. A working knowledge of pulse echo equipment is assumed, and individuals having little experience with ultrasound equipment are encouraged to read standard texts and familiarize themselves with operation of the equipment.

1.3 This document addresses specifically parameters related to imaging performance. Existing relevant standards related to equipment performance and test techniques are referenced. Tests concerning equipment electrical safety are not treated exhaustively here, as they are included in AAMI, U.L., IEC and other standards. However, brief statements are presented on ultrasound equipment safety, including electrical leakage at the transducer and acoustic intensity parameters.

1.4 Certain performance levels may be beyond the capabilities of many state of the art systems, and notable cases are indicated (Section 5 below). Also, it is recognized that there may be practical limitations on the ability to carry out specific tests as outlined here, even on state of the art machines. For example, the necessity of a calibrated gain control for many of the tests outlined is not met by all brands of equipment. However, in most cases acceptable accuracy for test results will still be obtained if external attenuators can be inserted in a linear portion of the signal line.

1.5 Manufacturers of certain test equipment are mentioned when at the time of this writing it is believed that suppliers of a particular type of test equipment are not well known to the medical physics community or that only the mentioned suppliers are known to produce the test equipment. Referencing of suppliers of test equipment in no way implies endorsement of that manufacturer's product.

1.6 The organization of the remainder of this document is as follows:

Section 2 lists the diagnostic instruments for which these acceptance tests are applicable.

Section 3 provides definitions relevant to equipment performance testing.

Section 4 discusses general considerations regarding equipment specifications and bid evaluating for ultrasound imaging systems.

Section 5 is divided into seven subsections, each dealing with an aspect of equipment performance. Systems capabilities which should be addressed when evaluating ultrasound equipment are indicated and, where appropriate, acceptable performance levels provided.

Section 6 discusses equipment performance related to electrical safety and safety with respect to acoustical exposures.

Section 7 describes tests for each of the performance variables listed in Section 5. The section is arranged to provide a one-to-one correspondence between it and Section 5. The authors have attempted to identify the best known methods appropriate for acceptance testing, taking into account the different types of imaging systems and configurations available. These tests are summarized below.

Section 8 briefly discusses test techniques applicable to safety, with appropriate standards or standard drafts listed.

Section 9 Acknowledgements.

Section 10 References.

Appendix I discusses use of a calibrated rf attenuator for testing ultrasound instruments.

The actual quality of pulse echo system imaging performance can be described under the following classifications -- system sensitivity or echo detection capability (sections 5.3 and 7.3), spatial resolution (5.4 and 7.4), ranges of signal levels displayed and minimal detectable changes in signal level (5.5 and 7.5), and, finally, geometrical accuracy in the image plane (5.6 and 7.6). The sections of 5.7 and 7.7 devoted to delination of the scan plane can be thought of as affecting resolution.

Sections 5.1 and 7.1, which are devoted to determination of ultrasonic frequency and bandwidth, are included even though they do not provide a direct indication of final imaging performance. This is-because the center frequency and range of frequencies employed to form the image affect quality in such an important and complex way that it is necessary to know those simple indicators of the ultrasound frequency spectrum. Knowledge of the frequency and bandwidth also is necessary for interpretation of the other performance data. Since frequency and bandwidth must be measured on each transducer, and transducers can be ordered from independent suppliers, it is convenient to have rigorous tests of transducer performance which are independent of the electronics in the ultrasound system. The system independent tests are given as well as system dependent tests which are to be performed with the complete ultrasound unit.

Since nearly all of the system performance tests require knowledge of the amplitude of echo signals relative to the system display threshold, considerable emphasis is placed on calibrating at least one system sensitivity control to measure relative or even absolute signal level. The step-by-step procedures given in section 7.2.1 on calibration of a system sensitivity control have not been given previosly in such detail or with such general applicability to real time and other newer systems. Calibration of range dependent controls such as swept gain, TGC and so forth also are given. Once one or more sensitivity controls are calibrated, the system's signal to noise ratio or minimum echo detectability can be determined. More rigorous tests relating the system noise level to the echo from a perfect planar reflector are given as well as several more convenient and eventually more useful tests such as maximum depth for imaging scatterers in tissue equivalent media. Attention is directed to relative sensitivity of the available display modes to make sure, for example, that what is visible in B mode is also visible in A mode. Uniformity of sensitivity throughout the image plane can be a problem with transducer arrays and test procedures are given for those transducer arrays for which tests now exist, i.e., parallel beam linear arrays.

Axial and lateral resolution are critical performance indicators which usually are not measured in quality control test objects by techniques which allow precise comparison and evaluation of ultrasound systems. Detailed procedures are given for measurement of axial resolution by several techniques which should give comparable results, and numerous expected values also are given for systems operating at different frequencies.- These axial resolution tests can reveal a great deal about the ultrasound transducer and early electronics, the scan converter and the display as well as the system as a whole. Meaningful lateral resolution measurements also are given in section 7.4.2 and a theoretical framework for evaluation of lateral resolution is given in section 5.4.2. The complexities of highly variable lateral resolution as a function of distance from the transducer are reduced to determination of the focal length, lateral resolution in the focal plane and depth of focus.

The information which can be obtained from an image is determined not only by the spatial resolution but also by the range of echoes which are included on the gray scale of the display and by the minimum detectible changes in echo signal amplitude. Stability of these gray scale characteristics also is of critical importance. The best available quantitative test of these features is measurement and evaluation of the gray scale characteristic curve as described in sections 7.5 and 5.5. Tissue equivalent or electronic test objects should be available in the next few years for direct determination of the minimum detectable echo signal changes a8 a function of other variables such as signal level.

As is well known ultrasound is used for very precise measurements of distances, areas and volumes. Section 7.6 presents well known, although somewhat more precise technique8 than usual, for measurement of distance marker calibration, image distortion, compound position registration and calibration of M mode time markers. Less well known, although equally important tests for accuracy of alignment of the active element in the transducer also are given. For compound scanning it is also important that the scan plane be defined well and, indeed, be a plane and not a cone or some other shape. Tests and typical values are given for scanning arm rigidity, although it should be noted that for certain applications some individuals prefer a certain amount of arm flexibility for finding or following very small structures. The section on finding whether the transducer face is normal to the scan plane covers part of the tests necessary to assure that the image plane is indeed a single plane in the body.

A detailed presentation on electrical, acoustic and mechanical safety tests is beyond the scope of this document but considerable background information is given on other available documents.

2. SCOPE

Performance tests described here are intended for all pulse-echo ultrasound imaging systems, including A mode, M mode as well as B scan apparatus. Special emphasis is given to single transducer element, compound B scan equipment such as is used for abdominal imaging and for obstetrics and gynecology. However, appropriate sections of the document are applicable to A mode, M mode and the various types of Auto-Scan imaging equipment.

3. DEFINITIONS

The definitions presented here refer primarily to variables regarding system performance discussed in Section 5 and in Section 7.0 - 7.6. Additional definitions, primarily regarding acoustic intensities and acoustic emissions, are found in Ref. 5.

A MODE: A method of echo display in which time (distance) is represented along one axis and echo amplitude is displayed along an orthogonal axis.

AXIAL RESOLUTION (RANGE RESOLUTION): The axial resolution by either the barely resolvable or clearly resolvable criterion is the minimum spacing of two reflectors along the axis of the ultrasound beam at which the two reflectors can be resolved and remain resolved for all greater spacings using the stated criterion. More formally, the reciprocal of this minimum resolvable spacing also may be quoted as the axial resolution.

BARELY RESOLVED: Two reflectors are said to be barely resolved in a pulse echo image if there is a gap visible between the displayed echoes from the two reflectors which indicates an echo signal amplitude less than the peak echo amplitude from either of the two reflectors. When measured quantitatively, the Rayleigh criterion is employed in place of the visual criteria above.

B MODE ECHO DISPLAY: Method of echo display in which echo signals are represented as intensity modulated dots on a display, the dots being positioned on the display according to the range of the echo source from the transducer. The B mode display is employed in most pulse-echo scanning procedures.

B MODE REGISTRATION ACCURACY (COMPOUND): The precision with which the position of a point target is registered on a B scan display when the target is scanned from different directions.

BEAM AXIS: A straight line joining the points of maximum pulse-echo response measured in the far field of a transducer. This line, calculated according to regression rules, should be extended back to the transducer assembly surface.

CENTER FREQUENCY: $\left(\frac{f_1 + f_2}{2}\right)$ where f_1 and f_2 are the frequencies defined in pulse echo bandwidth.

CLEARLY RESOLVED: Two reflectors are said to be clearly resolved in an image if a gap is observed between the echoes from the two reflectors and the displayed signal or image brightness in that gap is the same as in regions of the image which are well removed from any reflectors or reverberation echoes.

CLUTTER LEVEL: Signal level (in dB) below the peak response at a given depth at which the pulse echo beam width dramatically increases. Clutter is common to multiple element linear arrays and multiple element phased array systems.

DISPLAY SATURATION (For B Mode Displays): Display luminance or film density at which an increase in echo signal level or an increase in system sensitivity produces no change in luminance or density.

DISPLAY THRESHOLD (A Mode Displays): A barely discernible deflection on the A mode display.

(B Mode Displays): Intensity modulation which produces a barely discernible echo image.

DISPLAYED BEAM WIDTH: The distance normal to the beam axis over which a point or line target can be discerned on the display by scanning the ultrasound beam across it. The width depends on the system sensitivity, distribution of ultrasonic energy within the beam, signal processing, and strength of echo.

FAR FIELD: The region of a transducer beam which lies beyond the last point of axial pressure maximum, Y_0. The range of Y_0 is given approximately by $S/\pi\lambda$ where S is the area of the transducer and λ the wavelength.

FOCUSED TRANSDUCER (PULSE ECHO): A transducer in which the ratio of the smallest pulse echo beam cross sectional area to the area of the active transmitting element(s) is less than 0.25.

FRACTIONAL BANDWIDTH: Bandwidth divided by center frequency.

GEOMETRICAL FOCAL LENGTH: The distance along the beam axis from the center of the face of the transducer to the geometrical focal point. the point of intersection of the greatest number of rays from the active transmitting element (s) of the transducer. Each ray is perpendicular to a small surface element of area S and may be refracted by lenses and mirrors.

GRATING LOBES: Ultrasonic transducer beam energy transmitted into a direction other than that of the main lobe of the beam, resulting from the transducer consisting of multiple, regularly spaced elements rather than a single element. They are common to multiple element sequential array and multiple element phased array systems.

LATERAL RESOLUTION: The minimum spacing of two reflectors normal to the beam axis at which the two reflectors can be resolved and remain resolved for all greater spacings.

M MODE (TIME-MOTION DISPLAY): A method of display in which tissue depth is displayed along one axis and time is displayed along the second axis. M mode is used frequently to display echocardiographic data where the changes in range of echoes corresponding to heart wall and valve motion are displayed as a function of time. The intensity of the echoes may be displayed by modulation of the brightness of the CRT image, or of the shading of the hard copy.

NEAR FIELD: The region of a transducer beam lying between the transducer and the position of the last axial pressure maxima.

OUTLINE PROCESSING: A method of signal processing yielding a B mode display with emphasis on large amplitude echoes, such as originate from organ boundaries. Various forms of signal processing and display systems have been used for "outline processing," coming under names such as "leading edge," "bistable," etc.

PERFECT PLANAR REFLECTOR: A large smooth interface whose amplitude reflection coefficient for plane waves (at normal incidence) in a nondissipative medium is equal to 1.

PULSE ECHO BANDWIDTH: The difference in frequencies f_1 and f_2 at which the frequency spectrum of an echo signal from a reference planar interface is 50% (-6 dB) of its maximum value.

PULSE ECHO BEAM CROSS SECTIONAL AREA: The area on the surface of a plane perpendicular to the beam axis consisting of all points where the pulse echo response exceeds -12 dB of the maximum response in that plane.

PULSE ECHO FOCAL LENGTH (FOCAL DISTANCE): The distance along the beam axis from the center of the face of the transducer to the pulse echo focal plane.

PULSE ECHO FOCAL PLANE: The plane perpendicular to the beam axis of a focused transducer and containing the minimum -12 dB pulse echo response width (in a given direction normal to the beam axis.

PULSE ECHO FOCAL ZONE: The distance along the beam axis of a focused transducer from the first point at which the -12 dB pulse echo response width is 2 times the value in the pulse echo focal plane to the point beyond the focal plane at which the -12 dB pulse echo response width is again 2 times the value in the pulse echo focal plane,

PULSE ECHO RESPONSE PROFILE: A continuous plot in a given direction normal to and extending through the beam axis, depicting the echo signal amplitude from a specified target as a function of the distance from the center of the target to the beam axis.

PULSE ECHO RESPONSE WIDTH: The width of the pulse echo response profile of a transducer for a specified target at a given depth. The response is usually quoted with respect to the maximum response at that depth.

REFERENCE PLANAR INTERFACE: A planar interface large enough to encompass the acoustic beam by at least a factor of 3 and with a flatness of ±0.025 mm and finish roughness less than 1 μm. The reference planar interfaces are water-carbon tetrachloride and water-stainless steel as defined in reference 2.

REFLECTIVITY: The amplitude reflection coefficient relative to a perfect planar reflector.

SENSITIVITY: The minimum signal that can be satisfactorily detected. The sensitivity is generally limited by the input noise level of the system.

STANDARD WORKING DISTANCE: For unfocused transducers an axial distance corresponding to the position of the final axial pressure maximum, given approximately by $S/\pi\lambda$ where S is the area of the radiating surface of the transducer and λ the wavelength. (Different from "standard working distance defined in Reference 2.) For focused transducers, the distance at which a maximum echo is obtained; when reporting results this distance, together with the dimensions of the active transducer elements, the geometric focal length and the approximate center frequency of the transducer should be specified if they are known[2].

SWEPT GAIN: The process by which the gain of a pulse-echo system is controlled to vary with time to compensate for the effects of attenuation; also called Time Gain Compensation (TGC) or range dependent sensitivity control.

WAVELENGTH: The ratio of the medium's speed of sound to the center frequency.

4. MANUALS AND RELATED DOCUMENTS

Detailed manufacturer's specifications of system performance should be supplied prior to purchase of the equipment and must be available at the time of acceptance testing. Limits on the environment in which the instrument can meet the manufacturer's specifications should be stated clearly in the specifications. Common environmental variable8 which should be specified and usually are included, are allowable frequency and voltage range of the power line, required space, required lighting and allowable temperature range. Other important but less frequently specified environmental variables include ambient electromagnetic and power line noise, and acceptable vibration due to movement of the instrument in routine use. Other desired specifications are described in the following section.

Two sets of written operating instructions must be supplied with the instrument. These should describe accurately the system operation with the options supplied with the system delivered. Operator warnings, installation instructions, preventive maintenance intervals and procedures and calibration procedures should be included in these manuals. Service manuals or user service manuals should be supplied with the system and must contain schematics and system descriptions adequate to allow diagnosis of malfunctions and field service by appropriately trained staff. During bid evaluation it should be considered that missing specifications and manuals may result in reduced performance and increased costs to the purchasing institution. Upon receipt of the instrument it should be ascertained that controls perform as indicated in the operating instructions.

5. IMAGING PERFORMANCE -- MANUFACTURER AND USER SPECIFICATIONS AND EXPECTED LEVELS

5.1 ULTRASONIC FREQUENCY AND BANDWIDTH

For each transducer supplied with the system the center frequency and the fractional bandwidth should be specified with the system independent tests of section 7.1, or with the transducer mounted in the system. In the latter case, the sensitivity controls, including those for power output, damping and gain adjustments, should be specified as well. Center frequency should be accurate to within ±10% and fractional bandwidth to ±l5%.

5.2 SYSTEM SENSITIVITY CONTROLS

Both range independent and range dependent ("swept gain") sensitivity controls should be calibrated in decibels or dB/cm.

5.2.1 Range Independent

Range independent system sensitivity controls including controls of acoustic output as well as overall receiver gain should be stable within ±2 dB. This stability should be maintained beginning 10 minutes after turning on the system and at ambient temperatures from 15 to 32°C. Each of these controls should be accurate within ±0.l x R, where R is the full range of each control (in dB). (Itshould be pointed out that many modern systems do not meet this specification.) The differential error should be less than 2 dB for every 10 dB change in a calibrated control. On systems with less than 80 dB of range independent system sensitivity controls, the "initial" control or equivalent control on the swept gain should be calibrated as above for range independent controls.

5.2.2 Range Dependent

The total swept gain available in the system should be at least 60 dB. The rate or rates of swept gain available should be accurate to ±20% and should be variable from 0 to 2F dB/cm, where F is the maximum transducer center frequency in (MHz) specified in 5.1. For special purposes, such as a "near" TGC (swept gain) and swept gain in echocardiology, higher rates may be desirable. The rate of swept gain may be quoted, or the gains at different ranges (depths) may be given. Deviations from exponential swept gain to correct for increased ultrasound penetration at greater depths in tissue and for variations in transducer sensitivity with depth arc employed in some units. If such deviations are provided they should be described by the manufacturer.

5.3 SYSTEM SIGNAL TO NOISE RATIO, RELATIVE SENSITIVITY OF THE DISPLAY MODES AND UNIFORMITY OF SEQUENTIAL ARRAY TRANSDUCERS

5.3.1 System Signal to Noise Ratio Using a Reference Planar Reflector

The echo signal obtained from a perfect reflector at the standard working distance should be at least 105 dB greater than the system noise level for all transducers operating between 1 and 4 MHz. For a given transducer in a given electromagnetic environment, this signal to noise ratio should be stable within ±3 dB or within the measurement precision, whichever is greater.

5.3.2 Baseline Data for Future Quality Assurance Tests

During acceptance tests, it is appropriate to obtain baseline data of system signal to noise ratio, or simple system sensitivity settings to obtain a standard display from a target. These values should be obtained with the quality assurance test object preferred for routine testing.

5.3.3 Signal to Noise Ratio in Systems with a Limited Range of Sensitivity Control

Because of limited dynamic range of most ultrasound systems and the present limited experience in working with standard reflectors of lower reflectivity such as a water-carbon tetrachloride interface,2 it often is difficult to compare the system noise level with the signal from a reference planar interface such as described in section 7.3.1. It is convenient for comparison of ultrasound units using transducers of the same frequency, diameter and pulse echo focal length to compare system signal to noise ratios using an attenuating block of material as described in section 7.3.3. Examples of signal to noise ratios on a number of modern ultrasound scanners with several transducers are given in Table 5.3.3-l. The signal is an echo signal from the planar surface of an acrylic block

TABLE 5.3.3-l

Signal to Noise Ratio for Signal from Flat End of a 16 cm Thick Acrylic Block at 22°C

Transducer			Scanner Manufacturer and Year							
Freq. MHz	Diam. (mm)	Focus (cm)	A76	A77	A78	A78	A78	A78	B78	C78
2.3	19	(long)		67dB						< 49dB
2.3	13	(long	49dB							
3.5	19	(long)			49dB	37dB	42dB	46dB		
3.5	19	(long)							44dB	19dB
3.5	13	8.1 (long)	14dB	27dB						
3.5	13	(med)			30dB					
5.0	13	(med)			21 dB	10dB	18dB			< 0dB

in air after the ultrasound beam has traversed down and back through a 16 cm path of acrylic at 22°C. As described in section 7.3.3, the signal from the surface of the block can be referenced to the signal from a perfect planar reflector at the focal plane in water, but this comparison with a reference planar interface is not highly accurate because of differences in transducer beam divergence and characteristics of the frequency spectra.

5.3.4 Use of Volumetric Scatterers Imbedded Within Tissue Equivalent Material

Determination of the maximum range of imaging volumetric scatterers in a tissue equivalent medium as described in section 7.3.4 may become the most important practical method of determining effective system sensitivity.

5.3.5 Relative Sensitivity of Various Display Modes

The threshold for display of a signal from a single reflector in gray scale B mode images should be within -1 to +10 dB relative to the threshold for display of that signal in any A mode displays on the system. The threshold for display of the Same signal in outline processing of B mode or M mode displays should be within -1 to +30 dB relative to A mode display thresholds and should be within -1 to +20 dB relative to gray scale display threshold8 on that system.

5.3.6 Uniformity of Parallel Beam Linear Arrays

For parallel beam linear arrays the uniformity of response to a planar target as a function of distance along the length of the array should be within 6 dB. Nonuniformities greater than 6 dB are usually noticeable clinically. The target should be in the far field of the array.

5.4 GEOMETRICAL RESOLUTION

5.4.1 Axial Resolution

Acceptance levels for axial resolution often may be determined using values which have been obtained on the same model of equipment as that undergoing acceptance tests when the equipment used for reference values has been shown to provide clinically acceptable results. Absolute values for axial resolution acceptance levels must be employed cautiously because it may be justifiable to sacrifice high axial resolution for improved system sensitivity. Axial resolution in the near field of the transducer often is sacrificed for improved lateral resolution in the focal zone. Modern general purpose gray scale scanners usually do meet the following criteria at or beyond the focal plane and these values may be used successfully in most cases for system specification and acceptance.

TABLE 5.4.1-1
Recommended 20 dB Axial Resolution

Display Scale	Frequency	Separation of Barely Resolvable Reflectors
40 cm FOV 4 cm/div (4/1)	3.5 and 2.25 MHz	≤ 2.5 mm Digital ≤ 2.0 mm Analog
40 cm FOV 4 cm/div Zoomed	3.5 and 2.25 MHz	≤ 1.4 mm Analog
10 cm FOV 1 cm/div (1/1)	3.5 MHz	≤ 0.8 mm
10 cm FOV 1 cm/div	2.25 MHz	≤ 1.2 mm

5.4.2 Lateral Resolution

Lateral resolution for each transducer should meet the manufacturer's specifications. These specifications should be given in terms of widths of the pulse echo beam profiles at the -6, -12, -20, and, where possible, -40 dB levels. The clutter level and the angle of prominent side lobes or grating lobes also should be quoted for arrays.

These beam profile widths ideally should be specified at increments of 2 cm from the transducer and at finer increments in the focal zone. For abbreviated listings and measurements ranges for quotation of beam width should include:

a. The pulse echo-focal distance. For unfocused circular transducers this distance is taken to be $S/\pi\lambda_c$ where S is the area of the transducer face and $\lambda_c = \frac{c}{f_c}$, where c is the speed of sound and f_c the transducer center frequency. For unfocused rectangular transducers the distance is $\frac{b^2}{\pi\lambda_c}$ where b is half the length of the side which lies in the direction being scanned.[4]

b. Twice the focal distance or at the distal end of the focal zone.

c. One half the focal distance or at the proximal margin of the focal zone.

For asymmetrical transducers these measurements should be made in at least two orthogonal directions, the direction of the scanning plane and the direction orthogonal to the scanning plane.

Circular, spherically focused transducers are classed here as medium weak to strongly focused if the focal length is well less than the length of the near field of a flat disk transducer, that is, if

$$1.4\ F < D^2/4\ \lambda_c \qquad (1)$$

where D is the diameter of the active element, λ_c is the ultrasound wavelength at the center frequency, and F is the pulse echo focal length. For these transducers, the -20 dB pulse echo response width in the focal plane can be predicted approximately[9] by

$$W_{20} \simeq \frac{3\ \lambda_c\ F}{D} \qquad (2)$$

As the focusing is made weaker by moving the pulse echo focal length closer to the near to far field transition for a flat disk of the same diameter or as aspherical focusing is used to extend the depth of focus, the pulse echo response width becomes larger. When these formulas are used to evaluate medium weak to more strongly focused transducers, the acceptance level should be increased by approximately 40% to allow for uncertainties in the scanning technique and in the effects of the frequency spectrum on the beam profile. The pulse echo depth of focus, ΔZ, may be predicted very approximately for medium weak to more strongly focused transducers by the equation

$$\Delta Z \cong \delta\lambda_c(F/D)^2. \quad (3)$$

5.5 DISPLAY OF CHARACTERISTICS OF RELATIVE SIGNAL AMPLITUDE (GRAY SCALE AND A MODE DYNAMIC RANGE-DISCERNIBLE ON THE DISPLAY)

The echo signal maximum dynamic range discernible on the A mode and B mode displays and on the recording film should be at least 35 dB for modern gray scale compound systems. If more than one signal processing option is offered, this dynamic range may be less on some but not all options. For other gray scale scanning and display systems, including M mode systems, the display dynamic range should agree with the manufacturer's specifications to within ±5 dB. The echo signal dynamic range discernible on the display should be stable to within ±2.5 dB or within the precision of the measurement technique, whichever is larger. It also is informative to determine a curve of the signal level presented to the display as a function of relative echo signal amplitude.

It is recommended that manufacturers of all gray scale ultrasound systems provide for display of calibration gray bars which cover exactly the range of display luminance produced by actual echoes. This would facilitate daily or more frequent evaluation of image recording and processing as well as more complete tests of system display characteristics. Provision of a triggered burst generator with known decay rate at a linear stage in the signal processing or publication of the range of echo signal amplitudes corresponding to each gray bar also is recommended strongly. In order of preference the calibration signals may be added to the main signal line just prior to the preamplifier, main receiver, or scan converter. Having the calibration signal insertion point selectable by switch between either the first two positions, to a linear point or true logarthmic point in the signal processing, and to a point just prior to the scan converter would be most desirable. Calibration signals added prior to nonlinear elements and attenuators or gain controls could eliminate the need for routine acoustic tests of gray scale characteristics. If calibration signal insertion is at this early portion of the signal processing chain, it is recommended that the smallest calibration voltage step be specified in relation to the maximum system noise level specified by the manufacturer and, in the absence of reasons to do otherwise, this signal-to-noise level of the smallest gray bar should be 12 dB. Calibration signals inserted just prior to the scan converter would allow frequent or even continuous monitoring of recording and display systems, independent of sensitivity control settings.

System stability and reproducibility of standard control settings including those on the display and recording systems shall be such as to allow reproduction of the gray scale display threshold within ±1.5 dB on the system sensitivity control. Stability of the display luminance should be approximately within ±20% (0.2 EV at ASA 50 on a light meter) in background areas of the image as well as in areas covered with echoes which saturate the display. The background and maximum echo areas of the film should be stable to ±0.15 optical density or reflection density. Background luminance and optical density should be constant across the image to the same tolerance-as specified above for stability.

5.6 GEOMETRICAL ACCURACY IN IMAGE PLANE

5.6.1 Range Marker Calibrations

The system should have range markers, that is, depth markers or distance markers generated by internal circuitry and displayed on all system display modes. Accuracy of distance markers as determined with physical test objects should be within ±1% or ±lmm, whichever is greater, for any distance measured. For these measurements a speed of ultrasound propagation of 1,540 m/sec should be assumed unless specified otherwise. Distance markers actually should be accurate to much better than 1%, but it is difficult to measure that accuracy with a physical test object.

5.6.2 Image Distortion

Image distortion on recorded B scan images should be less than 2% (±l%) over a distance of half the screen height in any part of the inner 80% of the image area and less than 5% over the entire image. This means that the horizontal and vertical display scales should be linear and equal to within 2%. Most displays do not meet this specification. If units cannot meet these specifications on image distortion then electronic distance markers should be available in any position and orientation of the display for use in distance measurement. In that case extensive efforts also will be required to appraise all users of the need to use the distance markers by placing them at the same location and angle of any measurements requiring high accuracy.

For ultrasound imaging systems employed in radiation therapy planning additional assurance of geometric accuracy in the images is desirable. Scans of a solid object should indicate that the accuracy of external patient contours is ±2 mm. The orientation of the image on the hard copy also should be the same as the orientation of the actual solid object. That is, a scan along a horizontal couch should be parallel to horizontal grid lines or distance markers within ±.5°. This specification also is met only rarely and knowledge of that fact is essential in acquiring accurate data for treatment planning,

5.6.3 B Mode Registration Accuracy

Compound Registration: B mode registration accuracy should be such that the centers of all displayed echoes from a Tine target lying at a depth of at least 10 cm are within 5 mm of each other in the object space. The echoes should be produced by scanning the line target from three or more different directions separated by at least 90° and preferably 180°. The line target should be in a medium with a speed of ultrasound propagation of 1,540 m/sec unless specified otherwise. This test applies to any position of the scanner used for scanning patients.

Simple Scan Registration: In linear, sector or other simple scanning modes the separation of two line targets connected by a line which is normal to and bisected by the central ray of the image, should be displayed accurately to within ±3 mm. The line targets should be separated by 10 cm and lie at a distance of 10 cm from the surface of the test object. For scanners with maximum fields of view less than 10 cm the line targets should be separated by 80% of the imaged field width; the separation should be displayed accurately to within ±3%; and within any smaller segment of the image line target separations should be displayed accurately to within 3% or 1 mm, whichever is greater.

5.6.4 Alignment of the Acoustic Axis with the Axis of the Transducer Assembly

For all transducers supplied with the system, the acoustic axis should be aligned with the geometric axis of the transducer assembly to within ±0.04 radian (2°).

5.6.5 Accuracy of M Mode Time Markers

The time markers should be accurate to 3%. The spacing of one second time markers on strip chart recordings should not vary by greater than 5% over any distance corresponding to 10 seconds or less on the strip chart recording.

5.7 DELINATION OF SCAN PLANE

5.7.1 Scanning Arm Rigidity and Accuracy

The rigidity of 3-joint scanning arm systems should be such that for an applied force of 100 gm WT normal to the scan plane at the transducer position the angular deflection of the scan plane should be less than .02 radians (1°). For a force of 300 gm WT it should be less than .04 radians (2°).

Linear position indicators and angle indicators should be accurate and reproducible to within 0.5% and 2° respectively.

5.7.2 Transducer Face Normal to Scan Plane

The transducer face should be normal to the scan plane to within ±0.01 radians (½°) in all orientations.

6. PERFORMANCE AFFECTING SAFETY MARGINS

6.1 ELECTRICAL SAFETY

System electrical characteristics shall meet requirements of the American National Standard "Safe Current Limits for Electromedical Apparatus," ANSI/AAME SCL 12/78,[6] as summarized in Table 6.1.1. These tests are to be performed with all permutations of the following test conditions:

a. Power line polarity normal and reversed.
b. Power on and off.
c. Ground open and intact.

TABLE 6.1-1

DC to 1 kHz RMS Current Limits in Microamperes[1]

Patient connections[2] to chassis, metal scanning arm or transducer housing, and power ground	Chassis and metal scanning arm or transducer housing to power ground
50 μA[3]	100 μA

Footnotes:

[1] The ultrasound units are assumed to be portable for electrical safety considerations. The ANSI-AAME Standard should be consulted for units which are grounded permanently.

[2] Patient connections include the transducer face and ECG connections.

[3] Transducers and other connections which are to be placed in direct electrical contact with the heart or great vessels, e.g., in surgery or catheterization, must meet a 10 μA current limitation.

In addition, it is recommended that there be no externally grounded components on the transducer assembly that would come in contact with the patient or the technologist that handling the probe.

Much more comprehensive electronic and mechanical safety requirements are included in Ref. 8.

6.2 ULTRASONIC EMISSIONS

For detailed information, including measurement methods, refer to Ref. 5. In that Interim Standard manufacturers are expected to specify either on the instrument or in the operating and maintenance manuals the values for the variables listed below. Such values should refer to the generic type of equipment rather than to individual instruments. These values are to be quoted for each operating mode such as pulsed Doppler, manual scanning pulse echo, automatic scanning pulse echo, etc. In addition, the manufacturer may specify a nominal value and the specific value for each instrument of the quantities listed below in paragraph 6.2.1 - 6.2.3.

When instrument capabilities are changed through equipment modifications outlined in detail or performed by the manufacturer, it is the responsibility of the manufacturer to provide information on parameter changes associated with the modifications. For transducer assemblies sold directly to the clinical end users for use with equipment manufactured by other companies the transducer manufacturer should specify the quantities of 6.2.1 - 6.2.3 with reference to the instrument with which the transducer assemblies are to be used.

6.2.1 Acoustic Output Labeling*

For each generic combination of system and interchangeable transducer assembly the following parameters shall be specified at the control settings and beam axis orientations which produce the maximum values for each of these parameters (if these control settings are other than the maximum, then the settings shall be specified):

a. The absolute maximum ultrasonic power.
b. The absolute maximum spatial peak, temporal average intensity (SPTA).
c. The absolute maximum spatial peak, pulse average intensity (SPPA).

In addition, with the controls set for measurement b. above, the following shall be specified in the plane normal to the beam axis containing the point of absolute maximum spatial peak, temporal average intensity:

d. The absolute maximum spatial average, temporal average intensity (SATA).

*Underlined definitions relative to ultrasonic safety are found in Ref. 5.

e. The location of the plane of the absolute maximum spatial peak, temporal average intensity (SPTA).

f. The absolute maximum pulse repetition frequency.

If an ultrasound power control or indicator is provided, this control or indicator shall be calibrated such that the operator will know the percentage of maximum ultrasonic power being delivered by the instrument in combination with any compatible transducer with an accuracy of ±25% of maximum ultrasonic power output.

6.2.2 Transducer Assembly Labeling Requirements

For each transducer assembly which can be used with the instrument, the absolute maximum and absolute minimum values of parameters (a.-f.) shall be specified for the radiated field:

a. Center frequency.
b. Fractional bandwidth.
c. Entrance beam dimensions.
d. Focal length and depth of focus, if focused,
e. Focal area, if focused.
f. If electronic focusing on transmission is used, parameters a., b., d., and e. shall be specified as a function of range, angle, control settings or system functions which allow variations of-these parameters.

Each transducer assembly which can be used with the instrument shall have the following clearly and indelibly marked on the case:

a. Model Number
b. Serial Number

6.2.3 Additional Labeling Requirements for Automatic Scanning Instruments

For each transducer assembly which can be-used with the instrument, and for each operating mode, the following additional items shall be specified:

a. Type of scan (sector, rectilinear, interlaced, etc.).
b. Scanning method for transmission (piezoelectric array, single element, mechanical, etc.).
c. Scan cross sectional area.
d. Entrance dimensions of the scan.
e. Dimensions of image plane.
f. Scan repetition frequency (nominal value).

g. Number of discrete acoustic lines per scan (nominal value).

h. Time of scan during formation of a single image (nominal value).

These labeling requirements are based on and should be consistent with the document "Safety Standard for Diagnostic Ultrasound Equipment - Draft IV" developed by the American Institute of Ultrasound in Medicine and National Electrical Manufacturers Association with cooperation of the American Association of Physicists in Medicine and Acoustical Society of America. At the discretion of the physicst responsible for these acceptance tests test results and calculations provided by the manufacturer may be accepted as giving reasonable assurance that intensities produced by the system being evaluated do not exceed the specified maximum values.

7. TEST METHODS - IMAGING PERFORMANCE

7.05 GENERAL TEST MATERIALS

Specific tests outlined below require either generally available electronics laboratory instrumentation and/or test objects or phantoms that are commercially available. The system independent transducer tests described in Section 7.1 require use of an oscilloscope and a 50 ohm output impedance gated sinewave generator for measuring the center frequency and pulse echo bandwidth of the transducer[4]. Alternative methods utilize an oscilloscope while the transducer isconnected to the ultrasound system or a spectrum analyzer system.

For the frequency tests and various sensitivity tests of Section 7.2 reference is made to a perfect planar reflector. This is defined as a plane, smooth interface (roughness less than ±1μ) whose amplitude reflection coefficient is equal to 1. A water-stainless steel interface is a nearly perfect (-.58 dB) reflector and other interfaces may do equally well, providing their reflectivity with respect to a perfect reflector is known[2]. Planar reflectors should be immersed in a tank containing air free water at 20 ±5°C. When using such specular reflecting surfaces care must be taken to assure the transducer beam axis is perpendicular to the surface of the reflector. This is best achieved by mounting the transducer on a holding device capable of independent angular adjustment in two orthogonal planes containing the beam axis. The transducer angles are adjusted until a maximum echo is detected from the interface. If such care is not exercised anamolous results are likely to occur.

Swept gain, depth calibration and other geometric tests can be carried out using commercially available test objects or phantoms. The AIUM 100 mm test object has been adopted as a standard by the American Institute of Ultrasound in Medicine[1]. Figure 7.05-1 is a schematic diagram of this test object. Both an enclosed and open version of the test object are available. The stainless steel rods

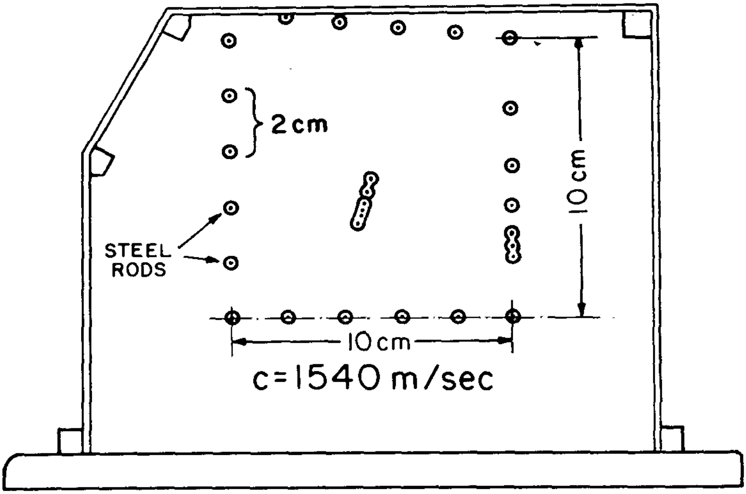

Figure 7.05-l

Schematic of the enclosed AIUM 100 mm test object.

are .75 mm in diameter and are immersed in a water medium whose speed of sound is 1540 ±1.5 m/sec, unless otherwise specified. In actual use the transducer beam is coupled to the test object using coupling oil or gel-if the enclosed version is used. The transducer scanning plane must be aligned perpendicular to the rods. Using the enclosed test object this is achieved by adjusting the transducer face flush against all sides of the tank prior to scanning.

Test objects or phantoms are also becoming available which employ weakly reflecting targets in tissue equivalent material. One such device is shown diagrammed in Figure 7.05-2. The targets are 0.3 mm diameter nylon lines arranged in a column for depth calibration and lateral resolution measurements. Additional fibers are provided for axial resolution checks and for assessment of B scan registration accuracy. The targets are embedded within a tissue equivalent gel 10 having a speed of sound of 1540 ±15 m/sec and an attenuation coefficient of 0.6 dB/cm/MHz. Attenuation within the gel material is proportional to ultrasonic frequency, in agreement with most measurements

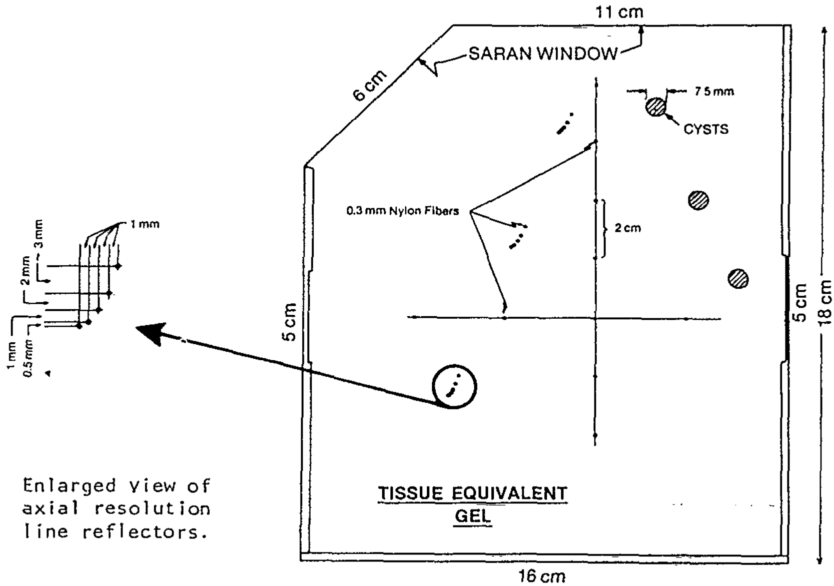

Figure 7.05-2

Tissue mimicking phantom employing .3 mm diameter nylon line targets. (Courtesy, Radiation Measurements, Inc.)

of soft tissue attenuation. Thus, the effects of spectrum hardening OR broad band pulses used for clinical diagnosis are mimicked within the gel material. Thermal and temporal stability are easily achieved, the latter facilitated by a .008" Saran Window to prevent loss of water. Versions of this phantom are available which produce sufficient backscatter to allow sensitivity changes to be estimated using the "depth of penetration" within the phantom (see Section 7.3.4).

Sensitivity tests in Section 7.2 are carried out using a precision rf attenuator. Its use is described in 7.2.1 as well as Appendix I.

Range dependent sensitivity controls and A mode and B mode display characteristics may also be checked using triggered pulse or sine wave burst generators[11,12]. The operation of the pulsed and sine wave versions are similar. Each replaces the ultrasonic transducer in the pulser-receiver circuit of the ultrasound system. In response to the excitation pulse normally applied to the transducer, the signal generator emits internally generated signals which are applied to the ultrasound system. The pulsed device emits pulses separated by 2.6 μsec intervals, alternative pulses being positive or negative in the first half cycle. Pulses can be exponentially attenuated by 0, 1.25 or 2.5 dB/cm over a greater than 70 dB range. The sine wave unit emits a 1 V peak-to-peak signal that decays exponentially at the rate of 2.5 dB/cm (or 0 dB/cm). A calibrated graticule is superimposed on the exponentially decaying waveform at every 10 dB change in voltage. The unit operates with a 2.25 MHz carrier frequency and has a dynamic range greater than 60 dB.

The following is a partial list of various suppliers which are known to produce equipment of the type used in tests of diagnostic ultrasound equipment:

Joe A. Anderson, 3360 Stuart Street, Denver, CO 80212.
ATA Corporation, 2600 West 2nd Avenue, Denver, CO 80219.
ATS Laboratories, Box 792, South Norwalk, CT 06856.
Danish Inst. of Biomedical Engineering, Attn: Peter Lewin, Park Alle 345, DK-2600, Glostrup, Denmark
Dapco Industries, 199 Ethan Allen Highway, Ridgefield, CT 06877.
Fred S. Dunning Company, 2910 Franklin Boulevard, Sacremento, CA 95818.
Echosonics, Division of Cone Instruments, 5351 - H. Naiman Parkway, Solon, OH 44139
Machlett Laboratories, Inc., 1063 Hope Street, Stamford, CT 06907.
Modern Electronic Diagnostic Corporation, 820 West Hyde Park Blvd., Inglewood, CA 90302.
Nuclear Associates, Inc., 100 Voice Road, Carle Place, NY 11514.
Polaron Instruments, Inc., 4099 Landisville Road, Doylestown, PA 18901
Radiation Measurements, Inc., 7617 Donna Drive, Middleton, WI 53562.
Ross Chemical Associates, Manufacturers & Consultants, P. O. Box 8144, San Marino, CA 91108.
UMA, Inc., Route 3, Box 18 D, Elkton, VA 22827.

7.1 ULTRASONIC FREQUENCY, FRACTIONAL BANDWIDTH

Tests presented in this section are used to measure center frequency and fractional bandwidth of the ultrasound transducer.

In most pulse-echo imaging systems the transducer is excited by a short duration electrical pulse causing it to "ring" at approximately its center frequency. The ultrasonic frequency and the fractional bandwidth are determined mainly by properties of the transducer itself. However, center frequency and bandwidth may also depend on the pulser and the electrical impedance of the receiver. On some units frequency and bandwidth may vary slightly for different sensitivity controls on the machine.

Wherever possible system independent transducer tests, described in section 7.1.1 are preferred. On many scanners the transducer cannot be isolated from the pulser-receiver system in order to carry out such tests. For these units measurements of "zero crossing frequency" or spectral analysis of the pulse-echo waveform may be carried out. Progress is being made in the development of acoustic tests of ultrasonic frequency and bandwidth[13]. These would allow rapid estimates of transducer center frequency with the transducer attached to the pulser-receiver.

7.1.1 System Independent Frequency Tests

"System independent" tests, as specified by "AIUM Standard Methods for Testing Single Element Pulse-Echo Ultrasonic Transducers"[4], provide a means of characterizing the frequency, bandwidth and sensitivity of transducers. The procedure described here utilizes a 50 ohm impedance tone burst generator and measures pulse-echo sensitivity as a function of frequency for a reflection from a planar reflector immersed in water. Figure 7.1.1-l is a block diagram of the procedure. The gated sine wave generator is arranged to produce tone bursts with a mini-urn of 15 cycles at all frequencies in the transducer bandpass , and with a time interval between successive pulses no less than four times the ultrasonic travel time from the transducer to the interface and back. The transducer-interface distance should be established at the nominal pulse-echo distance or, for a flat face circular transducer, a distance of $\frac{a^2 f}{c}$ where a is the radius of the radiating element of the transducer, f is the nominal frequency of the transducer, and c the speed of sound. The transducer beam is oriented normal to the reflecting surface by fixing at the angle which results in a maximum echo signal from the plate. The frequency of the generator is then swept throughout the transducer bandpass and the echo signal amplitude from the interface relative to the driving signal amplitude is plotted (Fig. 7.1.1-l). From the plot the frequencies f_1 and f_2 are determined where the echo signal is reduced to half the amplitude of peak response. The center frequency is then

$$f_c = \frac{f_1 + f_2}{2} \tag{4}$$

The fractional bandwidth is

$$BW = \frac{f_2 - f_1}{f_c} \tag{5}$$

It is important to maintain a constant input voltage from the pulse generator to the transducer for all frequencies.

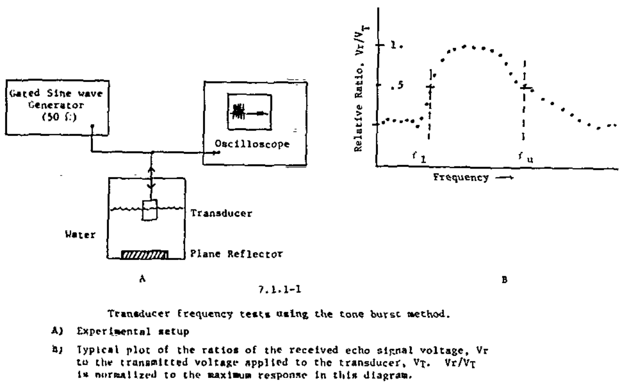

Figure 7.1.1-1

Transducer frequency tests using the tone burst method.

A) Experimental setup.
B) Typical plot of the ratios of the received echo signal voltage, V_r to the transmitted voltage applied to the transducer, V_T.

V_r/V_T is normalized to the maximum response in this diagram.

7.1.2 Zero Crossing Frequency (Ref. 3)

This method allows for crude estimates of transducer center frequency while the probe is connected to the pulser-receiver of the imaging system. The experimental set up for the transducer and reflector are the same as for the swept frequency test above. However, the transducer is excited by the pulser unit of the ultrasound imaging system. The echo signal waveform at the transducer terminals is applied to an oscilloscope using a low-capacitance probe. The amplitude, V_{max}, of the largest half cycle of the rf echo signal is measured and then consecutive half cycles (irrespective of polarity) having an amplitude of at least 0.3 V_{max}

are identified. The zero crossing working frequency, f_w, is given by

$$f_w = n/2t_n \quad (6)$$

where t_n is the time measured between the zero crossing points at the start of the first half-cycle and at the end of the nth half cycle.

The zero crossing method can introduce anomalies, particularly if ripples on the waveform do not register as zero crossings. Furthermore, center frequency obtained using this technique may differ by more than 10% from that determined by the swept frequency technique[14],

If it is not possible to measure the echo signal waveform at the transducer terminals, it can be measured at later stages of any rf amplifiers which are before nonlinear sections. To facilitate such measurements manufacturers are encouraged to provide test points on the instrument, if this is feasible, to allow access to the echo signal waveform.

7.1.3 Spectrum Analyzer

When using a spectrum analyzer for characterizing transducer frequency the probe is attached to the broad band pulser as above and an echo signal obtained from the planar reflector. The rf echo signal is applied through a delayed stepless gate to the spectrum analyzer. The delay and trigger settings on the gate are set so that only the rf pulse resulting from the first reflection of the planar interface is passed to the spectrum analyzer. Center frequency and bandwidth are taken directly from spectral plots. More details on this technique are found in Ref. 4. (An alternative system independent transducer test also employs a spectrum analyzer system in conjunction with a standard pulse generator-receiver whose characteristics are specified in Ref. 4.)

7.2 SYSTEM SENSITIVITY CONTROLS

7.2.1 Range Independent System Sensitivity Controls

Purpose: The purpose of these tests is to verify the calibrationof the gain, output, attenuator, or other calibrated controls which determine the system sensitivity. On those systems which do not have a calibrated system sensitivity control, it may be possible to provide a calibration for one or more of the sensitivity controls. Availability of controls which provide an accurate measure of relative system sensitivity is necessary for the majority of the remaining tests. For example, axial and lateral resolution are a function of the signal amplitude from resolution targets compared with the display threshold for those targets. Therefore, a calibrated system sensitivity control, or a calibrated external attenuator which may be inserted in the signal line, is necessary for resolution measurements just as it is for determining the system signal to noise ratio. Other system tests which do not depend on the transducer may be performed with a calibrated system sensitivity control or a calibrated signal source.

Measurements are most accurate and much simpler on ultrasound systems in which there is access to the transmitter line or a segment of the receiver line in which the signal is linear, i.e., the signal is proportional to the integrated pressure across the transducer. If such electrical access is not possible, calibration by purely acoustic means of varying the signal returned to the transducer is possible as outlined in section 7.2.1.2, but it is difficult to obtain accuracies of ±2 dB over greater than a 30 dB range.

7.2.1.1 Systems with Electrical Access

Materials: A calibrated rf attenuator, as described in Method 2 of Section 7.2.2 and in Section 7.5, is required. A high quality radio frequency attenuator is relatively inexpensive and at least as accurate as other techniques.* Its use will be described here. The use of active signal sources is quite similar.

Any stable source of relatively strong echoes is required when an attenuator is employed for this test. For example, the transducer can be held against one side of a small, e.g., 4 x 4 x 4 cm, block of acrylic plastic. This block can be coupled acoustically to the transducer and held tightly to observe a stable echo from the far side of the block. The recommended approach, when possible, is use of a stainless steel reference planar interface in water, as described under "Method," Section 7.3.1. This provides a strong signal which, with the use of external attenuators, allows calibration of the full range of all system sensitivity controls and provides data necessary for determination of the-system signal to noise ratio as described in Section 7.3.1. Use of the flat ends of a stainless steel cylinder is recommended, where the cylinder is approximately 6 cm in diameter and 10 cm long, with ends which are parallel to ±0.05° (±50 μm) and surface ground for smoothness of

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**There are many suppliers of accurate 50 ohm rf attenuators with convenient BNC or TNC connectors at a price of $100 to $180. Attenuators typically are available with an attenuation range of 82 to over 100 dB in 0.5 to 1 dB steps. Additional external attenuation may be desirable if the 82 dB attenuator is employed. Attenuators using thin film resistors may require a 10 dB attenuator placed between the pulser and the attenuator. The high peak voltages in the pulser may break down the thin film resistors even if the average power rating is not exceeded. Two common suppliers of rf step attenuators are Alan Industries, Inc., Columbus, Indiana, and Kay Elemetric, Pinebrook, New Jersey.

±1 μm and flatness of ±25 μm. Mechanical apparatus is required for changing the separation between the transducer and the stainless steel plate without changing the angle of the transducer. A gimbaled optical mount, linear slide and a few custom made transducer clamps can meet these requirements.

Procedure: The procedures for this measurement are given here in great detail as an example of the care required to make measurements of reasonable accuracy and as an example of the problems which often are encountered. The result of these tests is a plot of the system sensitivity control setting required to provide a standard echo deflection as a function of absolute signal amplitude relative to the signal from a perfect planar reflector. Multiple curves are recommended which give the settings on the most accurate system sensitivity control as a function of signal amplitude for different positions of the other system sensitivity controls. These procedures are summarized below as Steps l-5.

Most of this section concerns the determination of the absolute signal level relative to the signal from a perfect planar reflector. This absolute information facilitates reproduction of the results by others and provides the necessary basis for signal to noise ratio determinations (Section 7.3.1) essentially simultaneously with the calibration of sensitivity controls. If only a crude calibration of a system's sensitivity control is desired, ignoring the possibly large effects of the absolute signal amplitude and effects of other control settings, Step 2 below can be replaced by setting the external attenuator at an initial value of 20 dB, so A_M in Step 4 is equal to 20 dB, Steps 3 and 5 would then be deleted.

The following summary of the procedural steps will prove useful in understanding what each procedure is accomplishing. The detailed instructions follow this summary.

Step 1: Alignment of the transducer with the water-stainless steel interface and adjustment of the transducer-to-interface distance for a maximum signal.

Step 2: Determination of the need for, and magnitude of, a minimum external attenuation setting A_M or minimum "actual" external attenuation A_{MA} required to match impedances so that subsequent changes in external attenuator readings are accurate.

Step 3: Measurement of the total actual insertion loss L of the external attenuator while set at the minimum setting A_M and with any associated terminations.

Step 4: Calibration of "Control #l", the system sensitivity control which is believed to be the most calibrateable, or most accurate.

Step 5: Determination of the effect of other system sensitivity controls on the calibration curve of control #1,

Electrical Setup: Insert an external rf attenuator and appropriate termination at a point where the signal is linear. Two common connections are diagrammed in Figure 7.2.1.1-l. Attenuators of 50 ohm impedance usually are recommended. If the receiver is a high impedance receiver, the 50 ohm resistor to ground in the top diagram in Figure 7.2.1.1-l should provide rigorously accurate measurements. When separate access to the pulser and receiver are not available, the bottom diagram in the figure is recommended. In this case, the individual round trip attenuation is twice the reading on the attenuator settings. The term "actual external attenuation" will be employed frequently in this context throughout this section. See Appendix 1 for further discussion of matching of rf attenuators.

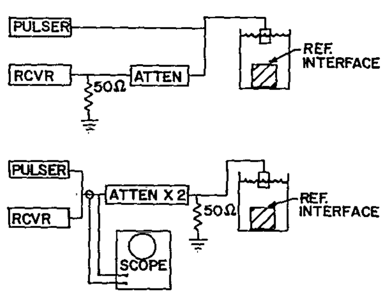

Fig. 7.2.1.1-l Configuration for calibrating system sensitivity controls.

<u>step 1:</u> Set the transducer in degassed water, aimed at the top of the stainless steel plate. Move the transducer to a distance of $S/\pi\lambda$ from the interface for unfocused transducers (S = surface area of the active aperture) and to the approximate focal length for focused transducers. Adjust the angle of the transducer alternatively on each of two orthogonal axes until the maximum signal is obtained from the stainless steel plate. This will require frequent reductions in the system sensitivity controls and possible use of external attenuators.

With focused transducers, increase and decrease the transducer distance from the water-stainless steel interface to determine the range at which the echo signal is a maximum. When an apparent maximum is determined, readjust the transducer angulation to ascertain that the signal is a maximum. Recheck the range (transducer to interface distance) to see that the signal is maximized. Repeat these procedures until no further increase in echo signal can be attained. Record the transducer to reflector distance.

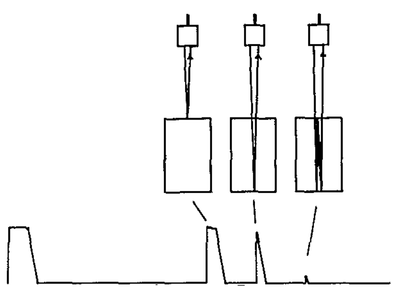

Fig. 7.2.1.1-2 Shown from left to right at the bottom are the transmitter complex, the A-mode signals from the first echo from the water-stainless steel interface, the first echo from within the stainless steel cylinder and the second echo from within the stainless steel cylinder. A schematic diagram of the corresponding sound paths is shown above. In this case the relatively strong first reverberation from the stainless steel, to the transducer, to the stainless steel and back to the transducer would be just off the diagram to the right. The first echo from within the stainless steel (middle diagram) should be greater than 18 dB below the first echo from the water-stainless steel interface (on the left).

Step 2: A calibrated external attenuator nearly always will provide accurate readings of changes in attenuation at attenuations above a certain minimum attenuation setting A_M. To determine that minimum setting is the subject of this test.

Set the swept gain to zero slope and all swept gain and other system sensitivity controls at recorded, repeatable positions. Set the external attenuator to 6 dB attenuation and observe the A mode signal from the second echo from within the stainless steel cylinder. See Figure 7.2.1.1-2.

Change one or more of the system sensitivity controls until a one division or 1 cm A mode signal is obtained from the second reverberation echo. See Figure 7.2.1.1-3. For short transducer to reflector distances the reverberations between the reflector and transducer may interfere with these measurements. The distance to the reflector then should be-adjusted slightly. It may be-necessary to set the range dependent system sensitivity controls for minimum sensitivity at all ranges and then adjust the output or gain to obtain the one division A mode deflection.

Change the round trip external attenuation from 6 to 0 dB and record the A mode amplitude from the second echo from within the cylinder. Define this deflection as D_1. The term "actual external attenuation" is defined in the first paragraph of these procedures.

Insert external attenuation until a one division A mode deflection is obtained from the first echo from the water-stainless interface. Reduce the external attenuation for an actual 6 dB reduction and observe the A mode amplitude D_2. D_2 should be as close to D_1 as the change in D_2 caused by addition or subtraction of an actual 1 dB attenuation on the external attenuator. If so, no minimum attenuation is required for accurate readings and $A_M = 0$.

If D_2 is not within 1 dB of D_1, increase one of the range independent system sensitivity controls by approximately 3 to 20 dB, and repeat the above tests. That is, set the external attenuator to the setting which will provide a one division A mode deflection from the second echo from within the stainless steel cylinder. Remove 6 dB of actual external attenuation and determine the A mode deflection amplitude D_1. Measure the deflection D_2 again using the first echo from the water-stainless steel interface and determine whether it is within 1 dB of D_1. If not, continue increasing the range independent system sensitivity control in 3 to 20 dB steps and repeat the above process until the A mode amplitude D_2 is within 1 dB of the A mode amplitude D_1. When this condition is

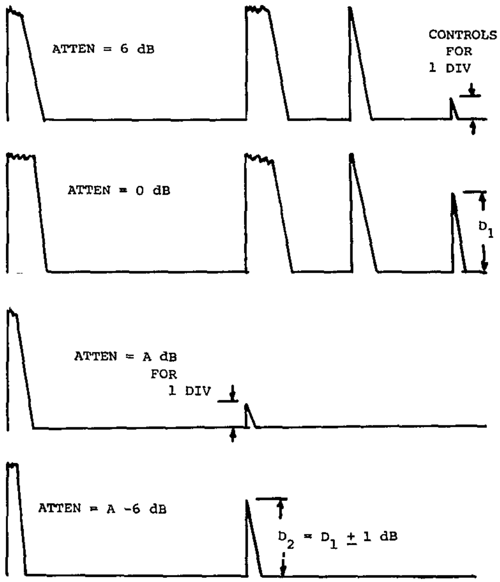

Figure 7.2.1.1-3. A mode displays in procedure (step c) to determine if a minimum external attenuation setting A_M is required. In finding setting A_M, the tests are similar but the external attenuator settings are all increased a fixed amount.

reached, record the external attenuator setting A_M as the minimum attenuation setting which must be left on the external attenuator for the external attenuator to provide calibrated attenuation changes.

Step 3: The loss in signal amplitude due to insertion of the attenuator and termination also should be determined if signals and the noise level are to be calibrated accurately relative to a perfect planar reflector.

This insertion loss, L, includes a fixed insertion loss plus the true attenuation due to the attenuator setting A_M. To measure L, remove the external attenuator and termination from the circuit and determine the system sensitivity settings which will provide a one division A mode deflection from the second echo from within the stainless steel cylinder. This may require setting of the range dependent as well as range independent controls at or near minimum system sensitivity levels. If necessary, the one division A mode deflection referred to here might be replaced by a larger deflection. Record the position S_1 of the most calibrated range independent system sensitivity control, control #l. Replace the attenuator and termination in the signal line with the attenuator set at 0 dB, or set at A_M attenuation if A_M was nonzero. Adjust the same control #l to settings S_2 at which a one division A mode deflection is obtained from the same echo used in the previous measurement with the attenuator present.

The insertion loss L equals the true change in sensitivity between settings S_2 and S_1. To measure this change, observe the first echo from the water-stainless steel interface with control #1 still set at S_2 and adjust the external attenuation until the A mode deflection is one division. Record that external attenuator to that setting A_1 at which a one division A mode deflection is obtained from the first echo from the interface.

The total insertion loss L is given by

$$L = A_2 - A_1 \text{ dB}. \tag{7}$$

Step 4: To calibrate a range independent system sensitivity control, select the range independent system sensitivity control which is believed to be calibrated the most accurately. Define this control as control #1. Set all range independent and range dependent system sensitivity controls so the ultrasound system is as insensitive as possible. Adjust the external attenuator to obtain a one division A mode deflection from the first echo from the water-stainless steel interface. If it is not possible to obtain a one division A mode deflection, increase the system sensitivity with one of the controls

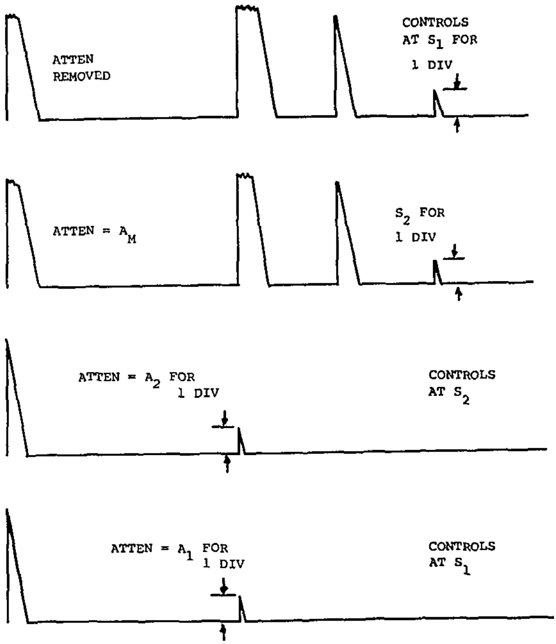

Figure 7.2.1.1-4. A mode displays in procedure to determine insertion loss L of external attenuator set at A_M. $L = A_2 - A_1$ dB.

other than control #1 to obtain a one division A mode deflection with the external attenuator set at A_M.

Change the settings on control #1 in steps equal to approximately 1/10 the range of control #1. It may be necessary to tape polar coordinate graph paper behind continuously variable controls which do not have up to ten calibration markings on the control panel. At each control setting, determine the external attenuation required to provide a one division A mode deflection from the water-stainless steel interface. Plot the resulting curve of settings on control #1 as a function of "actual" external attenuator settings. Note the positions of all the other system sensitivity controls. Place a second set of labels on the abscissa below the external attenuator settings which give the signal S to the receiver relative to the signal from a perfect planar reflector in dB. $S = -A_A - A_F - E$, where $A_A - A_{MA} + L$ is the true total attenuation from the external attenuator termination. A_A is the "actual attenuation" equal to the setting A or 2A, A_{MA} is the "actual attenuation" corresponding to A_M ($A_{MA} = A_M$ or $2 A_M$) and E is the ratio in dB of the signal from a perfect planar reflector to the signal from the planar reflector employed in this test. The echo from a stainless steel plate in degassed water at room temperature is 0.6 dB below the echo from a perfect planar reflector, so E is + 0.6 dB for a water-stainless steel interface.

Step 5: To check that the calibrated control #1 is not affected by the positions of the other system sensitivity controls, change each of the system sensitivity controls, other than control #1, to its maximum sensitivity setting and repeat several points at the extreme ends of the calibration curve of control #1. If the total range of sensitivity change covered by control #1 is different when any or all of the other system sensitivity controls have been changed to positions of maximum sensitivity, then one or more families of curves should be plotted for control #1 as a function of the other system sensitivity controls. An example of a system sensitivity control calibration in which such a family of curves was required is given in Ref. 15. A similar example for a late model ultrasound scanner is presented in Figure 7.2.1.1-5.

The swept gain calibration of Section 7.3.2 and the A mode and B mode gain characteristic determination of Section 7.5 also may be a function of signal amplitude at the input to the receiver. It is convenient at this point to use the apparatus already set up to carry out the calibration of the swept gain and A mode characteristic curve obtained at the different range independent system sensitivity settings. B mode display characteristics, being relatively difficult to perform are best carried out only once using signal levels beginning near the system noise level.

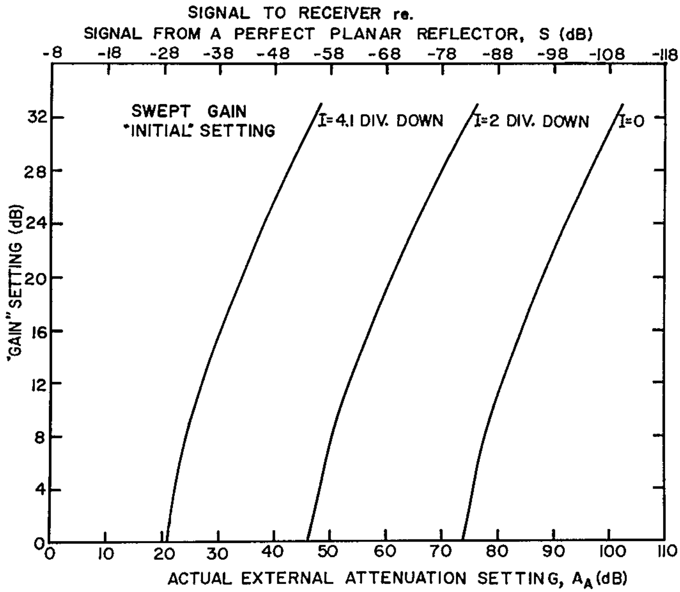

Figure 7.2.1.1-5

Example of calibration of the main system sensitivity setting (the "gain" setting) on an ultrasound scanner (Unirad Sonograph III EP). The gain setting required to produce a one division A mode response from the echo from a stainless steel-water interface is plotted as a function of the signal to the receiver relative to the signal from a perfect planar reflector. The experimental configuration was that diagrammed in the lower section of Figure 7.2.1.1-l.

7.2.1.2 Acoustic Calibration

Purpose: In systems in which access is not available to a linear portion of the signal line, acoustic calibration is possible, but requires extreme care.

Materials: The acoustic gray wedge described in section 7.5.2 and Ref. 16 can provide echo signal amplitudes varying over a 60 dB range. The wedge must be calibrated with a transducer having the same aperture, focusing and frequency characteristics as the one employed for the instrument calibration.

Planar blocks of various materials with differing reflection coefficients can be calibrated with any ultrasound unit operating in the general frequency range of a unit to be tested[17]. This method is described further here. Specific materials include planar samples, at least 6 mm in thickness, 6 cm on a side, and of varying reflectivities, such as a stainless steel, glass, acrylic, polystyrene, polyethylene and materials that match very closely to water. Among these are Dow-Corning SYLGARD 170 electronic potting compound.

Method: To calibrate the relative reflectivities of the interfaces between water and the above planar samples, a calibrated ultrasound unit is employed with the interfaces at a fixed distance from the transducer. The transducer is angled for a maximum reflection from each interface at the time of measurement on that interface, and the temperature of the materials is measured to be sure it is the same as that in the surrounding water. This usually requires equilibration over night in the water. The relative signal amplitude from each reflector is measured using the most accurate system sensitivity control on the calibrated ultrasound unit. These relative signals can be quoted in relation to the signal from a perfect planar reflector if it is noted that the signal from the water-stainless steel interface is 0.6 dB below that of a perfect reflector.

To calibrate one of the system sensitivity controls on the ultrasound unit of interest as a function of echo amplitude, the transducer is aligned normal to each of the reflectors at a standard range in degassed water at the same temperature as was employed for calibration of the reflectors. Insertion of a sheet of attenuating material in the water between the transducer and reflectors may be necessary to place the signal at a measurable level on the ultrasound unit under test. The attenuating sheet should be normal to the ultrasound beam and not be touching the reflectors or the transducer. The system sensitivity control setting to obtain a standard A mode or B mode display level (one division A mode echo or B mode display threshold) is determined as a function of the relative signal amplitude from each of the reflectors.

To cover a wider range of echo amplitudes than is available from the reflectors, additional sheets of attenuating material are inserted between the transducer and reflectors and the measurement of system sensitivity settings as a function of relative signal amplitude is repeated. The system sensitivity settings iii this part of the calibration must overlap with the settings employed when less attenuating material was placed between the transducer and reflectors. If possible, additional attenuating material should be added and this process repeated as many times as possible.

System sensitivity setting as a function of relative signal amplitude is plotted for the data in which a minimum amount of attenuating material was placed in the ultrasound beam. If measurements were accomplished with no attenuating material, the relative signal amplitude can be quoted as the signal relative to the signal from a perfect planar reflector. On the same graph the data points from the next set of data with (more) attenuating material interposed is plotted such that points measured with system sensitivity settings less than the maximum system sensitivity settings utilized in the first set of data lie on the curve established by the-first

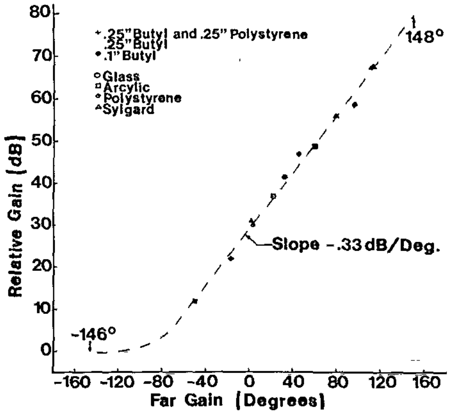

Figure 7.2.1.2-l

set of data. This essentially is a calibration of the attenuation provided by the attenuating material. This process is repeated for any additional sets of measurements of different amounts of attenuating material in the ultrasound beam. An example of this calibration is given in Figure 7.2.1.2-1, where the thickness of butyl and polystyrene attenuators are given as well as the type of reflecting material such as glass.

7.2.2 Range Dependent (Time Gain Compensation, Swept Gain)

Purpose: Swept gain is applied to the receiver in order to compensate for attenuation of the ultrasonic beam in tissue. Average ultrasonic attenuation in the soft tissue of some patients appears to be as high as 1 dB/cm for 1 MHz beams and is approximately proportional to frequency. Thus, for pulse echo imaging, swept gain rates ranging from 0-2F dB/cm where F is the frequency in MHz, are needed. Higher rates may be desireable, for example, to compensate for "body wall attenuation" in the first few centimeters below the skin surface or to enhance the sensitivity over a selected range interval in echocardiography studies. Both the available swept gain rate and the total range dependent gain change available should be assessed. The measurement techniques presented below allow these quantities to be determined for specific control settings.

Method 1: (Refer to AIUM Standard 100 mm test object[1], also reference 18). This technique utilizes a test object or phantom having an arrangement of parallel rods or nylon lines spaced at known distances from the transducer. The ultrasonic transducer is coupled to the test object or phantom, with the beam directed perpendicular to a vertical row of targets. The transducer is aligned so that the axis of the beam passes through each line target. With the swept gain off, the range independent sensitivity setting necessary to display an echo signal at a preset amplitude is recorded for each target, along with the target depth. Swept gain is now applied, and the measurements are repeated for each target. The difference between the range independent sensitivity settings found with and without swept gain is plotted as a function of target depth. The curve allows the swept gain rate to be determined (Fig. 7.2.2-l). Tests should be carried out using the maximum available swept gain rate and using a series of appropriate, repeatable settings. For the maximum setting, the total swept gain available should be determined in a similar fashion.

Method 2: An electronic burst generator may be employed as a source of simulated echo signals, rather than the acoustic targets employed in the above method[11,12]. The electronic generator replaces the transducer in the pulser-receiver system. The unit emits a continuous wave or pulsed signal train in response to the excitation pulse normally applied to the transducer. Echo signals at prescribed depths may be measured both with swept gain off and with swept gain applied as in the previous method. Alternatively, electronic burst

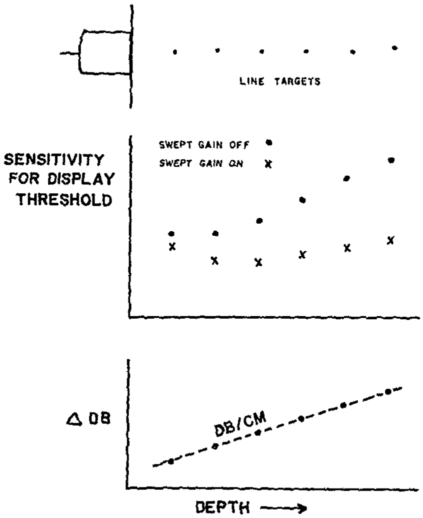
LINE TARGETS
SWEPT GAIN OFF
SWEPT GAIN ON
SENSITIVITY FOR DISPLAY THRESHOLD
Δ DB
DB/CM
DEPTH

Figure 7.2.2-1

generators are available with calibrated exponential signal decay factors.* (Fig. 7.5.1-l). This feature may be used to calibrate swept gain by adjusting the gain controls to produce an A mode signal display which is constant with depth (time) for a known pulse burst attenuation factor. When this is achieved the swept gain rate is equal to the rate of signal decay.

7.3 SYSTEM SIGNAL TO NOISE RATIO, RELATIVE SENSITIVITY OF THE DISPLAY MODES AND UNIFORMITY OF SEQUENTIAL ARRAYS

7.3.1 System Signal To Noise Ratio Using Reference Planar Reflector

Purpose: To assess the ability of the ultrasound system to detect low level echo signals in the presence of noise. Perhaps the most critical factor in ultrasound system performance is the system signal to noise ratio, or weak echo detection ability, at the frequencies of interest. Achievable performance in this area is changing rapidly, and many systems do not perform at state of the art levels of sensitivity. Also, electromagnetic interference limits system sensitivity in many hospital environments, so it is essential that system sensitivity (signal to noise) measurements be made during acceptance tests. These should be obtained for every transducer supplied with the system.

Method: The AIUM Standard on Echoscope Sensitivity and Noise Level will be employed here[2]. All measurements are referenced to a perfect planar reflector (reflection coefficient equals one). A water-air interface represents such a reflector. For measurement purposes, a "working interface" where the reflection coefficient is known with respect to the plane perfect reflector may be employed. For example, for a degassed water path at 22°C, a water-stainless steel interface has a reflection coefficient 0.58 dB below the perfect reflector. The AIUM Standard specifies a flatness of ±0.025 mm and a surface finish roughness of less than 1μ for the stainless steel plate. Use also may be made of a water-carbon tetrachloride interface, also included in the 1979 Interim Revision to the AIUM Standard. At 24°C, such an interface has a reflection coefficient 43.5 dB below a perfect reflector. Care should be taken here, since the reflection coefficient of this interface is a strong function of temperature.

The transducer is positioned normal to the planar interface at a distance equal to the pulse echo focal distance for the transducer as determined by finding the range of maximum signal from the planar interface. All swept gain and nonlinear gain controls such as "reject" are set to zero (0). A calibrated sensitivity control described in 7.2.1 above then is adjusted to place the echo signal from the Planar interface to a given preset amplitude on the A mode display

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*Eg. Victoreen-Nuclear Associates, Inc., 100 Voice Road, Carle Place, New York 11514, and Wolf Ingeneuring now called ATA Corporation, 2600 West 2nd Avenue, Denver, Colorado 80219.

and to the level at which it is just barely discernible on a B mode image*. These selected display amplitudes are termed the "standard echo deflections." Sensitivity controls are then adjusted so that noise is displayed on the A mode or B mode displays at the same signal strength as obtained from the planar perfect reflector above. The A mode and B mode signals to noise ratios are then X_A and X_B dB where the X's are the differences in sensitivity settings required to display the perfect reflector and the noise signals at the same preselected amplitudes on the display modes.

More accurately, if the system is still set up for calibration of system sensitivity controls according to procedures in Section 7.2.1, X_A is equal to -S of Step 4 in that section, with a slight modification. S is defined here as minus the total actual external attenuation required to reduce the signal from a perfect planar reflector to the signal level of the A mode system noise when external attenuation is removed. For this measurement, system sensitivity controls are set at any level where the amplitude of the A mode noise is measurable. The B mode signal to noise ratio is measured analogously.

If there is insufficient amplifier gain to raise the noise level to a discernible echo deflection whose amplitude can be measured, the statement may be made that the signal to noise ration in A and B modes is better than X_A and X_B dB, respectively.

Noise, in the sense that it is used here, may be a random noise covering a broad frequency range or may be signals which are either synchronous or asynchronous with the system pulser. In the former case, the A mode noise will appear as a uniform bright band in which occasional random peaks may be discernible. The amplitude of this random noise level should be measured at the point where the luminance of the display appears to be the same as that of the echo from the standard planar interface. This is accomplished best by adjusting the display intensity to the level where the echo from the planar interface is barely discernible. A similar criterion can be used with random noise in B mode and with noise which is synchronous with the pulser. Noise which is neither random nor synchronous with the transmitter pulses should be measured when the amplitude of that noise is equal to that from a perfect planar reflector, even though the temporal or spatial density of such noise may be relatively low. Measurement of the level of coherent noise which is asynchronous with the pulser can be accomplished accurately on an external signal line using an oscilloscope which is triggered by the noise, The

*This test with a very strong reflector may require use of a series of measurements including the use of nonlinear and uncalibrated controls or external attenuators. See Section 7.3.3 for test using an external attenuator. A weak reflector such as a nylon line can be employed to determine the insertion loss of an external attenuator or the effective attenuation of uncalibrated controls.

signal to noise ratio should be quoted for each of the above types of noise which is discernible.

7.3.2 Baseline Data for Future Quality Assurance Checks

Use of a very small reflector as a "standard target" producing a weak signal is not recommended in this document because a signal from small reflectors is a much stronger function of transducer beam pattern than is reflection from a planar reflector, or scattering from a uniform volumetric distribution of small scatterers. The volumetric distribution usually is the weakest source of echoes of primary interest in gray scale imaging. However, tests of consistency of equipment sensitivity may be performed using a small, weakly reflecting target, such as a rod in the AIUM test object, or even a smaller rod[1]. With swept gain controls in known, repeatable positions, the sensitivity is adjusted to display an echo of a predetermined signal level in A mode or at the "barely discernible" level in B mode, the B mode display threshold. The sensitivity setting thus obtained with a rod in a known location is recorded for future quality assurance checks. (Also see Section 7.3.4.)

7.3.3 Tests for System Signal to Noise Ratio Using Acoustic Attenuation of the Echo from a Planar Target

Introduction: With many commercial ultrasound systems, the limited range of system sensitivity controls makes impractical the use of a planar reflector in water as a means of field measurement of system signal to noise ratio. To measure the system noise level conveniently on such systems, echoes from planar interfaces can be reduced to a value near the system noise level by interposing an attenuating medium between the transducer and reflector interface. Absolute quantification of the attenuation interposed presents difficulties because the attenuation varies with the frequency of the ultrasound, and the temperature of the materials. In addition, an ultrasound pulse is comprised of a range of frequencies and the attenuation characteristics of that pulse are not always represented easily by a single frequency specification such as the center frequency. For example, if an ultrasound pulse is at a frequency 10% different from the assumed frequency, it will undergo 10% more or less attenuation than the expected value if the attenuating material is a solid, such as acrylic, with a linear frequency dependence. If 80 dB of attenuation is provided by the acrylic block, the deviation from the expected signal level due to an imprecise knowledge of frequency would be approximately 8 dB. Moreover, "beam hardening", or preferential attenuation of higher frequency components of the pulse, results in a lower frequency, more penetrable beam at depth. Since the maximum range at which tissue structures in the body can be visualized also is a relatively strong function of transducer frequency, use of an attenuating material in a practical or secondary method of evaluating system sensitivity has some merit. See the subsequent paragraph on "accuracy" for a comparison of using a signal to noise ratio which is dependent on the test object as opposed to calibrating the-attenuating test object to give a signal to noise ratio referenced to the standard perfect planar reflector in water.

One device which has been used for many years as at least a relative test of system sensitivity has been an acrylic block with parallel sides. The transducer is placed against one surface and the relative echo amplitude from the other surface is measured or the number of reverberations discernible in the block is quoted. Procedures for employing a large acrylic block as a practical test of the system signal to noise ratio are given in the following section. However, test blocks constructed of an acrylic block bonded to a urethane block are being developed as a future alternative to a single-acrylic block.* This two part system can be constructed such that the attenuation is relatively independent of temperature over any reasonable range near room temperature.

Materials: An acrylic block or rod is recommended which has lateral dimensions at least 5 cm by 5 cm, or 5 cm in diameter, and a length designed to give the desired attenuation. Data is provided in Table 7.3.3.-1 for a 16 cm block, diagrammed in Figure 7.4.1-i. The surfaces at each end of the block must be-parallel and meet the flatness and smoothness specifications of the reference planar reflector.

More accurate methods of measuring the signal to noise ratio of the system in the A mode display are described in more detail in reference 3.

Procedure: The transducer is coupled with a generous amount of coupling gel or oil to one side of the block to display the echo from the other side, 14 or 16 cm away. The 16 cm side is employed when operating at 2.2 MHz and 3.5 MHz and the 14 cm side is employed with 3.5 MHz and 5 MHz systems. The side of the block employed should be chosen so that the echo can be imaged at the display threshold by adjustment of the range independent sensitivity control. This test may require use of the swept gain (TGC) controls-(including the delay) at values allowing for minimum or maximum system sensitivity. If the echo is still too strong one side of the block can be supported by plastic legs in a container of degassed water. This will reduce the echo from the submerged side of the block by 9 dB.

(a) Control settings should be as follows: Display, swept gain and function controls at known, reproducible settings. Reject or suppression at zero.

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*ATS Laboratories, Box 792, South Norwalk, Connecticut 06856, and Hoffrell Instruments, Inc., Moody's Lane, Norwalk, Connecticut 06851.

(b) The system sensitivity control(s) is adjusted so that the echo from the far side of the block is just barely displayed in B mode. The coupling gel should be checked to assure that the echo cannot be displayed at a reduced sensitivity setting, with a scanning speed of 1-3 cm/sec. Record the threshold sensitivity setting(s).

(c) The system signal to noise ratio may be determined by recording the maximum sensitivity setting(s) available. If no electronic noise is visible on the display when scanning at the maximum system sensitivity, the signal to noise ratio for this system and acrylic block (reflector-absorber) is quoted as "greater than X dB." X is calculated as the difference between available sensitivity setting and the display threshold setting(s) in step (b) above. If electronic noise is displayable, the maximum system sensitivity settings at which the electronic noise is just barely visible in B mode are recorded. The difference in decibels between the net system sensitivity settings determined in this step and the net settings in step (b) above is the signal to noise ratio for the system and the acrylic block employed. When possible, this signal to noise ratio should be used to calculate approximately the standard signal to noise ratio which would result from use of a standard perfect planar reflector in water.

Accuracy: The signal to noise ratio measured with an acrylic block of specified dimensions and temperature should be accurate to approximately ±6 dB for comparison of systems including transducers with the same nominal frequency, bandwidth characteristics, diameter and focal length. It is less accurate, but an acrylic block signal to noise ratio also can he calibrated relative to the "Standard Signal to Noise Ratio" for a perfect planar reflector at the standard working distance in water. The calibration should be accurate to approximately ±20% if it is performed with a transducer and electronics in which the sensitivity controls, center frequency, bandwidth, focal length and transducer diameter each are accurate to at least ±10%. More accurate calibrations of an acrylic block can be obtained when: 1) they are performed on a given model of transducer and a given model ultrasound instrument with sensitivity controls calibrated to several dB accuracy; and 2) the calibration is applied to measure the signal to noise ratio of another instrument and transducer of the same model, and meeting other relevant acceptable levels. A few calibration factors are given in Table 7.3.3-l for the acrylic block of Figure 7.4.1-1.

Table 7.3.3-1

SIGNAL FROM FLAT END OF 16 cm TRICK ACRYLIC BLOCK AT 22°C
RELATIVE TO THE SIGNAL FROM A PERFECT PLANAR
REFLECTOR AT THE FOCAL PLANE IN WATER

Transducer	Relative Signal
3.5 MHz, 13 mm, 7 cm Focus, 40% bandwidth	-73 dB
2.3 MHz, 19 mm, 9 cm Focus, 40% bandwidth	-57 dB
2.3 MHz, 13 mm, 6 cm Focus	-63 dB
5.0 MHz, 13 mm, 7 cm (Medium) Focus	-101 dB

Temperature Correction: An acrylic block attenuates the sound more as the temperature increases. If room temperature varies by more than 3°C (5°F) the following corrections should be made:

For each degree Celsius (Farenheit) above or below the standard block temperature decrease or increase the system sensitivity settings by the following amount:

0.75 (0.42) dB at 2.2 MHz on the 16 cm side.

0.70 (0.39) dB at 2.2 MHz on the 14 cm side.

1.1 (0.61) dB at 3.5 MHz on the 16 cm side.

1.0 (0.56) dB at 3.5 MHz on the 14 cm side.

Example: Using the 16 cm side at 2.2 MHz, the temperature is 5°C cooler than normal, resulting in a stronger than usual echo. The threshold for displaying the echo from the side-of the block was obtained at 23 dB of gain, so add 0.75 x 5 = 4 dB yielding 27 dB as the gain that would have been required to display the echo at the standard temperature.

7.3.4 Use of Volumetric Scatterers Imbedded Within Tissue Equivalent Material

The ultimate test of the sensitivity of an ultrasound imaging system is the ability to detect weakly reflecting targets in tissue. Certainly this ability is expected to be related directly to the sensitivity as measured in 7.3.1 above. However, other parameters, including the sensitivity as a function of range and the frequency and bandwidth of the system (while the sensitivity is at a maximum setting) also enter in. The relationship between these parameters and the ability to detect echoes from weakly reflecting targets in tissue is not straightforward.

Progress is being made rapidly on the development of meaningful tests employing tissue equivalent materials as measures of system sensitivity. One such phantom employs powdered graphite imbedded in a water based gel matrix.*[10,19] The powdered graphite serves both to control ultrasonic attenuation in the phantom and to provide low amplitude backscattered echo signals. The system sensitivity determines the maximum range in the sample at which backscattered echo signals are detectable.

To determine such a "depth of penetration" gain controls are adjusted to provide echo signals as far as possible into the phantom. Depth of penetration is estimated on the image as the maximum depth at which echo signals resulting from scatter within the phantom appears with a dense enough texture to allow detection of a real or imaginary 1 cm diameter cylinder of nonscattering material whose axis is normal to the scan plane. This is shown in Figure 7.3.3-l for a 3.5 MHz, 13 mm diameter transducer. Two notes of caution should be

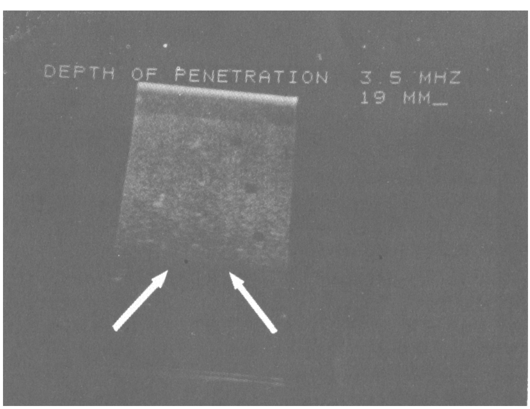

Fig. 7.3.3-l Depth of penetration (arrows) in a tissue phantom for use in determining consistency of system sensitivity.

*Available from Radiation Measurements, Inc., P.O. Box 44, Middleton, WI made. First, the scatter characteristics of the present version of the tissue phantom are temperature dependent and are of weaker amplitude and different frequency dependence than typical liver tissue. Consequently, the penetration depth determined using this test does not transfer directly into a depth of visualization in human liver scans. Except for effects of transducer focusing and beam divergence, the range of visualization for the phantom should be a fixed distance shorter than that in liver at a given transducer frequency and temperature. Secondly, at any depth within this phantom a range of echo signal amplitudes is detectable. The ability to visualize echoes at a given depth depends upon the image display characteristics of the machine. In addition, such a measure also is a subjective assessment and consequently may differ to some extent from individual to individual for the same machine. Despite these difficulties, with further experience and more quantitative measures of scattering becoming available on some digital scanners, tests with volumetric scatterers should become the ultimate test of effective system sensitivity for gray scale general purpose scanners. Certainly, the range of imaging volumetric scatterers in an attenuating medium provides a rapid check of system sensitivity without the difficulties of aligning the transducerwith a single target.

7.3.5 Relative Sensitivity of Various Display Modes

Introduction: The relative sensitivity of various display modes and display and recording devices is determined here by recording the sensitivity settings required to obtain a barely discernible display on each display and recording device. The relative sensitivity of the various display and recording devices is a critical factor-in the effective and efficient operation of diagnostic ultrasound systems. For example, one of the greatest chances of loss of important diagnostic information occurs when the recording medium, such as photographic film or strip chart recording, requires a higher system sensitivity to display the same echo than is required by that display which is used by the operator during examinations. Similarly, A mode displays can be used by experienced operators to obtain additional information from particular structures which are being scanned in B mode. For this to be practical, however, a change in the system sensitivity should not be required to display approximately the same range of echo amplitudes in the A mode as is viewed in. the B mode.

Materials and Procedure: Any stable source of echoes from a single interface or from volumetric scatterers may be employed for this test. For simplicity, it is recommended that this test be performed at the same time as the system signal to noise ratio measurements of Section 7.3.1, 7.3.2 or 7.3.3. The system sensitivity settings are determined which allow the chosen reflector to be imaged at the display threshold for each display and recording device. Any significant differences in these sensitivity settings should be noted and the reasons for the differences accepted or the differences corrected.

7.3.6 Uniformity Tests of Real-Time, Parallel Beam Linear Arrays

Introduction: The flat surface of the sensitivity and resolution test-object of Fig. 7.4.4-1may be used to assess uniformity of the system response along the length of parallel beam linear arrays. It is assumed that a real-time array should image a uniform, flat surface as a line of reasonably uniform brightness, i.e., with the same display threshold along the length of the interface.

Procedure: A generous amount of coupling gel is placed on the transducer which is positioned with its face up on a level, sturdy surface. It may be necessary to use some masking tape to hold the cord steady. The uniformity block is carefully set on the transducer face. The presence of even a few air bubbles of moderate size will invalidate the test. Thus, the transducer-block interface must be observed to verify that there is uniform acoustic contact. With a generous amount of gel this is usually easy to attain. The swept regain (TGC) is adjusted so that the slope is flat or at some other reproducible setting. The rejection is set to zero and other signal processing or display controls are set to reproducible positions.

Nonuniformities in transducer response are visualized and quantified most accurately when the system sensitivity is adjusted so that echoes from the flat surface of the block are barely perceptible. For 5 MHz transducers, the 14 cm length of the block is used, and for 3.5 and 2.2 MHz transducers, the 16 cm length is employed. The echoes from the far surface of the block may be so strong that they are displayed even at the lowest system sensitivity settings (including use of lower swept gain settings). If so, and if the 14 cm length of the block is being employed, the 16 cm length should be used. If the signal still is too strong, the block may be set on its acrylic legs in a pan of room temperature water which is degassed.

The system gain or sensitivity setting required to detect the strongest echoes from the far block surface at the display threshold is noted. The sensitivity is increased until the weakest segment of the echo line from the far wall of the block is discernible. The difference between the settings for the strongest and weakest signals is the array nonuniformity. The degree of nonuniformity which is accepted will depend on experience with the model of equipment being tested; however, a 6 dB nonuniformity usually is noticeable clinically and should be adjusted.

7.4 GEOMETRICAL RESOLUTION

7.4.1 Axial or Range Resolution

Purpose: These tests are designed to test the system resolution along the axis of the ultrasound beam, i.e., the direction of travel of the ultrasound pulse. The axial resolution nearly always is the best resolution achievable with pulse echo systems, and its determination at various fields-of-view during recording of the display allows evaluation of the transducer and signal processing, the image recording system (scan converter) and the display and hard copy recording.

Test Materials: Reflectors can be two or more single interfaces or monofilament lines of diameter no greater than 0.4 times $\frac{1.54}{f}$ mm, where f is the center frequency in MHz of the ultrasound transducer studied. Planar films also may be used if their thickness is less than 0.2 times 1.54/f (nun). The speed of ultrasound in the medium between the reflectors should be 1480 to 1570 m/sec, or corrections should be made for the speed of sound in that medium.

Solid-Solid and solid-fluid interfaces have been used effectively for these reflectors as have stainless steel wires and nylon and other polymer monofilament lines. Arrangements should be made to aid alignment of the ultrasound beam axis perpendicular to the reflectors, and the spacing between the reflectors should be known or calculable.

A continuous change in the reflector spacing is preferred because of the quasicoherent nature of the ultrasound pulse and signal processing. For continuously variable spacing, the reflector separation should not vary by greater than 0.3 mm per cm of distance normal to the ultrasound beam axis. If discrete reflector spacings are employed, reflector spacings should change in increments-of no greater than 0.3 mm, up to a spacing of 2.5 mm. If more than two reflectors are spaced along the beam axis, correction should be made for shadowing by overlying reflectors.

Measurements should be made with the reflectors at a distance equal to or greater than the focal length of the transducer in the medium between the transducer and the reflector. Additional measurements at shorter transducer to reflector spacings also may prove useful if the equivalent transducer to reflector distance in tissue is quoted. The material between the transducer and reflectors can be essentially unattenuating as in the case of water or it can be attenuating material with specified attenuation no greater than 2.4 dB $cm^{-1}MHz^{-1}$ times F, where F is the focal length of the transducer in a material with speed of ultrasound propagation equal to 1540 m/sec.

A recommended test object for axial resolution measurements is diagrammed in Fig. 7.4.1-1*. The 14 cm dimension may be as small as 4 cm and the thermometer is optional for axial resolution measurements. If the focal length of the transducer is greater than 10 cm, the

*Radiation Measurements, Inc., P.O. Box 44, Middleton, WI and Nuclear Associates, Inc., 100 Voice Road, Carle Place, NY 11515.

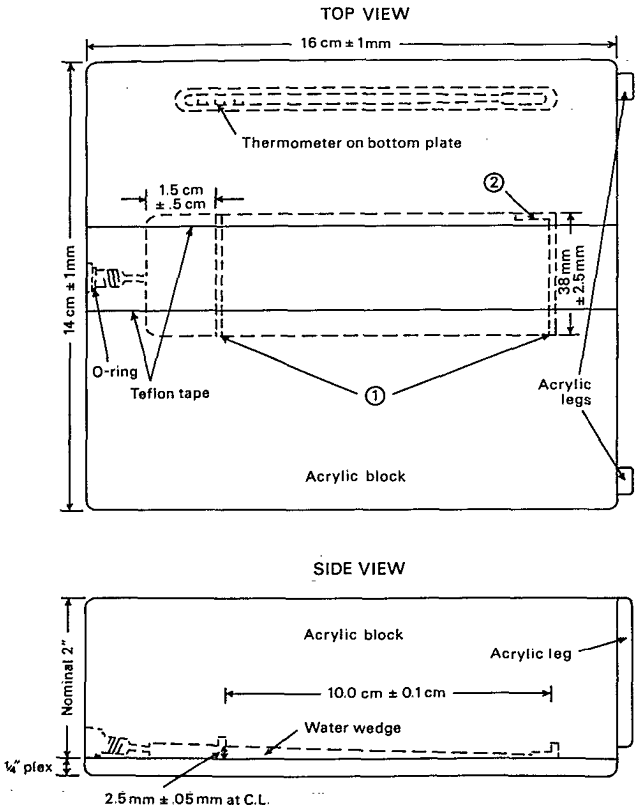

Fig. 7.4.1-1 "SUAR" test object for axial resolution and sensitivity tests and for assessing the uniformity of parallel beam linear arrays. Top view from the scanning window: Bottom view from the side showing axial resolution wedge.

4.5 cm dimension should be increased. The axial resolution wedge in this test object consists of a water filled wedge whose thickness ranges from 0 to 2.5 mm. A wedge-shaped groove is machined in a 4.5 cm thick acrylic block, and marker grooves are machined across the wedge at points where the wedge is 0 and 2.5 mm deep. An acrylic plate is bonded to the bottom surface of the block, and the wedge-shaped space between the two acrylic surfaces is filled with water or other liquid exhibiting the appropriate speed of ultrasound propagation. Teflon tape of approximately .010" thickness placed on the block as in Fig. 7.4.1-1 provides a surface with minimum friction for scanning the transducer over the wedge.

Measurement Procedures: The test object should be placed on a rigid surface and the ultrasound beam directed normal to the reflectors. The system sensitivity settings to barely record the proximal reflector of any reflector pair should be recorded as the test object is scanned. The axial resolution on the final recorded image and on the display monitor should be recorded when the reflectors are scanned at system sensitivity settings of 20 dB and, if desired, 6 and 40 dB above the display threshold for the proximal reflector in a pair. These axial resolution measurements should be performed at recording and display scales which will test effectively the various system components. A protocol which has proven useful for axial resolution measurements on modern general purpose scanners is as follows:

a. Field-of-view set at 8 - 12 cm horizontal field-of-view.

b. System sensitivity settings arranged such that the proximal reflector can be viewed at the display threshold and one of the system sensitivity settings can be increased by known amounts covering at least 20 and preferable 40 dB. It is necessary to check that as the system sensitivity is increased by 20 dB using this control early stages of the receiver electronics are not being saturated due to the echoes from the reflectors being stronger than common reflectors from tissues.

c. The wedge or other reflector arrangement is scanned at a sensitivity setting of 20 dB greater than the display threshold setting determined in b. Adequate coupling material must be employed and the scan should be in one direction at a rate of 1 to 3 cm/sec. The recorded image is photographed.

d. Steps b and c are repeated for all transducers.

e. Steps b and c are repeated with the recording and display scale set at approximately 32 cm vertical field-of-view (4 cm/div or 4/1).

f. The recorded image is photographed both at approximately 32 cm vertical field-of-view (unzoomed) and, for analog scan converters, with the display zoomed to an 8 to 12 cm horizontal field-of-view.

g. For TV displays, steps e and f are repeated with the reflectors or the display rotated 90° to provide resolution both parallel to and normal to the TV lines.

h. The barely resolved criterion is used to determine the axial resolution from the images of steps c, d, f and g. The resolution from steps c and d is recorded using the clearly resolved criterion as well. The number of TV scan lines photographed in step c should be counted.

7.4.2 Lateral Resolution

Lateral resolution at any depth is determined by the beam profile of the ultrasonic transducer, the echo signal strength for the targets being resolved and the receiver sensitivity corresponding to that depth. For a thorough characterization of a transducer beam, pulse echo response profiles taken using a line or spherical target should be obtained at several depths throughout the transducer field. These are generated by measuring the echo amplitude from a suitable target as the target is scanned in a plane normal to the beam axis or in an arc about the center of the transducer face[4,20].

Transducer beam data in the form of pulse echo response widths for different amplitude levels may be obtained by scanning a column of line targets with the beam perpendicular to the lines, and measuring the resultant line widths on the B mode display[20]. The advantages of this technique are it is much less time consuming than the field mapping techniques mentioned above and the displayed beam widths are a property not only of the transducer but also include the effects of system signal processing and display. Pulse echo response widths should be carried out in a plane lying as closely as possible to the pulse echo focal distance of the transducer. In addition, they should be obtained at least in planes lying at twice the focal distance and at half the focal distance.

Method: For nonattenuating paths the swept gain should be off completely except that compensation for transducer sensitivity with depth may be left on in systems providing that feature. The scanning plane is oriented normal to the target rod(s) specified above and the sensitivity adjusted using the best calibrated sensitivity control so that an echo signal from a given rod is just barely discernible on the B mode display. (Threshold level.) The sensitivity is increased by 6 dB and the target scanned. By inserting distance marker dots perpendicular to the transducer beam axis at this depth, the width of the line is measured and recorded as the 6 dB beam width. Subsequent tests should be taken for the 12, 20, and, if possible, the 40 dB beam width. If acoustic noise from the target is detected over a very wide beam width, the sensitivity for detection of this noise should be quoted in dB relative to the display threshold for the rod target.

The most meaningful tests of lateral resolution are carried out using tissue equivalent paths[11,21]. For test objects containing tissue mimicking material*, swept gain will be required to compensate for attenuation of the beam. For lateral resolution tests the initial setting of system sensitivity should be similar to the previous-case where the gain is adjusted in order to obtain a "threshold image" for a given target in the phantom or test object. Since the signal is significantly attenuated by the tissue mimicking material it may not be possible to obtain 40 dB beam widths at all depths. Pulse echo response profiles or beam widths obtained here are useful in that they include effects of frequency dependent attenuation (beam hardening).

The X dB lateral resolution is quoted rigorously as the reciprocal of the X dB beam width. But the lateral resolution and beam width often are equated in common usage.

7.5 DISPLAY CHARACTERISTICS OF RELATIVE SIGNAL AMPLITUDE

7.5.1 A Mode

The purpose here is to determine the relationship between echo signal strength and A mode display amplitude. This information is necessary for considering whether the A mode dynamic range is as specified. It provides useful diagnostic information in certain system malfunctions, and is useful in extending the range of quantitative measurements such as those in Section 7.3.

Method: An echo from an isolated target or a signal from a pulse burst generator is displayed at a standard echo display level on the A mode monitor. With the transducer fixed in place a range independent system sensitivity control, calibrated in Section 7.3, is then increased in fixed steps. The A mode signal level deflection is plotted as a function of sensitivity setting over the entire A mode dynamic range. The A mode dynamic range may be determined from the difference between the sensitivity setting required to just barely display an echo signal and the setting at which maximum A mode signal deflection occurs.

The A mode display characteristics may be rapidly and conveniently assessed using a triggered electronic burst generator with exponential decay[11,12]. Pulses from the generator are applied to the system receiver through the transducer terminal. System swept gain is off and the range independent sensitivity controls adjusted to provide maximum A mode deflection for the pulse generator signals. A known exponential decay rate is applied to the generator pulses (Fig. 7.5.1-1). The relationship between A mode deflection and signal variation may thus be determined.

*Radiation Measurements, Inc., P.O. Box 44, Middleton, WI.

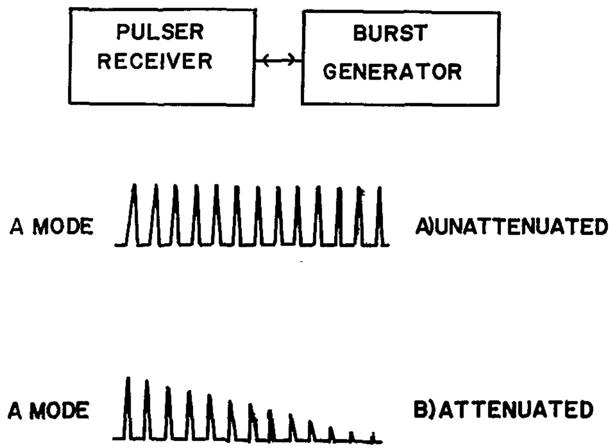

Fig. 7.5.1-1

Schematic representation of the use of a triggered burst generator for testing echo signal amplitude display characteristics. The burst generator replaces the ultrasonic transducer in the pulser receiver chain of the ultrasound instrument. With the pulse burst generator, depicted here, signals are produced on the A-mode monitor at regular spatial intervals following initiation of the burst. A known decay rate can be applied to the burst (B), allowing changes in the displayed signal amplitude to be related to the actual signal amplitude changes produced by the generator.

7.5.2 Gray Scale

The primary purpose of tests outlined here is to determine the echo signal display dynamic range available on the gray scale image. This is a minimum necessary test for characterizing the transfer curve of the gray scale circuitry: Complete characterization of the curve would consist of a determination of the signal level to the display, the display luminance and film density as a function of echo signal amplitude. The gray scale display dynamic range may be measured using any stable source of one or more echo signals, or simulated echo signals from a source such as an electronic burst generator. Alternatively, an attenuating wedge or a series of acoustic interfaces of know reflectivity may be employed.

Method 1: Tests of B mode dynamic range which employ a stable source of an echo signal or signals are carried out most conveniently using an M mode display if the M mode display characteristics are the same as in B mode. The transducer is held stationary over a target and the sensitivity reduced so that the echo signal from the target is not displayed. During an M-mode sweep of the display, the system sensitivity is varied in fixed increments in order to increase the echo signal strength from the target until well above the point at which saturation occurs. The image of the echo is said to be saturated when an increase in system sensitivity no longer produces a change in display luminance or film density. The echo dynamic range discernible on the display or film is obtained then by determining the sensitivity change needed to vary the echo signal amplitude strength from just barely discernible on the display or film to a level at which saturation of the display or film first occurs.

In most cases changes in echo signal amplitude will result in changes of both the intensity of the display and the spot size on the display. In attempting to determine the point of saturation care must be taken to avoid mistaking changes in spot size for changes in display luminance or film density.

Method 2: A convenient echo signal source for gray scale tests is a signal burst generator with a built in, known signal attenuation factor[11,12]. The signal generator is connected to the pulser-receiver terminals as in Sections 7.5.1 and 7.3.1. Signals from the generator are introduced at a known decay rate, as suggested in Fig. 7.5.1-1. These signals are displayed in gray scale using M mode if the processing in M mode is the same as in B scan display. Alternatively, a sweep of the B scan arm may be used to display the signals on the scan converter and video monitor (Fig. 7.5.2-l). The signals which are just barely displayed and those which saturate the display are identified. The actual strength between these two echo signals is determined from the corresponding spatial separation of the signals (in cm) and the attenuation factor in the generator in dB/cm. As the M mode or B mode trace is swept across the display, the system sensitivity should be increased abruptly by approximately 10 dB. This

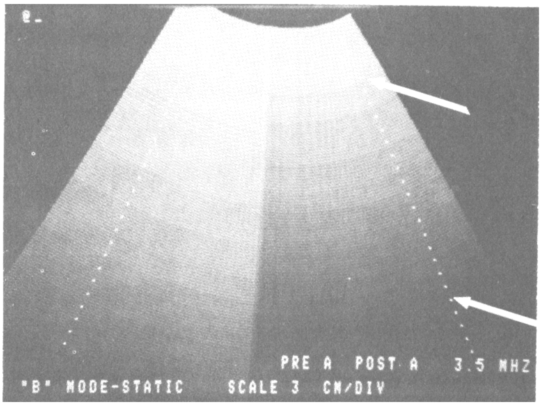

Fig. 7.5.2-1 Measurement of gray scale displayed dynamic range using a triggered pulse burst generator. The B-scan shown in this figure was obtained by carrying out a slow sweep of the scanning arm while a signal decay rate of 1.25 dB/cm was applied to the generator. Two distinct regions on the image were obtained by increasing the receiver sensitivity during the scan. For the region on the right, the lower arrow indicates the just barely perceptable signal, and the upper arrow indicates the weakest signal that saturates the display. The separation of these signals corresponds to a range of 16.5 cm. The displayed dynamic range is thus 20 dB.

provides a region of echo signals which clearly are saturated adjacent to 'echo signals which are just becoming saturated. This improves greatly the reproducibility of measurement of the echo dynamic range discernible on the display or film compared with any other method described here.

A plot of signal voltage to a video monitor as a function of relative echo signal amplitude can be displayed directly on a test oscilloscope. With a triggered burst generator at a known decay rate, the transducer is scanned with the beam axis displayed parallel to the horizontal sweep lines on the display monitors and the oscilloscope time base triggered with the horizontal synchronization pulse. Frequent placement of distance marker dots on the display will provide an accurate calibration of the oscilloscope display.

The stability of the recorded image density on transmission films may be measured with a portable densitometer of the type employed commonly for radiographic film process control. Polaroid type 105 positive-negative film may be employed for densitometric testing of image stability on systems employing Polaroid film pack cameras.

Display luminance can be measured with a photometer or calibraed photographic light meter, preferably one with a fiberoptic probe.* Used with a view box, the light meter and fiberoptic probe can serve as a densitometer. Relative measures of display luminance on a system with stable spectral emissions can be accomplished with an even simpler meter and photo cell.** Measurement can be performed easily on gray bars which are known to mimick exactly the range of display luminance produced by echo signals and the normal display background level. If the gray bars fail in this respect a large area on one side or corner of the image can be filled with echoes which saturate the display. A coin held on the transducer with coupling gel can produce the necessary echoes of high amplitude when the swept gain and system sensitivity are set for maximum signal amplitude. Weak echoes at the display threshold can be produced in the center of the image by reducing the system sensitivity and scanning the transducer and attached coin past the location corresponding to the center of the image. One side of the image should be left open for measurement of the display background level.

Method 3: Gray scale dynamic range has also been measured using acoustic targets of different reflectivity[16,17,22]. One such technique employs a tapered polypropanol wedge designed to attenuate acoustic echoes over a range of 0 to 60 dB. The system is shown schematically in Fig. 7.5.2-2. The transducer is scanned in a direction parallel to the bottom surface of the wedge. The echo amplitude from the back surface depends on the position of the transducer along the length of the wedge. If the receiver sensitivity is adjusted so that this echo signal obtained through the thinnest portion of the wedge saturates the display the dynamic range may be

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*The Gossen Luna-Pro or Luna Pro SBC are examples of light meters with a convenient calibrated fiber optic probe.

**For example, the S & M Model 102 or A-3 photo meter; Science & Mechanics, Instrument Division, Davis Publications, 229 Park Ave. S., New York, NY 10003.

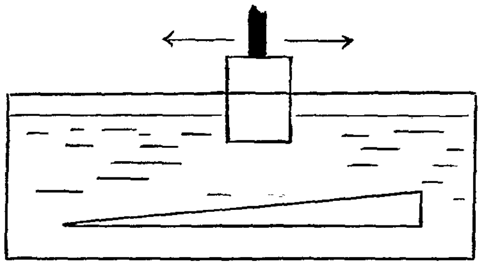

Fig. 7.5.2-2

Gray scale calibration technique employing an attenuating wedge. As the transducer is scanned from left to right in the diagram, the echo amplitude from the bottom surface of the wedge decreases.

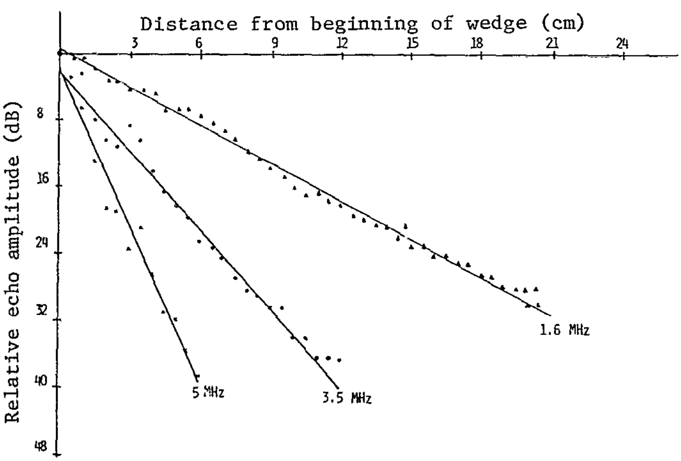

Fig. 7.5.2-3

Typical calibration data for using the wedge technique for evaluating gray scale display characteristics. (Reproduced from reference 16 with permission.)

determined by measuring the shortest distance between the region where saturation occurs and where the back surface echo is too weak. to be recorded on the display. A separate calibration curve must be obtained for each transducer employed (Fig. 7.5.2-3). The calibration curve may be valid for a given model of transducer with a given pulser model.

With any stable gray bar generator which is external to or built into the ultrasound scanner, acoustic tests of gray scale characteristics can be performed by superimposing lines of echo traces across the gray bars. For any stable source of echoes (a reflector), the sensitivity setting to place the echo at the display threshold is determined and echo lines are displayed normal to the gray bars at gain or attenuator settings varying in fixed increments from the recording and display threshold(s) to the recording and display saturation level(s). Gain or attenuator settings are then recorded as a function of the number of the brightest gray bar at which the echo line may be discerned in the recorded and displayed images. A specific example of this type of test is included in Ref. 11.

7.6 GEOMETRICAL ACCURACY IN IMAGE PLANE

7.6.1 Range Marker Calibrations

Range marker calibrations are carried out using a test object or phantom with a column of at least five line targets, separated by 2 cm and positioned with an accuracy of ±0.25 mm. Care must be taken to assure that the speed of sound in the test object is 1540 m/sec ±15 m/sec, or the same value assumed for distance measurements in the equipment. For units having internally generated electronic depth markers, an initial scan of the test object is taken and marker dots displayed alongside the images of the line targets. This test may be used to verify that the speed of sound in the test object is satisfactory. If there is disagreement in the position of the target images and calibration dots the marker dots and/or test object should be examined to assure that the marker dot timing and/or the speed of sound in the test object is correct.

A convenient time reference for use with an oscilloscope is the 127 μs time interval between horizontal sync pulses in standard TV signals. It can be compared with the 129.9 μs time delay for-10 cm of marker dots calibrated properly for 1540 m/sec.

From a B scan image of a set of five or more parallel, evenly spaced wires in the test object or phantom, measured target depths, y, are recorded as a function of corresponding true depths of the wires, x. The y values are corrected for image magnification or display scale. The actual or approximate linear regression line through all points (x, y) are calculated or drawn on a graph. This line can now be described by a function of the form:

$$x = ay + b.$$

From this the following can be determined:

a. Error in zero calibration, $E_o = b/a \cong b$ (mm).

b. Maximum observed deviation from linearity, $E_1 = \delta x$ (mm), where δx is the largest distance of any point (x,y) from the straight regression line derived for all measured points.

Unless it is known that the range markers and echoes are distorted equally by differences in the horizontal and vertical display magnifications, the line targets should be arranged in a horizontal plane and scanned from the side. The results should be analyzed as above.

7.6.2 Image Distortion

Image distortion is assessed using range markers or other electronic distance measuring devices which have been tested by methods such as those in Section 7.6.1 to meet the accuracy requirements of Section 5.6.1. An array of physical line targets similar to those in Section 7.6.1 also may be used.

The display scale is set to approximately 20 cm vertical field of view. Marker dots or actual echoes are recorded vertically down the center of the image and down each side of the image at a distance from the edge equal to approximately 5% of the width of the image. Centimeter marker dots are placed horizontally across the center of the image and at the top and bottom of the image at a distance from the edge equal to approximately 5% of the total height of the image. On the central vertical set of markers, the physical distance X (mm) is measured for each marker from the first (top) clear marker. This is the actual distance on the film or other hard copy. Let Y (mm) be the distance of each marker from the first clear marker in the object space, the space of the scanned object. The actual or approximate linear regression line thorugh all points (X, Y) may be calculated or drawn on a graph. This line can now be described by a function of the form X = AY + B, and the minification A (in mm of object space per mm on film) should be determined accurately.

The distances X (mm) are measured on the film for all points (X, Y) in each of the vertical and each of the horizontal lines of markers. For each line of markers the deviation D_y (mm) is plotted as a function of Y, where:

$$D_Y (\text{mm}) = AX - Y.$$

Study all of the plots in the inner 80% of the image area to determine the maximum <u>change</u> ΔD_Y, which occurs over any 0 to 10 cm distance of object space. ΔD_Y, in mm is quoted as the maximum percent distortion occurring over half the screen in the inner 80% of the image area.

For example, a ΔD_Y of 2 mm = 2% or ±1% distortion, which is at the threshold of acceptability according to specifications in Section 5.6.2. The plats for each marker line should be re-examined to determine the maximum ΔD_Y over any 0 to 10 cm length anywhere in the image. A consistent change in ΔD_Y, from one edge of the screen to the other is described as a nonlinearity.

7.6.3 Compound Registration Accuracy

Method 1: Using the AIUM 100 mm test object, RMI 412, or similar test objects, B scan echo registration accuracy is determined by first aligning the scan plane normal to one or more line targets which are positioned at a depth of at least 10 cm.

If the test object includes two solid planar surfaces lying parallel to the line targets and orthogonal to each other scan plane alignment will be facilitated by placement of the transducer face flush against those solid surfaces. See Section 7.7.2 for methods to assure that the transducer face is normal to the scan plane. Line targets are scanned from at least three directions, separated by a total of 90° and preferably 180°. The velocity of sound in the medium must be 1540 ±15 m/sec, as determined in Section 7.6.1 above. B mode misalignment will be quoted as the maximum separation between the centers of any two scan lines imaging the same rod (Fig. 7.6.3-1). Note : When using the enclosed AIUM Standard 100 mm test object with a scanner for which position registration specifications approach 2 mm, correction must be made for target rod diameter and the increased velocity of 2700 m/sec in test tank windows which are approximately 1.5 mm thick[23].

Method 2: Mechanical Arm Techniques--The arm calibration can be duplicated conveniently using a mechanical pivot arm system and a suitable echo source. In one such arrangement[24] an ultrasonic delay line is used to produce simulated echo signals at intervals of 63.943 microseconds with an accuracy of ±5 nanoseconds. This corresponds to echoes from sources separated by 49.24 mm in a mediumwhose velocity of sound is 1540 m/sec. A dummy transducer is connected to the scanner, and the transducer is attached to a 147.71 mm pivot arm* (Fig. 7.6.3-2). Rotating the pivot arm of the scanner yields two concentric circles with a point in the center for a properly calibrated system. Misregistration is detected by movement of the 3rd echo on the display as well as by asymmetries in the other echo images.

At least one manufacturer of ultrasound scanners has employed this method for system calibration, but using the 1 cm marker dots as simulated echoes. Any synchronization error in the starting time

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*One supplier of such a device is Diagnostic Sonar Ltd., 35 Baron's Hill Avenue, Linlithgow EH 49 7JU, Scotland

Fig. 7.6.3-1

Compound B-scan registration accuracy using line targets. Top, scan of the AIUM 100 mm test object using a 20 cm field of view. Bottom, magnified view of a portion of the top scan, showing a 4 mm registration error.

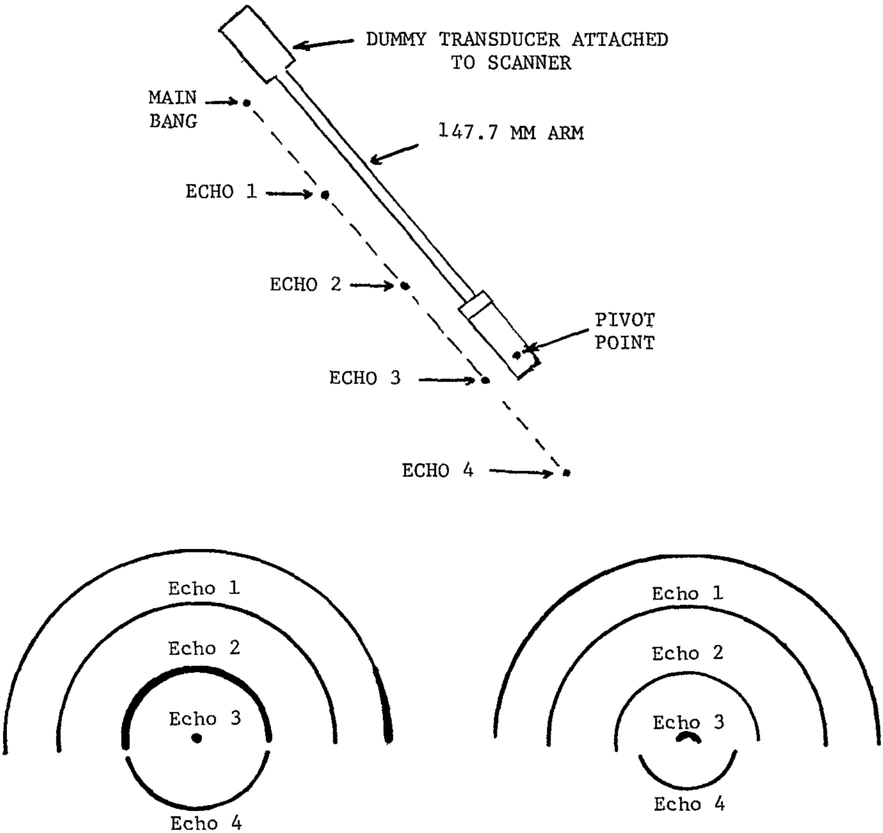

Fig. 7.6.3-2

Mechanical arm technique for assessing compound position registration accuracy. The lower section of the figure depicts resultant B-scan images as the arm is rotated about the stationary pivot point. A "bull's eye" image is obtained for perfect calibration (left). The pattern breaks up (right) for miscalibration. (After Hall, ref. 24.)

of the marker dots compared with initiation of the transducer transmit pulse will result in an apparent B mode alignment error, even if the arm is properly calibrated.

7.6.4 Alignment of Acoustic Axis and the Axis of the Transducer Assembly

For accurate spatial location of targets in a B scan image, it is necessary for the axis of the transducer and its connector to coincide with the acoustic beam axis.

Alignment of the acoustic axis and transducer axis may be checked easily if it is possible to rotate the transducer 90°, or preferably 180° on the scanning arm without introducing substantial play in transducer angle. Addition of a rubber "O" ring on the transducer connection should provide the necessary rigidity with the transducer rotated. A column of line targets is scanned as in Section 7.6.1 at a system sensitivity 6 dB above the display threshold for the bottom rod in the column. After photographing the image, the transducer is rotated 180° relative-to the scanner arm; a new scan of the column of targets is superimposed over the old one. The images from the targetsshould coincide within ±l mm. Misalignment of the beam axis and the transducer axis would be recognized by misalignment of echo signals from the two sets of scans.

7.6.5 Calibration of M Mode Time Markers

Purpose: Time markers are employed in M mode (time-position) recording to calibrate the horizontal (time) axis of these recordings which are used primarily in echocardiography. Accurate time calibration is assumed in calculation of the time rate of change of the distance of various interfaces in the heart from the ultrasound transducer. Left ventricular stroke volume and diastolic descent slope of the mitral valve are examples of such quantities which are quoted commonly. The patient pulse rate also may be evaluated retrospectively from the M mode time markings. For these applications, a time calibration error of 5% may be clinically significant.

In many M mode recording devices such as strip chart recorders, the spacing of the echoes and time markers along the time axis varies substantially with distance along the time axis due to problems such as nonlinear chart paper feed speeds in the strip chart recordings. Nonlinearities in the time axis calibration of greater than 5% necessitate remeasurement of the time axis calibration factor at each point along the time axis at which a measurement is made. This is an inconvenience and a possible source of error which should be avoided whenever possible.

Measurement Techniques: A reference signal of well-known frequency can be introduced on the ECG portion of the M mode recording by grasping the ground lead in one hand and one of the active leads in the other so your body serves as an antenna for 60 Hz power line radiation. The electrical contact often is recessed in a plastic housing and it may be necessary to employ an ECG contact pad to make adequate electrical contact with your skin. The ECG gain is adjusted until the power line oscillation signals are the equivalent of several centimeters on the M mode display. The strip chart recording speed is adjusted to at least 50 mm/sec and a strip chart recording taken for at least 10 seconds while you remain very stationary so that the ECG signal is reasonably stable. In the United States the power line frequency is 60 Hz to a very high degree of accuracy.

If the power line frequency is in doubt it may be measured with a calibrated frequency meter using appropriate precautions of not applying-115 volts directly to a frequency meter which is not designed for such high voltages. The accuracy of the M mode time markers is measured by counting the number of 60 Hz ECG oscillations during each second of M mode time markers.

7.7 DELINEATION OF SCAN PLANE

Purpose: The scanning arm functions both to track the position and angulation of the ultrasonic transducer-and to define the scanning plane by constraining the transducer to that plane. Critical components should be inspected for mechanical rigidity and accuracy of all position indicators-~ All arm joints should be examined to determine whether they allow free motion of the transducer in the scanning plane. Tests outlined below are to be carried out to determine whether the scanning plane is adequately maintained under typical patient scanning conditions.

Test Equipment: Ruler, small fishscale or, preferably, a bi-directional force gauge* rectangular block or tank such as the AIUM test object, clearance gauge down to 0.002", protractor, level, and plumb bob.

7.7.1 Scanning Arm Rigidity

The rigidity of the arm mechanism is measured against a force perpendicular to the scanning plane with the arm extended to its maximum position employed in patient scanning. The scanning arm should be balanced so the transducer rests with only a slight force on the edge of a ruler which is mounted rigidly with the edge horizontal and normal to the scan plane. Using a small scale, or bi-directional force gauge, a force of plus and minus 100 grams equivalent is applied to the transducer in a direction normal to the scanning plane and the resultant transducer displacement is measured as ±x mm. The accuracy with which the transducer returns to the same zero position after application of the 100 gram equivalent force in

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*For example, the Ametek Model T1000G or T500G trim series force gauge. Division of Hunter Spring Corporation, Hatfield, Pennsylvania.

each direction should be noted. A thick rubber band is a convenient device to attach the force gauge near the end of the transducer. The test should be repeated at ±300 grams-equivalent applied force.

The ruler, protractor, level and plumb bob may be used to verify that the scan plane position and angle indicators are accurate within the specifications of Section 5.7.

7.7.2 Transducer Face Normal to Scan Plane

Determine whether the transducer face is normal to the scan plane for all orientations. Using a rectangular block or the enclosed AIUM Standard 100 mm test object, determine whether the transducer face can be placed flush against all sides of the block.

When the block is aligned so the transducer face is flush against one side of the block, the maximum allowable gap between one edge of the transducer face and the other side of the rectangular block is measured with the clearance gauge. For a 20 mm diameter transducer housing the maximum gap is 0.4 mm (0.016") to meet the 0.02 radian specification quoted in Section 5.7.2.

8 ELECTRICAL SAFETY, ULTRASONIC EMISSIONS

8.1 ELECTRICAL SAFETY TESTS

Tests of safe current limits listed in Section 6.1 shall utilize procedures described in detail in the American National Standard "Safe Current Limits for Electromedical Apparatus," 1978[6]. Numerous multifunction "safety testers" are available commercially to allow rapid and safe performance of these tests. Use of these safety testers and product literature on many commercially available safety testers is given in Ref. 25. Several practical electrical and mechanical precautions are noted in Ref. 26.

8.2 ULTRASONIC EMISSIONS

At present, measurements of ultrasonic emissions at the low power and intensity levels produced by diagnostic ultrasound systems require specialized equipment, careful and repeated calibraton of that equipment, and a knowledge of the limitations and sources of error in the techniques[27,28]. At the present time verification of available manufacturers data should be left to the discretion of the physicist. It is anticipated that in the near future it will be necessary to carry out measurements of power and ultrasonic intensity on equipment in the field to determine output levels of machines which haven't as yet been measured and to verify reproducibility of manufacturer's data. In cases in which an ultrasound unit has been modified or a nonstandard transducer is employed calculations or measurements relative to resultant ultrasound emissions should be done. Measurements to be performed and techniques for carrying out these measurements are described in Ref. 5.

9. ACKNOWLEDGEMENTS

In addition to the co-authors of this document, individuals who have contributed substantially to the draft through the Ultrasound Task Group, General Medical Physics Committee and Publications Committee of the AAPM are: Stephen Thomas, Ph.D., Michael Flynn, Ph.D., David Taylor, M.S., Gregory Dubuque, Ph.D., Gregory Gibbs, M.S., John Niemkiewicz, B.S., William R. Hendee, Ph.D., Hans Govaars, M.S., Stan Schorum, Ph.D., Max Magginnes, Ph.D., Al Goldstein, Ph.D., Ralph LaCanna, Ph.D., Robert Moore, Ph.D., and Norman Baily, Ph.D., Chairman of the General Medical Physics Committee. Liberal use was made of existing standards and interim standards, particularly those of the American Institute of Ultrasound in Medicine, the International Electra-Technical Commission, the National Electrical Manufacturer's Association, and the Electrical Manufacturer's Association of Japan.

Ms. Kathy McSherry, Ms. Nancy Clark, Ms. Cynthia Nail, and Ms. Linda Taylor contributed substantially by typing versions of the manuscript.

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11. APPENDIX*

RADIO FREQUENCY ATTENUATOR

Several of the measurements described in this document call for the use of a correctly matched and calibrated attenuator as part of the echoscope system. Although many of the diagnostic equipment systems now in use provide such facilities in some form, it is desirable to check the correctness of the calibration independently.

There are several possibilities for the connection of such an attenuator. These are: (1) between the electrical pulse generator and the transducer; (2) between the transducer and the first stage of r.f. amplification; (3) at some intermediate point in the r.f. amplification or transmitter circuits (e.g., following the pre-amplifier or before the final power amplifier); or (4) in the common lead which connects the transducer to the electrical circuitry.

The performance of the attenuator in any of the above positions is equivalent if suitable precautions are taken. There are a number of special problems peculiar to each of these four arrangements. The first two arrangements can result in internal leakage bypassing the signal around the attenuator and making its readings inaccurate at high attenuation settings. Because of the relatively strong echoes obtained from working standard interfaces, the total attenuation required is-generally greater than 120 dB. The internal isolation between the transmitter and receiver sections of the echoscope must be of an order of magnitude greater than the maximum attenuation.

In the third arrangement, the signal levels must be sufficiently small to prevent overload of the preamplifier stage when the attenuator follows the preamplifier and receiver. Signals of several volts can result from the working standard interfaces and the pre-amplifier must be linear to this signal level. Internal connection within a transmitter is not subject to any particular problems except that current clinical echoscopes generate a pulse in the output stage and provide no intermediate stages between which the attenuator can be connected.

The fourth position is quite commonly used since it may be the only available position or connection of an attenuator without physical modification of existing equipment. Because the impedance can generally only be matched on the electronic end of such an attenuator, it will not read correctly in absolute terms; but relative readings, i.e., differences in attenuator settingswill still be correct. The actual change in attenuation is twice the indicated change because of the double traverse of the signal through the attenuator.

*Reprinted from Ref. 3, courtesy of Ultrasound in Med. and Biol., D. N. White, ed. and Pergammon Press.

Connection of the attenuator must provide for proper impedance terminations. In the most commonly used T or Pi attenuator comprised of a multiplicity of resistor sections switched in and out by double-pole, double-throw switches, proper impedance termination is required at both ends of the attenuator for the readings to be correct. In the tests described in this document, however, only changes in attenuator reading are used and in this case it is necessary only to terminate the attenuator in its characteristic impedance on one end. This follows because the impedance of the attenuator as viewed from the external portion of the mismatched will be constant. The mismatch loss at this end, although not being indicated by the attenuation, should be consistent; but it would be advisable to check if this is, in fact, the case.

To maintain adequate bandwidth, it is recommended that systems employ low impedance attenuators matched to the characteristic impedance of the transmission lines (usually 50 Ω) used in the system. Noninductive carbon resistors of *not* greater than five percent tolerance should be used as terminations. Shunt capacitance at the termination end should be small enough to provide a shunting reactance at least twenty times the value of the resistance.