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Development of Standard Measurement Methods for Essential Properties of Ultrasound Therapy Equipment

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ABSTRACT

A European collaborative programme has been organised between TNO (Holland), PTB (Germany) and NPL (UK) by the Bureau Communautaire de Reference (BCR). Its objective was the development of reliable methods of measurement for characterising the output and performance of ultrasound therapy equipment. Fundamental to these methods is the determination of the effective radiating area of the ultrasonic transducer utilising small hydrophones to map the pressure distribution in the acoustic field. This report details studies undertaken by NPL to assess the accuracy of measurements of effective radiating area using a new, improved definition of the radiating area. Experimental results are presented for a range of normal and defective therapy transducers and important sources of measurement uncertainty identified. Studies undertaken to assess the influence of the measurement system and measurement procedure are presented. The implications of the study for the revision of IEC 150: 1963 are discussed in detail.

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CONTENTS

1. INTRODUCTION

Methods for the testing and calibration of ultrasonic therapeutic equipment are specified by the international standard IEC 150: 1963 [1]. For a number of years this standard has been in need of revision, particularly in respect of the method for determining the effective radiating area (ERA) of the ultrasonic transducer, which utilises a series of conical baffles. It is planned that this method will be superseded by techniques which use miniature hydrophones to map the distribution of acoustic pressure in the field of the transducer. These new techniques were first proposed in an early draft of a Revision of IEC 150 entitled "Testing and calibration of ultrasonic therapeutic equipment" which in this report will be referred to as 87(Benwell)1. Of crucial importance to this Revision is an improved definition of the beam cross sectional area (BCSA) [2] and this is described in detail in Section 2 of this report.

The new procedures and definition of the effective radiating area embodied within 87(Benwell)1 illustrated a need for studies to be undertaken on several key aspects of measurement. The document therefore formed the starting point for this collaborative project between TNO, NPL and PTB. This report describes the work completed by NPL to validate the principles being adopted in the planned Revision of IEC 150. The tasks undertaken by NPL are listed in Table 0 together with references to the sections of this report in which the results are described.

Table 0 Summary of tasks undertaken during this project and references identifying relevant areas of text.

TASK	REFERENCE TO SECTION
NPL will measure the ERA of poorly behaved transducers using raster scans	Section 5.2
NPL will investigate the determination of ERA using diametrical scans on well and poorly behaved transducers	Section 5.3
NPL to investigate linear regression to determine $BCSA_o$ from measurements made at different distances	Raster scan specification: - scan plane position (4.2) - scan area (4.3) - raster step size (4.4) - influence of measurement system (6) - accuracy assessment (8) - summary of transducer measurements (5.2)
NPL to investigate the difference between high and low power measurements of ERA	Section 5.1
NPL to investigate accuracy of pressure measurements when hydrophone active element is strictly too large	Transducer 'hot-spots' (6.2) Section 7.1, BNR (7.1)

2. GENERAL PRINCIPLES AND DEFINITION OF TERMS

The primary safety requirement addressed by existing Standards characterising acoustic output and performance of therapy equipment is the determination of the effective intensity being applied to the patient. Pressure measurements made using miniature hydrophones may be used to derive values of the acoustic intensity. For the therapeutic fields of interest in the current project, this procedure may be subject to large uncertainties. This is partly due to the practical difficulties of measurements in continuous wave fields but, more specifically, is due to the uncertain relationship between pressure and intensity close to the face of an ultrasonic transducer.

An alternative approach is to consider the effective intensity as the quotient of the output power of the transducer and an area through which the majority of this power is transmitted. Using this description, protocols for determining effective intensity may be divided into two distinct areas: those used to determine therapy transducer output power, P, which are now well developed [4] and the methods used to determine the area, commonly known as the Effective Radiating Area (ERA). It is the investigation of reliable test methods for determining ERA that provides the rationale behind the current project.

In this Section we describe and define the major terms used in this report. ERA may be determined from relative measurements by mapping the pressure distribution using miniature hydrophones. By moving the hydrophone in a well defined manner through the acoustic field, normally to define a square grid or raster scan, the pressure distribution may be sampled in terms of measurements of the hydrophone output voltage, either peak or rms, v_i. For measurements over all significant space, the quantity I_T, given by

$$I_T = \frac{1}{M_L^2} \sum_{i=1}^{n} v_i^2 \qquad (1)$$

is termed the "total mean square acoustic pressure" and is equal to the pressure-squared integral over the whole of the raster scan. In equation (1), n is the total number of points acquired during the scan and M_L is the end-of-cable loaded sensitivity of the hydrophone.

Two important definitions of the beam area exist, characterised by different methods of analysis applied to the array of raster scan points. In the reporting requirements of the FDA [5], the effective radiating area is defined as the area which makes up all points for which the intensity (or more correctly pressure-squared values) are greater than 5% (-13 dB) of the peak intensity (peak pressure-squared) measured in the scan. For the FDA reporting requirements, the determination of the ERA requires a measurement 5 mm from the face of the transducer. In this report, the effective radiating area determined from this method of analysis will be abbreviated ERA, with the criterion itself being termed FDA(-13 dB).

Values of ERA determined from the FDA (-13 dB) criterion are very sensitive to the accurate determination of the peak signal (v_p) and large uncertainties may arise during measurements, particularly for divergent fields [2]. A more stable definition of the effective radiating area has been suggested by TNO [2] and involves computing an intermediate quantity known as the beam cross sectional area (BCSA). The BCSA is defined as the smallest region of space which contributes 75% of the total mean square acoustic pressure defined by Equation 1. In this report, the criterion will be referred to as the TNO (75%) criterion.

Whereas the FDA procedure requires measurements at 5 mm, 87(Benwell)1, which is based on the TNO (75%) definition, requires measurements in four planes, and the determination of BCSA(z) at each of the positions, z. A linear regression is performed on the four measurements to define:-

$BCSA_o$ the intercept of the linear regression on the BCSA(z) axis, it represents the beam cross sectional area extrapolated back to the face of the transducer (z=0)

m the gradient of the linear regression, a parameter which may be used to define beam-type (see Section 5.2.3)

The ERA derived from 87(Benwell)1, must be calculated by multiplying the derived $BCSA_o$ value by a constant factor. This should ideally compensate for the incomplete pressure-squared integration in which case its value should be equal to 1.333 (1/0.75). However, for some transducers, its value will depend on the specific distances chosen for raster scan measurements and in some cases may be greater than two in value. The theoretical evaluation of this conversion factor in this project is dealt with by PTB and within this report is briefly mentioned in Section 7.2.

The linear regression may also be used to interpolate values of BCSA at positions where measurements have not been specifically made. The interpolated or extrapolated values will be denoted by $BCSA_e(z)$ in this report.

Physiotherapy transducers do not insonate uniformly, the resultant pressure distributions are complex and exhibit large spatial fluctuations. For some transducers this may result in strong localisation or peaking of the acoustic intensity raising the possibility of harmful thermal effects to the patient such as burning. This spatial non-uniformity in the beam distribution may be characterised by a quantity known as the beam non-uniformity ratio (BNR) which is defined as:

$$BNR = \frac{I_{spta}}{I_{sata}} \qquad (2)$$

where I_{spta} is the spatial-peak temporal-average intensity and I_{sata} is the spatial-average temporal-average intensity. Due to the relative nature of the determination of BNR, the ratio essentially describes the ratio of the peak pressure squared (v_p^2) value obtained in the measurement plane of interest to the averaged pressure-squared value (denoted by the mean value of v^2) obtained over a specified area, either the ERA or BCSA. As the maximum BNR value for a therapy transducer is of particular interest, the plane of maximum rms acoustic pressure is normally used for the determination of v_p^2. It is possible to define two values for the BNR, dependent on which of these areas the pressure-squared averaged value is calculated. For the FDA definition of BNR [5],

$$BNR(FDA) = \frac{v_p^2}{\sum_{i=1}^{n(fda)} v_i^2} \cdot \frac{ERA}{s^2} \qquad (3)$$

where n(fda) is the number of raster scan points which contribute to the ERA defined by the FDA(-13 dB) criterion and s is the step-size used in the raster scan.

In Sections 7.1 and 7.2, values for BNR(FDA) are presented for a range of transducers along with values derived by averaging v^2 over the BCSA defined by the TNO (75%) criterion. BNR(TNO), defined in this way, is given by

$$\mathrm{BNR(TNO)} = \frac{v_p^{\,2}}{\sum_{i=1}^{n} v_i^2} \cdot \frac{1.333\ \mathrm{BCSA}(z)}{s^2} \tag{4}$$

where n is the total number of measurement points acquired during the raster scan. It is important to note that, as used in Section 7 of the present report, both definitions of BNR refer to ERA or BCSA(z) determined in a particular plane z. The FDA definition strictly requires the average v^2 to be determined over the ERA, as determined from a measurement 5 mm away from the face of the treatment head.

3. DESCRIPTION OF MEASUREMENT SYSTEM

Measurements were made utilising the NPL beam-plotting facility [3]. The transducer and hydrophone were immersed in freshly degassed/deionised water with the acoustic beam axis horizontal. The relative positions of the transducer and hydrophone were controlled by stepper motors and a Hewlett Packard (HP) 300 series computer.

Various hydrophones were used to determine BCSA and these are listed in Table 1. The probe hydrophones used for measurements of BCSA were held in a special purpose built conical mount covered in the acoustically absorbing material Wallgone. This anechoic material, which was also used to shield the hydrophone mount and placed at strategic positions in the tank, was used to minimise acoustic reflections. Using the 0.6 mm ceramic hydrophone the dynamic range of the whole measurement system was better than 50 dB. The signal from the hydrophone was measured using a Racal Dana Model 5002 wideband level meter and values of the rms signal transferred to the HP computer for data storage and analysis. Of relevance to the current study, the suite of menu-driven software allowed the following measurements to be made:

raster scans in a vertical scan plane of specified step size and area;

horizontal raster scans providing longitudinal slices through the acoustic beam;

axial scans, revealing the pressure distribution along the beam-alignment axis;

diametrical (line) scans; two orthogonal plots in a vertical plane which could be inclined at any specified angle to the horizontal plane;

as well as a whole range of data analysis options.

Table 1 Listing of hydrophones used during this project, both probe and membrane.

HYDROPHONE TYPE	ACTIVE ELEMENT SIZE	COMMENTS
ceramic probe Dapco Corporation (USA)	0.6 mm	used for BCSA measurements
pvdf probe Medicoteknisk Institute (Denmark)	0.6 mm	used for comparison with ceramic measurements
ceramic probe Dapco Corporation (USA)	1.0 mm	used to study effect of hydrophone size
pvdf membrane differential output GEC Marconi (UK)	1.0 mm	used to study the power dependence of BCSA
pvdf bilaminar membrane GEC Marconi (UK)	4.0 mm	used to study the effect of hydrophone size

4. FACTORS AFFECTING RASTER SCAN SPECIFICATION

The methodology adopted throughout this study was one of working to and testing out the existing revision of IEC 150 (87(Benwell)1). The results of measurements of BCSA made on a range of therapy transducers commonly encountered in therapy ultrasound are presented in detail in Section 5. This Section concentrates on observations gained by following 87(Benwell)1, and in particular on how the raster scan is specified in terms of the position of the scan planes, the area over which the scan is performed, and the raster scan step size.

Beam alignment axis

Before performing measurements it is important to align accurately one translational axis of the hydrophone with the acoustic axis of the ultrasonic beam. The 87(Benwell)1 definition of the beam alignment axis originates from IEC 1102 [6] and involves iteratively moving the hydrophone between two planes with, at each plane, adjustments being made to either the transducer or the hydrophone to maximise the hydrophone signal [7]. The two planes used are at distances of a^2/λ and either $2a^2/\lambda$ or $a^2/3\lambda$, from the transducer face, whichever is more suitable. If at either of the planes used, a unique peak is not found, then the plane may be moved to a nearby position at which there is a unique peak.

This alignment procedure is believed to be more critical for measurements of BCSA using diametrical scans, where misalignment would be expected to produce a greater spread in values produced by individual line-scans. Generally, this definition of the beam-alignment axis procedure worked well for the transducers studied. One beam where problems were encountered was from a defective transducer DE-12 (Type AL-3; Ø = 28 mm). Possibly due to a split crystal, the beam was separated into two similarly sized peaks - effectively two beams. In this situation, where strict alignment is not possible, raster scans were performed after centralising the hydrophone relative to the transducer face. It is interesting to note that diametrical scans performed on this transducer did not produce a significantly large spread in values of BCSA(z) from the eight half line-scans (see Section 5.3), until $z \sim 80$ mm.

Position of scan planes

87(Benwell)1 defines the raster scan measurement planes from an initial measurement of BCSA at 10 mm: if this is greater than 1.5 cm^2 then the positions of the measurement planes are 10, 20, 40 and 80 mm from the transducer face, otherwise they are at 10, 20, 30 and 40 mm. A linear regression is then performed on the four values of BCSA(z) obtained, so that a value for $BCSA_o$, at the face of the transducer, can be determined from extrapolation. This assumes a linear relationship between BCSA(z) and z and for certain transducers this was found not to be the case.

Particular problems were encountered for small transducers of both 1 and 3 MHz, with the nonlinear dependence being due to some of the measurements being carried out in the far field of the ultrasonic beam. Figure 1 shows measurements made on a small 3 MHz (CS-3 Ø = 10 mm) transducer whose last axial maximum is approximately 35 mm from the transducer face. In this situation, the points clearly form a curve.

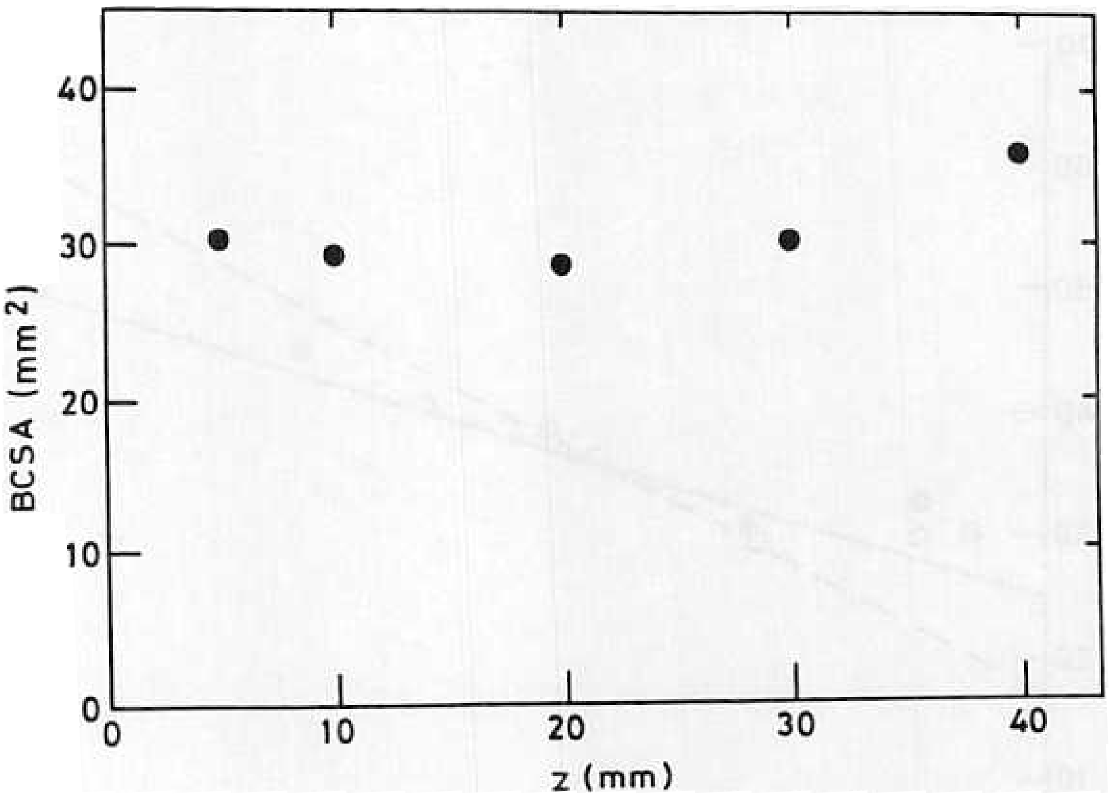


Figure 1 Plot of BCSA(z) versus the distance from the transducer face, z, for the 3 MHz transducer CS-3 (Ø = 10 mm).

In response to this problem, the planes of measurement were redefined relative to the position of the last-axial maximum, N. The following procedure was adopted:

i) if $N \geq 80$ mm then measurements at 10, 20, 40 and 80 mm;

ii) if 40 mm $< N <$ 80 mm then measurements at 10 mm, N and two equally spaced distances between 10 mm and N;

iii) if $N \leq 40$ mm then measurements at 5 mm, N mm and two equally spaced distances between 5 mm and N.

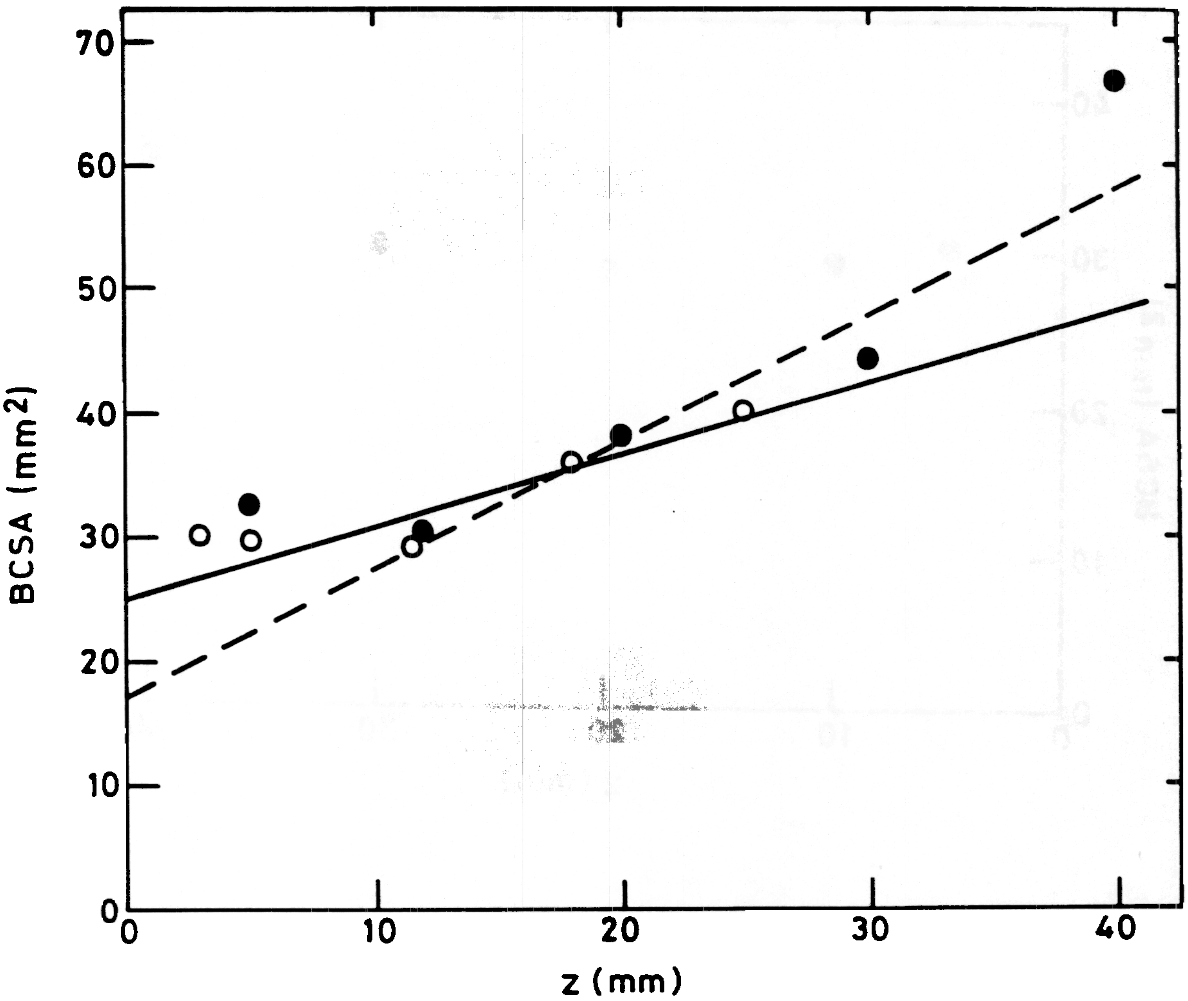


Figure 2 Variation of BCSA(z) with distance away from the treatment head, z, for a transducer exhibiting a nonlinear relationship between the two quantities. The symbols have the following meaning:-

• = values of BCSA at the initial fixed measurement planes defined by 87(Benwell)1,

⊙ = values of BCSA at the revised measurement planes plus an additional point close to the transducer face, at 3 mm.

Figure 2 shows two sets of points on which linear regressions have been performed for the 1 MHz transducer BS-1 Ø = 16 mm (N ~ 25 mm). The dashed line in Figure 2 represents the regression line for the values of BCSA measured at the initial fixed measurement plane planes, whereas the solid line represents a regression line for the values of BCSA measured at the revised measurement plane positions. The value for the $BCSA_o$ varies from 17.2 mm^2 to 25.1 mm^2 for the revised measurement plane positions. It is interesting to note from Figure 2, that the revised procedure, although an improvement, does not completely solve the problem, as some curvature still exists.

For transducers which have last axial maxima at distances greater than 80 mm, the four fixed position measurement planes produce values of the BCSA with a good linear dependence, as shown in Figure 3.

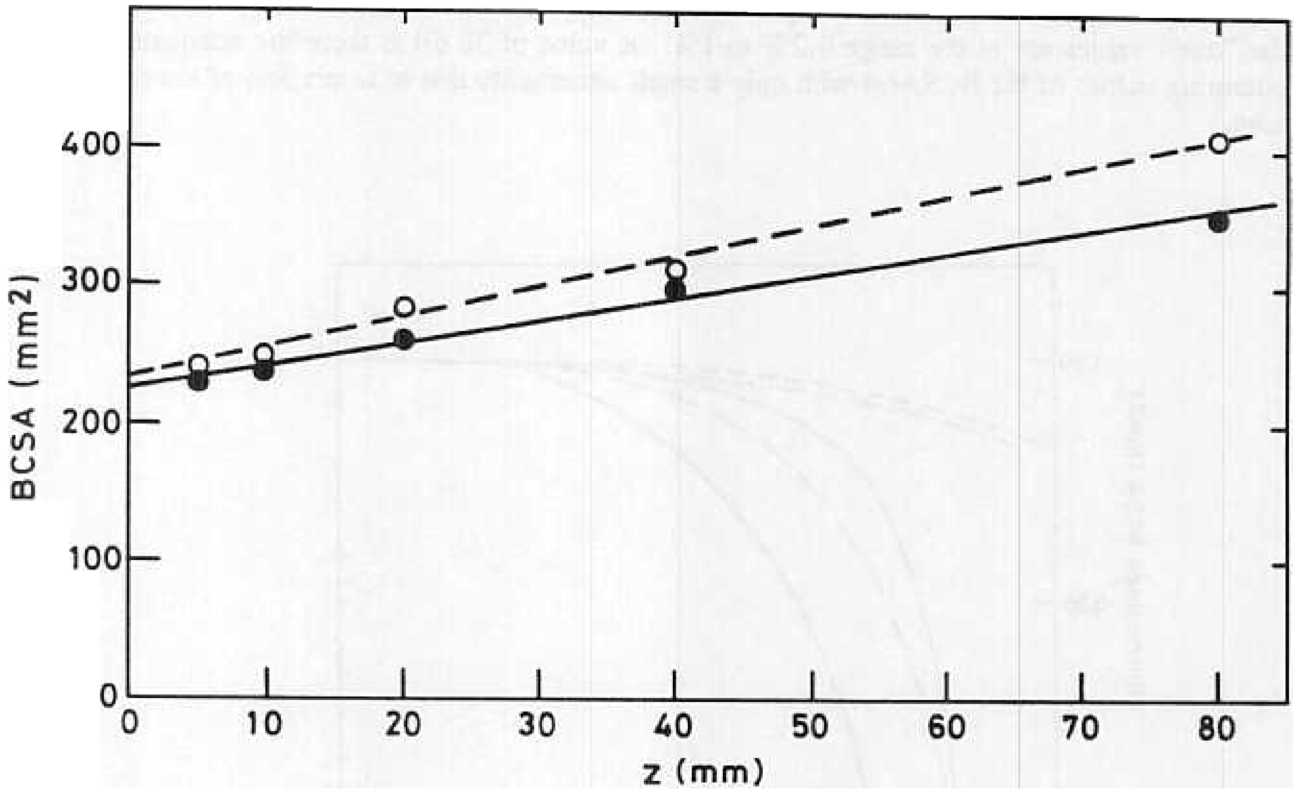


Figure 3 Variation of BCSA with position for: (•) a large 3 MHz transducer (AL-3) and (⊙) a large 1 MHz transducer (BL-1). Also shown are linear regression lines for the (-) 3 MHz transducer and (---) 1 MHz transducer.

4.3 Scan plane areas

After performing many raster scans on a series of different transducers, the method of defining scan area as a multiple of the transducer face area used by 87(Benwell)1 was found to be inadequate. In some situations, raster scans were missing a significant fraction of the ultrasonic beam producing artificially low values of BCSA(z). The problems were particularly acute for 1 MHz transducers, where the beams were strongly divergent.

An alternative method is to define the scan area in terms of the dynamic range of a scan - given by the signal level at the edge of the scan (or the pressure-squared value derived) relative to the peak signal recorded during the scan (peak pressure-squared value). To ascertain a suitable dynamic range for obtaining accurate measurements of the BCSA, raster scans were performed on several transducers at different transducer-hydrophone separations, over very large areas. These raster scans, typically, had dynamic ranges of 40 dB and could be regarded as giving values of the "true" BCSA(z). Software manipulation was used to reduce the raster scan area by an incremental removal of the peripheral raster lines. For each of the smaller scan areas, new values for BCSA(z) and dynamic range were evaluated. Figure 4 shows BCSA(z) plotted against dynamic range for a range of raster scans.

In Figure 4, the two curves shown as solid lines represent measurements performed on a small 1 MHz transducer (BS-1), the shallower being from a scan performed at 18 mm from the transducer, the other at 11.5 mm. The curves illustrate the divergent nature of the 1 MHz beam, but even for the "worst case", a dynamic range of 30 dB gives a maximum deviation from the "true" value of only 2.5%. More typically, the maximum deviations from the "true" values are in the range 0.2% to 1%. A value of 30 dB is therefore adequate for obtaining values of the BCSA(z) with only a small uncertainty due to truncation of the raster scan.

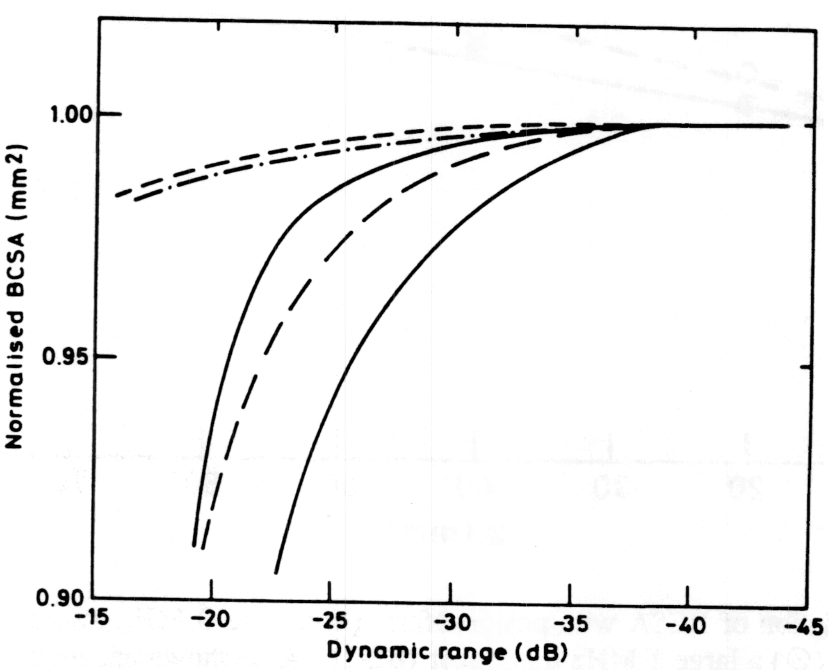


Figure 4 Variation of calculated BCSA with a progressive reduction of the raster scan area, derived from a software manipulation of the two-dimensional raster scan array. The BCSA value has been displayed against the dynamic range for five raster scans.

The curves represent the following: (a) ———— 1 MHz BS-1 Ø = 16 mm at 11.5 mm and 18 mm, (b) — — — — 3 MHz CS-3 at 30 mm, (c) —•—•—•— 3 MHz BL-3 Ø = 24 mm at 80 mm and (d) ------ 1 MHz BL-1 Ø = 24 mm at 10 mm.

4.4 Scan step size

Table 2 shows the values of BCSA(z) when the step size of a raster scan is increased to a multiple of the original step size, again by manipulation of the raster scan data array. The calculations were performed on many raster scans, at various measurement planes and covering a range of transducers of different diameter and frequency.

In general, there was very little change in the BCSA(z) until the step size had been increased significantly, and hence the number of points in the scan decreased. It should be pointed out that values for BCSA presented in Table 2 have been interpolated, hence the non-integer number of points contributing to BCSA in some of the columns. The analysis has also been carried out for reasonably symmetric beam profiles after accurate alignment of the transducer and hydrophone. It is significant that DE-07 presented in Table 1, a strongly asymmetric defective transducer, exhibits a greater sensitivity to a coarsening of the raster scan sampling.

The sensitivity of BCSA to step-size will inevitably depend on details of the pressure distribution in the field and the way this is sampled by the raster scan. This is reflected in the results presented in Table 2. In extreme cases, the BCSA(z) changed by as little as 2% even when the number of points contributing to BCSA(z) was as low as 16, although in others, it changed more significantly when the number of points within the BCSA(z) fell below 75.

Rather than define a step size that should be used, it is better to define the number of measurement points that should lie within the BCSA(z). To maintain accuracy of better than 2%, the number of points should be at least 80. In practice, this means that raster scans performed on small transducers (for diameters ~ 15 mm) should comprise of approximately 50 by 50 measurement points with a step size of 0.6 mm. For larger transducers (for diameters ~ 25 mm) the scan should comprise of approximately 33 by 33 measurement points with a step size of 1.8 mm. These values may depend weakly on the actual diameter of the transducer face and the position of the measurement plane.

Although the BCSA(z) value is very insensitive to step size an extra consideration is that diametrical information may need to be extracted from the raster scan measurements - for example, to give a characterisation of the cylindrical symmetry of the beam. In this case, a raster scan of 50 by 50 measurement points may be more appropriate.

Table 2 Variation of BCSA(z) calculated from a raster scan with a gradual coarsening of the sampling brought about by increasing the step-size. The total number of points contributing to the BCSA for each new value of step-size is also presented.

Trans ducer	Scan plane (mm)	Initial step size (mm)	Para-meter	Multiple of initial step size			
				x 1	x 2	x 3	x 4
1 MHz - BS-1 Ø = 16mm	5	0.3	BCSA (mm^2)	31.03	30.54	30.62	30.25
			Points in BCSA	345	85	38	21
3 MHz - AL-3 DE-12 Ø = 28mm	5	0.6	BCSA (mm^2)	235.9	235.1	234.0	232.8
			Points in BCSA	655	163	72	40
1 MHz - BL-1 Ø = 24mm	10	0.9	BCSA (mm^2)	249.3	249.4	239.8	235.0
			Points in BCSA	308	77	33	18
3 MHz - DE-07 Ø = 10mm	10	0.3	BCSA (mm^2)	42.35	39.96	39.66	34.51
			Points in BCSA	470	111	49	24
3 MHz - AS-3 Ø = 13mm	10	0.6	BCSA (mm^2)	32.24	32.15	29.91	33.97
			Points in BCSA	90	22	9.2	5.9
1 MHz - BS-1 Ø = 16mm	20	0.6	BCSA (mm^2)	37.70	38.90	35.33	36.08
			Points in BCSA	105	27	11	6.3
3 MHz - DE-07 Ø = 10mm	20	0.3	BCSA (mm^2)	60.96	61.11	62.34	55.38
			Points in BCSA	677	170	77	38
3 MHz - BL-3 Ø = 24mm	80	0.9	BCSA (mm^2)	207.0	206.0	206.6	202.2
			Points in BCSA	256	64	28	16

5. MEASUREMENTS OF $BCSA_o$

5.1 Power dependence of BCSA(z)

Measurements of BCSA(z) and $BCSA_o$ made on various transducers using raster and diametrical scans are described in Sections 5.2 and 5.3. An important characteristic of these measurements was that, to protect the probe hydrophones used from damage due to cavitation, all measurements were made with the therapeutic equipment generating powers of less than 0.5 watts. To verify that values of BCSA(z) obtained from low power measurements are valid at higher powers, measurements were made using a pvdf differential output coplanar membrane hydrophone up to an operating power of 15 watts. The results are shown in Table 3 for two 1.5 MHz transducers of Type AL-1 and illustrate that the dependence with power is small, typically one to two per cent.

Table 3 Variation in BCSA with increasing transducer output power. Raster scans were performed on the following:

Transducer A - AL- 1.5 MHz (Ø = 28 mm) at 40 mm;

Transducer B - DE-04 1.5 MHz Type AL-1 (Ø = 28 mm) at 29 mm.

Indicated Power (W)	Transducer A BCSA (mm^2)	Transducer B BCSA (mm^2)
1.25	354.3	298.9
5.00	349.9	292.1
7.50	352.3	280.0
10.0	348.2	279.0
12.5	350.7	279.7
15.0	349.0	286.8

Table 4 Summary of measurements of $BCSA_o$ made on twelve transducers. Measurement planes used for the linear regression are indicated in the right hand column.

Transducer		ka	N (mm)	m (mm)	$BCSA_o$ (mm^2)	Measurement planes (mm)
BS-1 1 MHz Ø = 16 mm		33.5	25	0.58 (± 0.25)	25.1 (± 4.5)	5, 11.5, 18, 25
BL-1 1 MHz Ø=24 mm		50.3	110	2.17 (± 0.25)	233 (± 12)	10, 20, 40, 80
	DE-128	50.3	-	2.44 (± 0.56)	264 (± 25)	10, 20, 40, 80
CS-3 3 MHz Ø = 10 mm		63	35	0.21 (± 0.16) 0 (± 0.08)	25.9 (± 4.5) 29.7 (± 1.4)	10, 20, 30, 40 5, 10, 20, 30*
AS-3 3 MHz Ø = 13 mm		81.7	34	0.32 (± 0.06)	27 (± 1.6)	10, 20, 30, 40
BS-3 3 MHz Ø = 16 mm		100.5	36	0.19 (± 0.05)	38.1 (± 1.0)	12, 20, 30, 40
AL-1 1.5 MHz Ø=28 mm		88	66	1.9 (± 0.3)	297 (± 16)	10, 20, 40, 80
	DE-04	88	64	1.87 (± 0.2)	267 (± 10)	10, 20, 40, 80
BL-3 3 MHz Ø = 24 mm		151	131	0.19 (± 0.06)	193 (± 5)	10, 20, 40, 80
AL-3 3 MHz Ø=28 mm		176	170	1.59 (± 0.02)	226 (± 11)	10, 23, 40, 80
	DE-08	176	last-axial max ~ 220 mm	0.36 (± 0.05)	234 (± 11)	10, 20, 40, 80
	DE-12	176	-	0.42 (± 0.14)	206 (± 7)	10, 20, 40, 80

the four measurement planes were all within the transducer near-field

5.2 Determination of $BCSA_o$ using raster scans

Table 4 summarises measurements on twelve transducers to determine values of $BCSA_o$. Values of $BCSA_o$ were derived from four raster scans whose separations from the front face of the transducer are given in the final column. Linear regressions performed on these measurements yielded values for the slope of the regression (m) and the intercept on the y-axis ($BCSA_o$) and these are presented along with the respective uncertainties expressed at the 95% confidence level. For ease of comparison, nominally identical transducers have been grouped together in Table 4.

The transducers highlighted in Table 4 include those which operate normally as well as those which exhibit defects whose nature is described in Table 5. In this report, defective transducers are denoted by the code DE.

From the measurements presented in Table 4, the random uncertainty in determination of $BCSA_o$ expressed at the 95% confidence level from the linear regression is typically ±5% for the large diameter transducers (Ø > 20 mm). For the smaller transducers, where there is a greater need to define the measurement planes relative to the last axial maximum, the uncertainties are higher, typically ± 8%. For the 1 MHz (Ø = 16 mm) transducer BS-1, the uncertainty is ± 18% due to the nonlinear dependence (see Section 4.2). Uncertainties in the determination of the slope, m, are typically ± 20% for large transducers and ± 40% for those for which Ø < 16 mm.

Table 5 Summary of defective transducers used in this study and a description of their defects.

Transducer type	Number	Description of defect
BL-1 1 MHz ka = 50.3 Ø = 24 mm	DE-128	Rejected by manufacturer due to high BNR at z = 5 mm
AL-1 1.5 MHz ka = 88 = Ø 28 mm	DE-04	'Hot-spot' transducer focussing with peak rms at z = 29 mm
AL-3 3 MHz ka = 176 Ø = 28 mm	DE-08	Transducer shows some focussing - peak at 219 mm, possibly due to a bubble
AL-3 3 MHz ka = 176 Ø = 28 mm	DE-12	Split crystal, strong asymmetry, no unique peak as z > 100 mm
CS-3 3 MHz ka = 62.8 Ø = 10 mm	DE-07	Split crystal, strong asymmetry

Measurements at 5 mm

The results presented in Table 4 may be used to infer the reliability of making measurements at 5 mm. Measurements at this distance are required as part of the FDA reporting requirements [5] and in the past concerns have been expressed regarding the possible influence of reflections from the probe hydrophone used for the measurements. To investigate this, measurements of BCSA ($z = 5$ mm) are compared with $z = 5$ mm values extrapolated from the linear regression ($BCSA_e$ ($z = 5$ mm)). The difference between these two values is displayed in Table 6 and is typically no more than 2%. On this basis, it would appear that measurements at 5 mm may be used to yield reliable values for the BCSA(z).

However, a word of caution is appropriate as the range of hydrophone types used in this study have been limited. Some designs of hydrophone may perturb the acoustic field to a greater extent and make measurements close to the transducer face less reliable.

Determination of $BCSA_0$ from a single measurement

Raster scans in four measurement planes to yield a single value of BCSA do not represent a practical routine testing procedure which should, ideally, involve a single measurement. This could, in principle, be made close to the transducer to minimise the effect of beam divergency. Figure 5 illustrates the modulus of the error incurred in making a single measurement at $z = 5$ mm relative to the value of $BCSA_0$ determined from the linear regression through the four measurement planes. The error has been plotted against N, the observed position of the last axial-maximum. From Figure 5, provided $N > 50$ mm, this single measurement process may be used to derive BCSA to within 2% to 4%. For $N < 50$ mm, the nonlinear dependence of BCSA(z) with z becomes important and the difference is much larger.

5.2.3 The slope as a characterisation of beam-type

Figure 6 gives the slope, m, in mm, plotted against ka for the transducers depicted in Table 4. The slope may be useful as a parameter which identifies the beam-type as, for example, divergent, collimated or convergent dependent on the sign and magnitude of m. It is of interest to note that all of the slopes presented are positive, and the beams are therefore divergent to differing degrees. The filled circles are values of m for transducers for which Ø > 25 mm and whose measurement planes will typically be at 10, 20, 40 and 80 mm. For such transducers a tentative possible classification regime is:-

> if $m > 1$ the beam is divergent - this corresponds to a typical increase in BCSA(z) from $z = 0$ to $z = 80$ mm of 30%;
>
> if $-0.5 \leq m \leq 1$ the beam is collimated - the change in BCSA(z) is between -16% to +30%;
>
> if $m < -0.5$ the beam is convergent - the change in BCSA(z) is greater than -16%

For smaller transducers the situation is more complicated. Defining the scan plane positions relative to N, as described in Section 4.2, may render this type of beam classification inappropriate.

Table 6 Comparison of direct measurements of BCSA(z) at z=5 mm with values extrapolated from the linear regression presented in Table 4 ($BCSA_e(z)$). Differences have been calculated using:-

$$\frac{BCSA(z) - BCSA_e(z)}{BCSA(z)} \times 100\%$$

Transducer		ka	BCSA(z) (mm^2) z = 5 mm	$BCSA_e(z)$ (mm^2)^e z = 5 mm	Difference (%)
BS-1 1 MHz Ø = 16 mm		33.5	-	-	-
BL-1 1 MHz Ø=24 mm		50.3	237.3	243.3	- 2.5%
	DE-128	50.3	282	276.3	2.0%
CS-3 3 MHz Ø = 10 mm		63	30.3	26.9(*)	11.2%
BS-3 probe 3 MHz Ø = 13 mm		81.7	29.1	28.6	1.7%
BS-3 3 MHz Ø = 16 mm		100.5	39.3	39.1	0.5%
AL-1 1.5 MHz Ø= 28 mm		88	293.1	307.1	- 4.8%
	DE-04	88	275.81	276.03	- 0.1%
BL-3 3 MHz Ø=24 mm		151	198.4	194.1	2.2%
AL-3 3 MHz Ø=28 mm		176	231	234.3	- 1.4%
	DE-08	176	235	235.7	- 0.3%
	DE-12	176	213	208	2.3%

* measurement planes defined by 87(Benwell)1

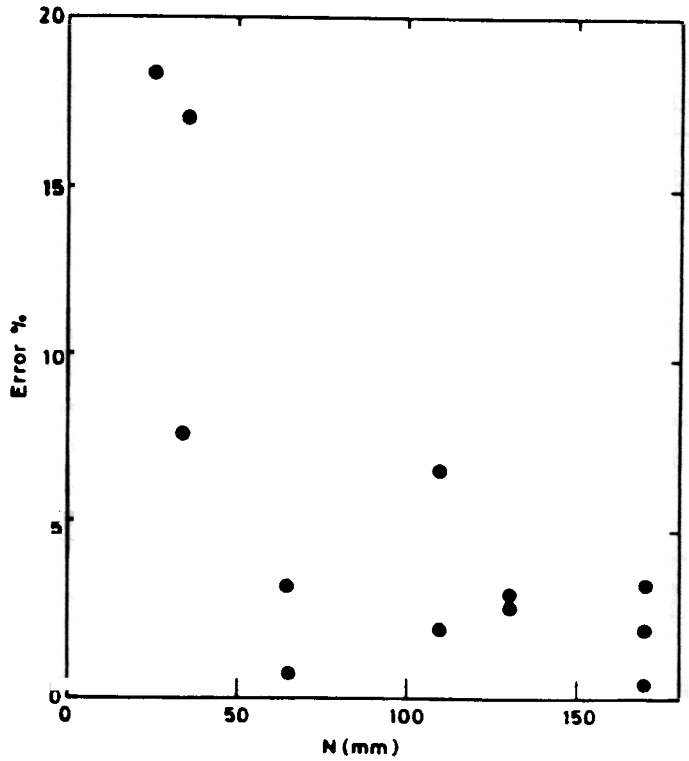


Figure 5 Accuracy of determining the value of BCSA from a single measurement 5 mm away from the transducer face. The | error | represents the difference between direct measurement and the value of $BCSA_0$ determined from the linear regression expressed as a percentage of $BCSA_0$. The error has been plotted against N, the position of the last-axial maximum.

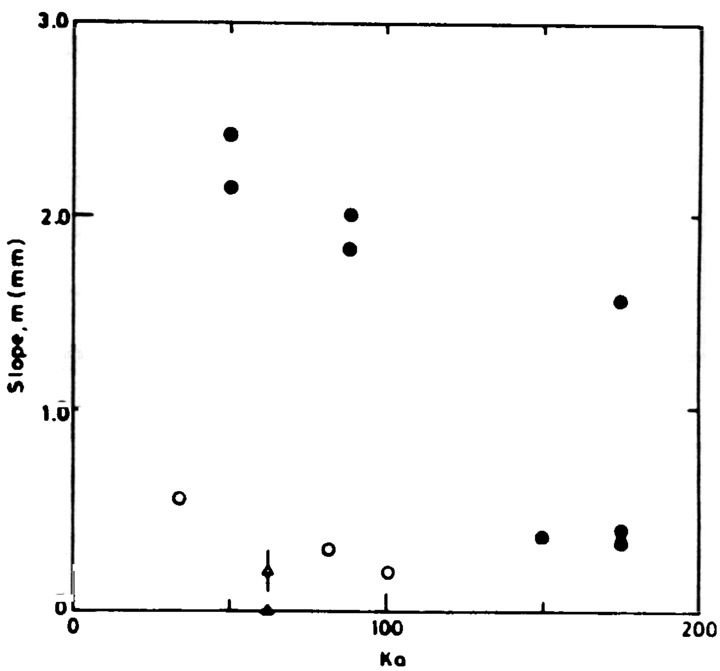


Figure 6 Plot of the linear regression slope, m, against ka for the transducers represented in Table 4. The filled circles are for the large diameter transducers (Ø > 25 mm) whilst the open circles are for transducers for which Ø < 16 mm. The Δ symbols represent results for the CS-3 3 MHz Ø = 10 mm transducer.

5.3 Comparison of raster and diametrical scans

The use of diametrical scans for measurements of BCSA(z) is attractive as a method for rapid measurements that could be used by a manufacturer for routine quality assurance. Table 7 presents a comparison between measurements made using diametrical scans compared with the reference, raster scan derived, values.

Diametrical values were derived from eight equally spaced half-scans (relative angular separation 45°), acquired using two sets of beam plots each of which consisted of an orthogonal pairing of scans. Table 7 demonstrates good agreement between raster and diametrical scans. The largest differences were produced for the 1.5 MHz transducer DE-04 Type AL-1 although even in this case the maximum difference was 6% - 7%, both for measurements of BCSA(z) and $BCSA_o$. More typically, differences were in the range 2% to 4%.

Table 7 Tabulated comparison of measurements on five therapy transducers of BCSA(z) and $BCSA_o$ performed using raster scans and diametrical scans. For each transducer, the upper row of figures were derived from raster scans and the lower row from diametrical scans.

Transducer	m (mm)	Calculated $BCSA_o$ (mm^2)	Measured BCSA (mm^2) at fixed distances of			
			10 mm	20 mm	30/40 mm	40/80 mm
BL-3 3 MHz (Ø = 24mm)	0.19 ± 0.06	193 ± 5	197	196	199	209
	0.08 ± 0.02	193 ± 8	197	188	194	201
AL-3 3 MHz [DE-12] (Ø = 28 mm)	0.42 ± 0.14	206 ± 6	214	213	219	243
	0.41 ± 0.17	208 ± 8	215	218	218	244
AL-1 1.5 MHz [DE-04] (Ø = 28 mm)	1.87 ± 0.21	267 ± 10	288	297	348	414
	1.77 ± 0.05	284 ± 2	302	319	357	426
BS-1 1 MHz (Ø = 16 mm)	0.73 ± 0.02	23.1 ± 5.3	30.6	38.1	41.2	53.1
	0.86 ± 0.15	20.7 ± 4.2	30.0	38.0	43.9	56.6
BS-3 3 MHz (Ø = 16 mm)	0.20 ± 0.08	38.7 ± 2.1	39.8	43.8	44.8	46.1
	0.188 ± 0.05	38.4 ± 1.3	40.6	41.7	43.3	46.2

5.4 Cylindrical symmetry

The standard deviation, or spread of the eight values of BCSA derived for diametrical scans gives a quantitative measure of the cylindrical symmetry of the acoustic beam and is therefore an indicator of transducer quality.

Raster scans may also be analysed in terms of a series of eight half-scans with values of BCSA for each derived assuming cylindrical symmetry. The spread in values is dependent on the method of analysis and may be reduced by defining centres of symmetry between the opposite halves of a diametrical scan - this process redefines the point in the diametrical scan about which the two half-scans are rotated. The method of analysis chosen must relate to the particular measurement requirement: either to determine a value of BCSA of improved accuracy or to derive information concerning the cylindrical symmetry.

If the central point in the raster scan (lying on the beam-alignment axis) is taken as the centre of rotation of the individual half-scans, the standard deviation in derived BCSA values is typically in the range 5% to 10% for transducers behaving normally. However, there is a considerable spread in values, normal transducers displaying standard deviations in BCSA values of up to 30% in some cases. For asymmetric transducers, the standard deviation is in the range 35% to 75%.

It is important to develop a criterion to test the accuracy of measurements of BCSA using diametrical scans. Again, this may be investigated by analysing raster scans in terms of half-scans. The results of a software analysis of 46 raster scans suggest that, in general, providing the standard deviation in cylindrical symmetry values is less than 20%, eight half-scans should provide an average BCSA value accurate to within 5% of the raster scan derived value. For standard deviations of the eight BCSA values > 30%, the error in the estimation of BCSA may be as high as 25%.

6. INFLUENCE OF MEASUREMENT SYSTEM

6.1 Hydrophone performance properties

The measurement protocol for BCSA(z) given in 87(Benwell)1 recommends the use of probe hydrophones. These are generally of effective active element area 0.6 mm or 1 mm but they may be manufactured from different piezoelectrically active materials such as the ceramic material PZT or pvdf, a polymer. An important aspect of the project was the investigation of whether the type of hydrophone affected measurements of BCSA(z). Measurements of BCSA(z) involve scanning the hydrophone through the acoustic field to, in some instances, significant distances away from the acoustic axis, where it is anticipated the directionality of the measuring hydrophone may become important.

6.1. Directional response

The very different directional responses of probe-type hydrophones has been documented [8]. In general, whereas pvdf probe hydrophones may be modelled as stiff-disc receivers, ceramic hydrophones typically possess a more complex and unpredictable directional response. Figures 7 a), b) and c) give the relative amplitude directional response of two of the hydrophones (0.6 mm ceramic and 0.6 mm pvdf) used in this study. The relative directional response is presented over the frequency range of interest for therapy measurements (1 to 3 MHz).

Figures 7 a), b) and c) illustrate the differences in the directional response, particularly at higher frequencies. At 1 MHz, provided the angle of incidence of the ultrasound is less than 35°, the response of the two types of hydrophone will be similar. For greater angles (greater distances off-axis for raster scans) the ceramic hydrophone will underestimate the acoustic signal relative to the pvdf hydrophone.

In certain types of acoustic field these differences may be significant. To illustrate this, results are presented of measurements made on a defective 3 MHz (ka = 62.8) transducer DE-07 Type CS-3 supplied to NPL by TNO. The exact nature of the transducer defect is unknown but is believed to be a split crystal. Table 8 presents a summary of the measurements made at NPL along with the values supplied to NPL by TNO. For ease of interpretation, the values are presented in graphical form in Figure 8.

Measurements presented in Table 8 were performed at the specific scan planes defined in 87(Benwell)1 and to the recommended scan areas. Scans over much larger areas were completed to achieve the required level at the edge of the scan (see Section 4.3). From measurements made using the ceramic hydrophone, the value of $BCSA_o$ = 25 mm^2 whereas for measurements made using the pvdf hydrophone, $BCSA_o$ = 31.5 mm^2.

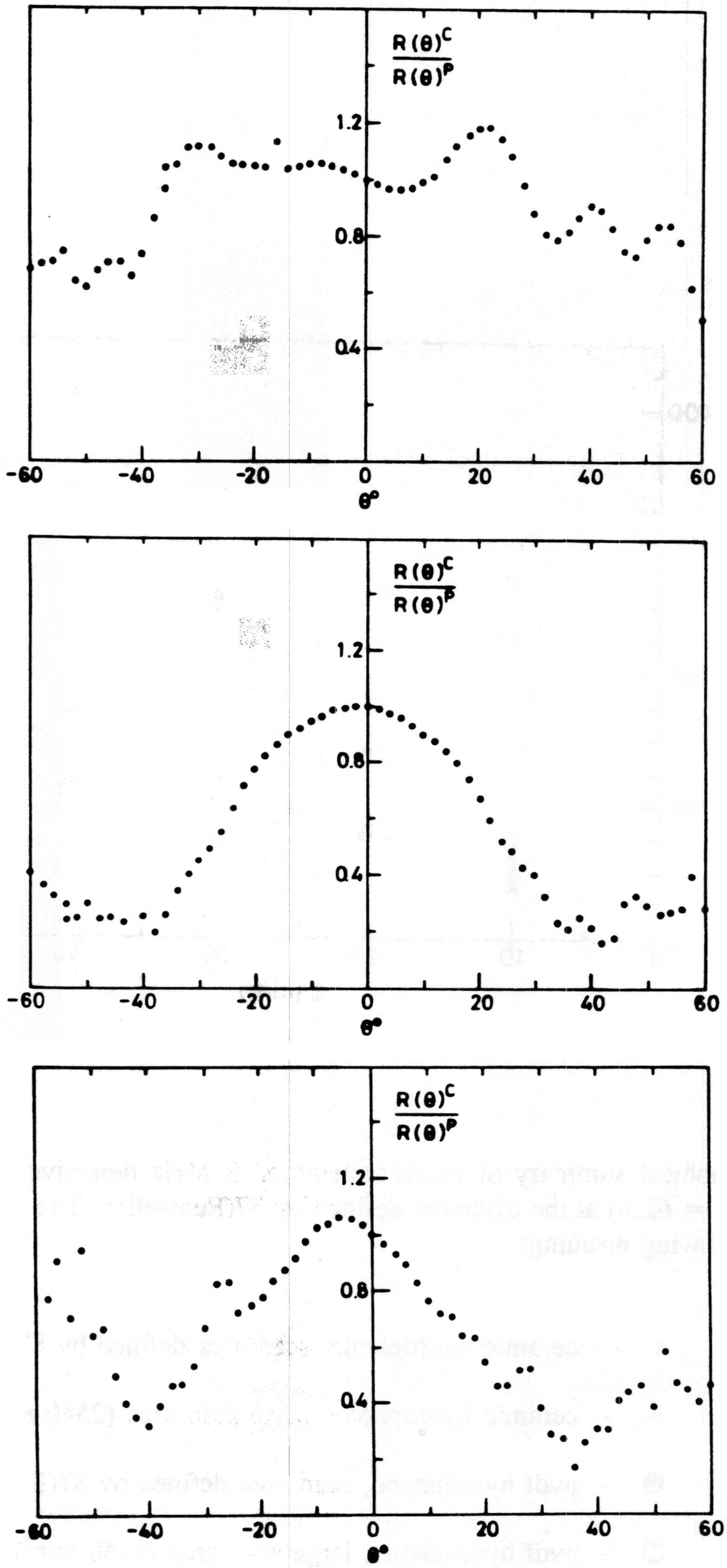
Table 8 Summary of measurements made on defective 3 MHz (ka = 62.8) transducer CS-3 with pvdf and ceramic hydrophones and over different scan areas.

Scan Area (mm^2)	Distance (mm^2)	NPL-ceramic		NPL-pvdf		TNO-pvdf BCSA (mm^2)
		BCSA (mm^2)	Dynamic Range (dB)	BCSA (mm^2)	Dynamic Range (dB)	
392	10.0	38.9	-31.6	49.8	-28.1	60.0
2540	10.0	43.6	-48.0	68.3	-35.8	
324	20.0	57.5	-16.0	78.1	-15.1	143.0
2540	20.0	85.8	-45.9	141.3	-33.1	
467	30.0	73.3	-16.2	107.2	-14.4	257.8
2540	30.0	117.9	-33.9	250.9	-33.6	
635	40.0	85.4	-21.3	114.7	-17.3	410.0
2540	40.0	166.0	-31.7	336.6	-28.0	

Increasing the scan plane area to 2540 mm^2 results in an increase in BCSA(z) at all z values for measurements made using both types of hydrophone but most particularly for the pvdf measurements to such an extent that $BCSA_o$, derived from the linear regression becomes negative.

The different values obtained using pvdf and ceramic hydrophones may be ascribed to the relative directional response shown in Figures 7. For this particular transducer, acoustic levels off the acoustic axis are significant and this is illustrated in Figures 9 a) and b) for measurements in the z = 40 mm plane. Figure 9 a) represents a two-dimensional plot of a raster scan completed using the ceramic hydrophone and its feature is the broad crescent of acoustic intensity approximately 13 mm off-axis. Figure 9 b) gives an identical figure, with the measurements made using the pvdf hydrophone. The figure clearly illustrates the relative enhancement of the low-level acoustic signal and, because the TNO (75%) definition depends on the integrated acoustic signal, its great effect on the measured BCSA(z).

This Section has demonstrated that measurements of BCSA(z) made on strongly divergent therapy fields, can depend on the properties of the measuring hydrophone. This is due to the directional response of the hydrophone and provides extra weight to the redefining of the positions of the measurement planes introduced in Section 4.2. In particular, the requirement is one of moving the planes of measurement away from the divergent transducer far-field.



a

b

c

Figure 7 Relative directional response of the two main hydrophones used in this study, the ceramic (c) and pvdf (p) hydrophones of 0.6 mm diameter. For the purposes of this figure, the relative directional response is the quotient of the individual hydrophone responses at angle Θ, $R^c(\Theta)/R^p(\Theta)$. The figures are for frequencies of frequencies of a) 1 MHz b) 2 MHz and c) 3 MHz.

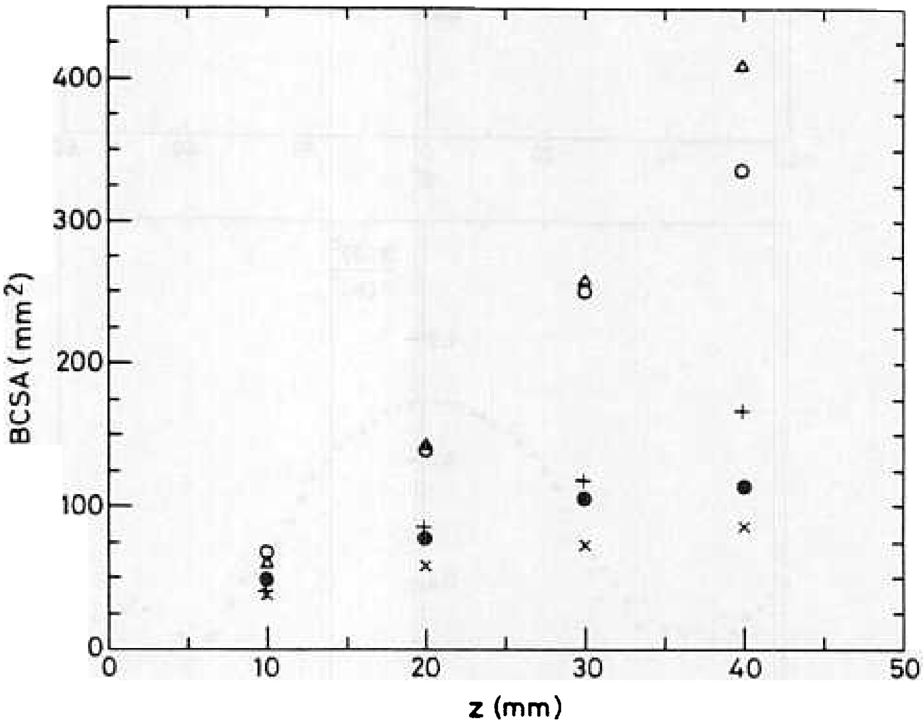


Figure 8 Graphical summary of measurements on 3 MHz defective transducer CS-3 (ka = 62.8) at the distances defined by 87(Benwell)1. The symbols have the following meaning:

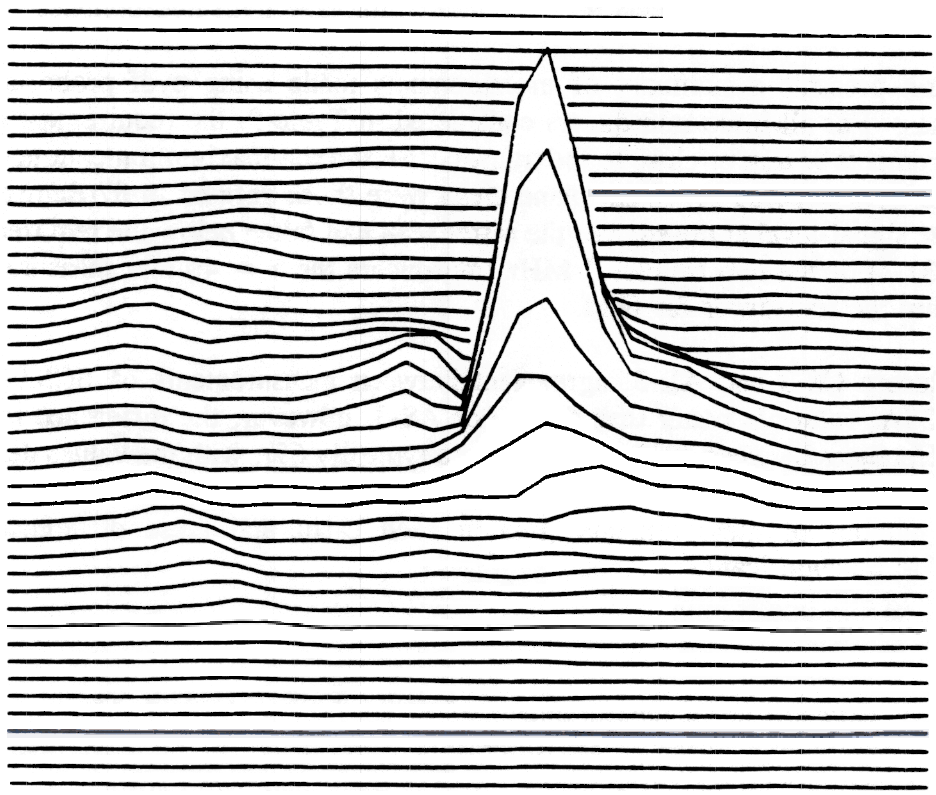
x ceramic hydrophone, scan area defined by 87(Benwell)1

+ - ceramic hydrophone, large scan area (2540 mm^2)

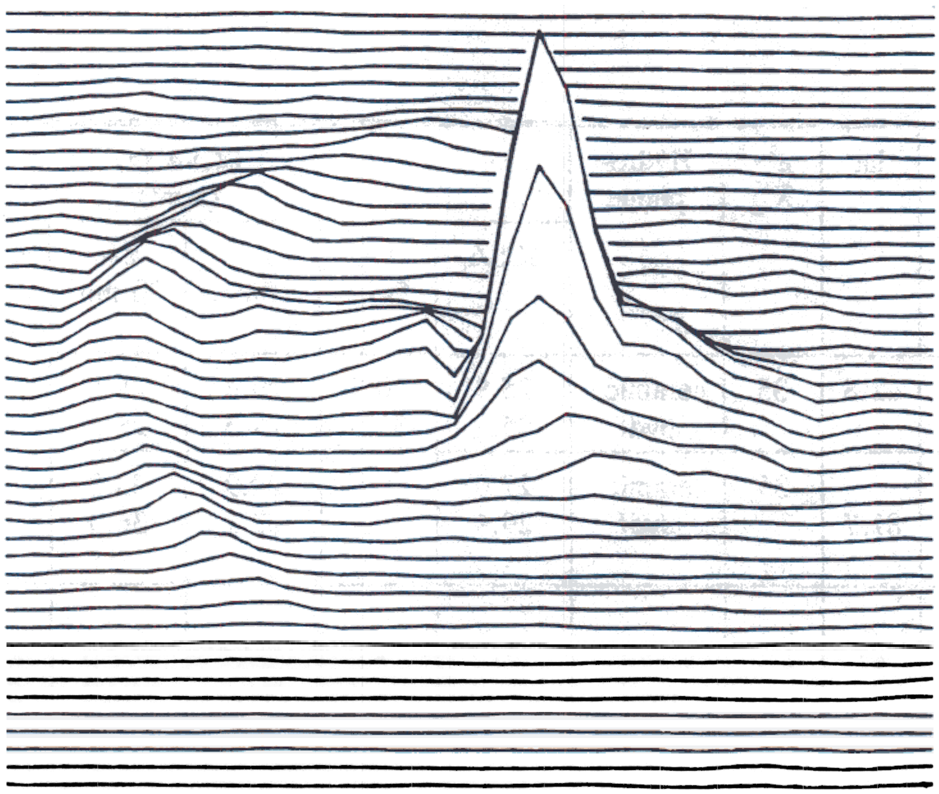
● - pvdf hydrophone, scan area defined by 87(Benwell)1

O - pvdf hydrophone, large scan area (2540 mm^2)

Δ TNO measurements (pvdf hydrophone).



a



b

Figure 9 Raster scans performed at 40 mm on the defective 3 MHz transducer using a) ceramic and b) pvdf hydrophones. The two figures illustrate the enhancement in the off-axis acoustic signal level recorded when using the pvdf hydrophone.

6.1.2 Summary of measurements made using ceramic and pvdf hydrophones

This Section presents a summary of measurements made using pvdf probe and ceramic hydrophones. For all three transducers considered in Table 9, the requirement of carrying out measurements within or close to the transducer last-axial maximum mentioned in the last Section has been adhered to. Scan plane areas were those defined in 87(Benwell)1 and in all cases the signal-level at the edge of the raster scan had fallen below the required level (see Section 4.3). For the two smaller 3 MHz transducers the z = 40 mm measurement plane is just within the transducer far field.

For transducers CS-3 and AL-3, agreement between measurements of BCSA(z) and the derived $BCSA_o$ values is better than 5%. For AS-3, however, the difference in $BCSA_o$ is 9% and differences between BCSA(z) values are typically 6%, with the values derived using the pvdf hydrophone being systematically higher. However, the results were derived from a limited number of measurements (two in each case) and these differences are not considered to be significant.

Table 9 Comparison of measurements of BCSA (z) and derived values of $BCSA_o$ for three transducers. Measurements were made at the scan plane distances defined by the 87(Benwell)1 using ceramic and pvdf hydrophones of effective diameter 0.6 mm.

Transducer	ka	$\frac{a^2}{\lambda}$ m	Hydrophone	BCSA (z) (mm^2)					
				$BCSA_o$	z= 5mm	z= 10mm	z= 20 mm	z=30 or 40mm	z=40 or 80mm
3 MHz CS-3	62.8	35	ceramic	25.9	30.3	29.4	28.8	30.2	35.9
			pvdf	25.7	31.6	29.3	28.3	31.2	35.6
3 MHz AS-3	81.7	35	ceramic	27.0	-	29.9	33.8	36.7	39.6
			pvdf	29.4	-	32.1	36.3	36.3	41.7
3 MHz AL-3 (Ø = 30 mm)	188	170	ceramic	226.3	-	237.6	262.5	298.9	350.1
			pvdf	237.5	-	246.3	267.2	297.4	338.5

6.2 Influence of effective hydrophone diameter

At megahertz frequencies using commercially available hydrophones (normally of diameter 0.6 or 1.0 mm), the accuracy of ultrasonic field measurements can be compromised by the effect of spatial-averaging. The IEC criterion [6] provides an estimate of the maximum hydrophone radius a_{max} that may be used in any particular field, such that

$$a_{max} = \frac{\lambda}{8} \cdot \sqrt{\left(1 + \frac{z^2}{a_t^2}\right)} \tag{5}$$

where λ is the acoustic wavelength, z is the distance of the source from the hydrophone and a_t is the radius of the transducer. Table 10 outlines the implications of the IEC criterion for the measurement of therapy fields commonly encountered. It is clear that, as many of the planes chosen for BCSA(z) measurements lie close to the transducer, the criterion will frequently be violated.

Table 10 Implications of the IEC criterion concerning hydrophone size to measurements on therapy fields. Calculations of z_{min}, the minimum permissible distance between transducer and hydrophone, have been carried out for various hydrophone and transducer diameters and for frequencies typically used in therapy ultrasound.

hydrophone diameter (mm)	Ø (mm)	f (MHz)	z_{min} (mm)
0.6	25	0.75	8.4
		1.0	15.6
		1.5	27.2
		3.0	58.6
	13	0.75	4.4
		1.0	8.2
		1.5	14.2
		3.0	30.6
1.0	25	0.75	21.6
		1.0	31.0
		1.5	48.4
		3.0	99.2
	13	0.75	11.2
		1.0	16.0
		1.5	25.2
		3.0	51.6

The IEC criterion strictly relates to the measurement of peak-pressures. For the purposes of the current project, it is important to investigate the influence of violation of the criterion for measurements of BCSA(z). From Table 10, the greatest violation occurs for large 3

MHz transducers close to the transducer face. For z = 10 mm, Ø = 25 mm, the value of a_{max} is as small as 0.08 mm.

To investigate the effect of hydrophone size, measurements were made at various distances for the 3 MHz transducer AL-3 using 0.6 mm, 1.0 mm and 4.0 mm diameter hydrophones. The results are shown in Table 11. For measurements at z = 10 mm, these hydrophones are too large by factors of 4, 6.5 and 26 respectively. The results presented in Table 11 indicate agreement typically within 1% to 2% between measurements of BCSA(z).

From these results it appears that even with a thirty-fold violation in the IEC criterion, measurements of BCSA(z) may still be made reliably. From Table 10, this could be interpreted as z_{min} < 3 mm for all measurements made using 0.6 or 1 mm hydrophones - effectively validating all measurement planes required in the revised Standard. The insensitivity of the BCSA(z) measurement to the effect of hydrophone size must be due to the fact that spatial-averaging of the pressure distribution does not significantly alter details of the beam profile.

Also presented in Table 11 are values of the beam non-uniformity ratio (BNR(TNO)) evaluated over the TNO(75%) beam cross sectional area. The results of the BNR(TNO) obtained for the three hydrophones are surprisingly consistent. Differences, even in using the 4 mm hydrophone when strong violation has occurred, are generally no greater than 20%. Again, this may be understood in terms of the resultant pressure averaging over the active element of the hydrophone leaving the beam-shape largely unchanged. Although BNR relies on a peak measurement, it also depends on the averaged value of pressure-squared over the beam profile and the spatial-averaging of the two quantities may be similar.

Table 1 Comparison of measurements of BCSA(z) made using hydrophones of active element diameter 0.6 mm, 1.0 mm and 4.0 mm. Measurements were made on a 3 MHz transducer Type BL-3 (Ø = 28 mm) at four distances.

Hydrophone	Measurement	Distance, z (mm)			
		10	20	40	80
ceramic a=0.6 mm	BCSA(z) (mm^2)	199.8	196.5	200.9	207.0
	BNR(TNO)	1.60	1.60	1.75	2.88
ceramic a=1.0 mm	BCSA(z) (mm^2)	193.3	196.1	198.9	207.8
	BNR(TNO)	1.70	1.73	1.66	2.45
pvdf bilaminar membrane a=4 mm	BCSA(z) (mm^2)	201.2	200.2	202.0	210.1
	BNR(TNO)	1.98	1.93	2.08	2.47

Further measurements to investigate the influence of hydrophone size on BCSA(z) are presented in Tables 12 and 13 for transducers BL-1 and BS-3 respectively. The former is a 1 MHz transducer of diameter 24 mm. 87(Benwell)1 requires measurements at z=80 mm where the field will be divergent. Differences between BCSA values obtained using the 0.6 and 4 mm hydrophones at distances of 40 and 80 mm may be ascribed to the influence of directional response described in Section 6.1.1. For smaller separations the difference is 9%.

Table 13 presents a comparison of measurements of BCSA made using the 0.6 and 4 mm hydrophones for the 3 MHz transducer of diameter 16 mm (BS-3). The agreement between BCSA values is again in the range 2% to 6%. For BNR(TNO), the agreement is 14% at z=10 mm and decreases to 30% at z=40 mm.

Table 12 Comparison of measurements of BCSA(z) made using hydrophones of active element diameter 0.6 mm and 4.0 mm. Measurements were made on the 1 MHz transducer BL-1 (Ø = 28 mm) at four distances.

Hydrophone	Measurement	Distance, z (mm)			
		10	20	40	80
ceramic a=0.6 mm	BCSA (mm^2)	249.3	285.2	313.7	407.0
	BNR(TNO)	2.94	1.58	2.29	3.75
pvdf bilaminar membrane a=4 mm	BCSA (mm^2)	275.9	280.8	278.6	290.3
	BNR(TNO)	2.43	1.31	1.81	2.05

Table 13 Comparison of measurements of BCSA(z) made using hydrophones of active element diameter 0.6 mm and 4.0 mm. Measurements were made on the 3 MHz transducer BS-3 (Ø = 16 mm) at four distances.

Hydrophone	Measurement	Distance, z (mm)			
		10	20	30	40
A ceramic a=0.6 mm	BCSA (mm^2)	39.88	42.46	46.09	48.34
	BNR(TNO)	2.00	2.22	2.61	2.66
pvdf bilaminar membrane a=4 mm	BCSA (mm^2)	42.42	43.30	44.97	49.47
	BNR(TNO)	1.72	1.98	2.03	1.88

The insensitivity of the derived BNR and BCSA(z) to hydrophone size needs to be treated with some caution, in particular the almost thirty-fold violation demonstrated. The extent to which spatial-averaging occurs will inevitably depend on details of the acoustic pressure distribution from the transducer. For example, a 'hot-spot' transducer can be characterised by a 6 dB beam-width as small as 2 or 3 mm. In this situation, a 4 mm hydrophone would be expected to produce a large underestimate in the BNR due to spatial-averaging. It is therefore prudent to limit the allowable violation of the IEC criterion, and a factor of eight has been recommended for use as a limit in the new Standard. For the specific example of IEC criterion given earlier (z=10 mm; Ø=25 mm; 3 MHz), use of this factor of eight would result in an a_{max} value of 0.64 mm. This would validate measurements made using 0.6 or 1.0 mm hydrophones, thus permitting reliable measurements of BCSA(z) and BNR on the range of therapy systems currently available.

6.3 Influence of measurement noise

The process of determining BCSA involves integrating the square of the hydrophone signal over the plane of the raster scan and it can be sensitive to noise. Table 14 shows the effect of 'noise' on four raster scans. The level at the edge of the scan for each was of the order of 36 dB and the Table shows the effect of adding intensity (pressure squared), at some specified level of the peak value, to each point in the scan. In practice, subtraction of noise can be carried out after a raster scan, although Table 14 gives an idea of the uncertainty due to noise. Values for the BCSA(z) of the small divergent transducers are particularly sensitive, even a noise level of 37 dB (1.4% amplitude) has an effect of 1.5% to 2%. To keep the effect of noise to below 1%, the signal-to-noise ratio should be better than 40 dB.

A more important problem may lie in the extent of electromagnetic pick-up recorded when using pvdf probe hydrophones for measurements on certain therapy equipment. For certain measurements made during this study, this was as high as 15 dB to 20 dB relative to the peak signal acquired during the raster scan, rendering BCSA(z) determination impossible. This raises the requirement of specifying a limit to the susceptibility of the hydrophone to electromagnetic pick-up.

Table 14 Variation of the BCSA(z) as a specified 'noise' level is added to every point in the raster scan. The scans are as follows:

Scan A - AL-3 3 MHz (Ø = 28 mm) at 10 mm;
Scan B - BL-1 1 MHz (Ø = 24 mm) at 10 mm;
Scan C - CS-3 3 MHz (Ø = 10 mm) at 30 mm;
Scan D - BS-1 1 MHz (Ø = 16 mm) at 11.5 mm.

Noise level (dB)	Scan A BCSA (mm^2)	Scan B BCSA (mm^2)	Scan C BCSA (mm^2)	Scan D BCSA (mm^2)
-	235.78	249.33	30.23	28.93
37	237.59	250.35	30.69	29.49
35	237.32	251.01	30.67	29.66
33	239.12	252.31	31.12	30.23
31	241.83	254.27	31.81	30.98
29	246.41	257.54	32.97	32.32
27	252.94	262.15	34.71	34.43
25	264.46	270.24	37.96	39.10

7 OTHER IMPORTANT TOPICS CONCERNING BCSA MEASUREMENTS

7.1 'Hot-spot' transducers

Along with the need to validate 87(Benwell)1 comes a requirement to develop test methods to identify and characterise transducers that produce high local intensities or acoustical 'hot-spots'. Figure 10 gives an example of such a transducer: the 1.5 MHz (DE-04) transducer Type AL-1 of nominal diameter 25 mm produces a local high intensity at z = 29 mm and exhibits subsidiary maxima at z = 5 mm and z = 60 mm. Figure 11 illustrates an axial scan performed on a nominally equivalent transducer that appears to be operating normally. It is of interest to note that the maxima in the axial plot appear at the same distances from the transducer face.

Figure 12 shows the variation of the beam area, calculated using both the FDA (-13 dB) and the TNO (75%) definitions, with distance from the transducer, z. The dashed line represents a linear regression through the measurement planes identified in the revised Standard. It is clear that the change in the TNO (75%) in the region of the acoustical 'hot-spot' (29 ± 3 mm) is relatively small (-11%). The FDA (-13 dB) definition is particularly sensitive to the 'hot-spot' and decreases to approximately a third of its extrapolated value at the face.

Another test for a 'hot-spot' may come from the value of the beam nonuniformity ratio (BNR). Figure 13 shows values of BNR(TNO) and BNR(FDA), where the averaged intensity in each of the respective cases has been evaluated over the areas defined by TNO (75%) and FDA (-13 dB). Also included in Figure 13 are BNR values for normal transducers and these demonstrate the smooth relation between BNR(TNO) and BNR(FDA) up to a BNR(TNO) value of approximately eight. This is very different to the dependence of BNR(TNO) for DE-04 where, in the region of the 'hot-spot' its value increases to between 15 and 20. Over the same region the change in BNR(FDA) is small, from six to seven. The sensitivity of BNR(TNO) to the acoustical 'hot-spot' is due to the relative insensitivity of BCSA calculated using the TNO definition demonstrated in Figure 12.

The measurements made on DE-04 allow two conclusions to be drawn:-

i) The first involves classification of the beam-type. In both the FDA reporting requirements and in 87(Benwell)1, the characterisation of a transducer as focussed involves comparing measured beam areas at the face of the transducer to its value at the 'focus' (as defined by the position of peak hydrophone signal). For a 'hot-spot' transducer (such as DE-04) such a transducer may be identified by a BNR(TNO) value > 8. In general, the transducer will not be classified as 'focussed' using the TNO definition although it may be under the FDA definition.

i) For true, deliberately focussed transducers, a transducer will have BNR(TNO) values typical of normal transducers (certainly BNR < 8) but would additionally fulfil the definition of focussed described in i).

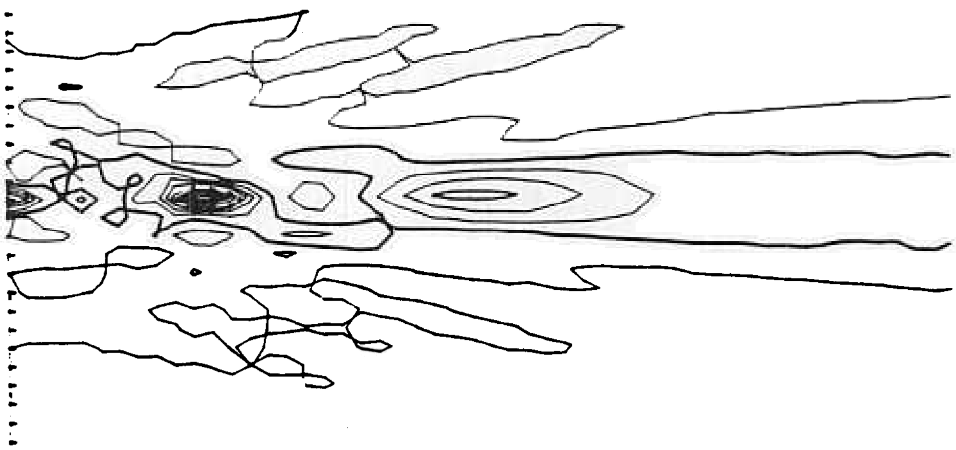


Figure 10 Sectional view of the acoustic field distribution of the 'hot-spot' transducer DE-04 (AL-1 1.5 MHz) showing local maxima at 5, 29 and 60 mm.

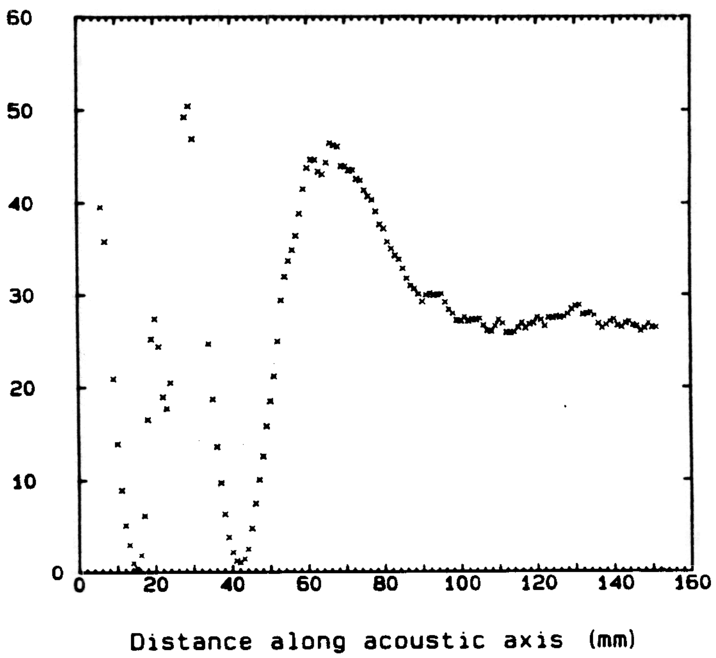


Figure 11 Axial scan carried out on the 1.5 MHz transducer AL-1, equivalent to DE-04 but which appears to be operating normally. The y-axis represents the square of the hydrophone voltage depicted in arbitrary units. The position of the axial maximum occurs at z = 29 mm.

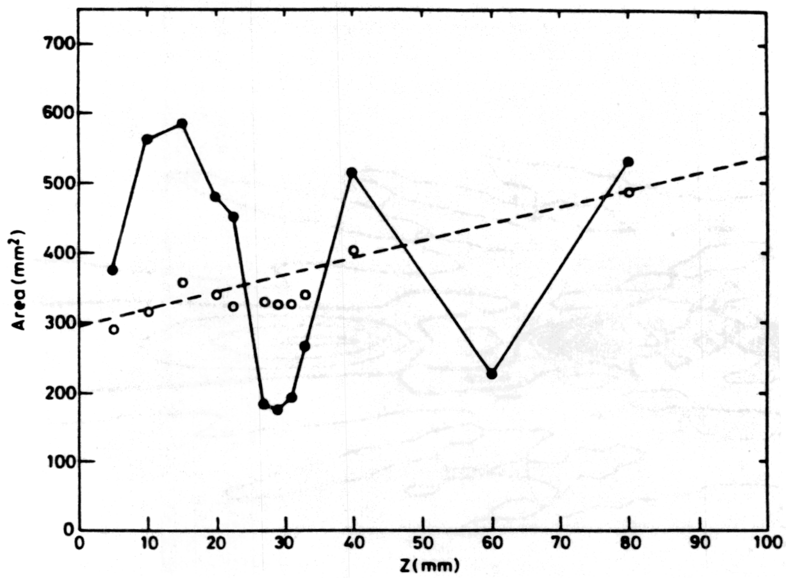


Figure 12 Variation of the beam area, calculated using different definitions, TNO(75%) (⊙) and FDA (-13 dB) (•), along the acoustic axis of the 'hot-spot' transducer DE-04.

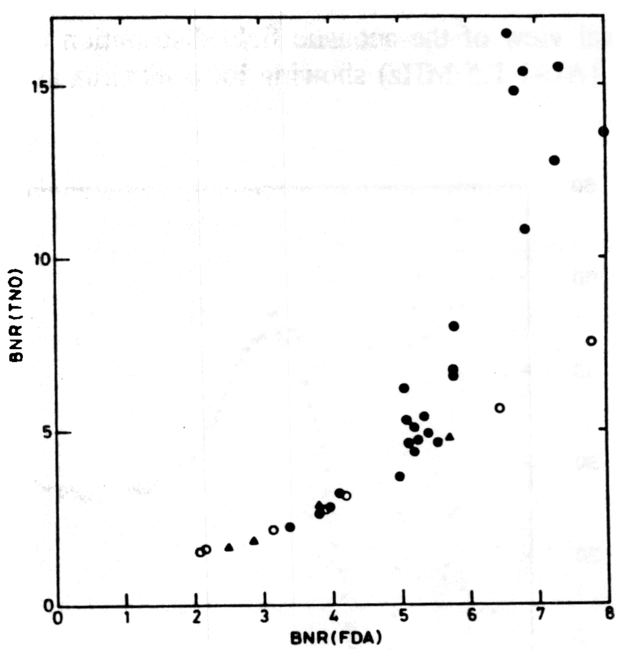


Figure 13 Plot of BNR (TNO) versus BNR (FDA) for several transducers:-

● DE-04 AL-1 1.5 MHz
⊙ BL-1 1 MHz (ka = 50.3)
Δ BL-3 3 MHz (ka = 151)

The diagram illustrates the rapid increase in BNR(TNO) close to the region of the 'hot-spot' for the transducer DE-04.

At the end of Section 3, the distinction was made between BNR(TNO) used in this report which applies to measurements in a particular plane and the FDA definition which requires I_{sptu} averaged over the effective radiating area. The principle behind the latter definition will be used in the revised IEC Standard to calculate the BNR. The expression for BNR, relating as it does to the averaged intensity over the face of the transducer, will be more sensitive to identifying focussed transducers. These transducers will have high BNR values. The two distinct definitions of the beam nonuniformity ratio may be differentiated as follows: $BNR(TNO)=I_{sptu}(z_p)/I_{satu}(z_p)$ and $BNR=I_{sptu}(z_p)/I_{satu}(z=0)$; and they are related by the expression

$$\frac{BNR}{BNR(TNO)} = \frac{Factor}{1.333} \cdot \frac{BCSA_o}{BCSA(z_p)}$$

where the term Factor is used to convert $BCSA_o$ to the effective radiating area. Its calculation forms the theoretical content of the current BCR project undertaken by the PTB and will be dealt with elsewhere in the overall project report. Factor is equal to 1.354 for transducers of ka product greater than 40 ($k=2\pi/\lambda$, where λ is the wavelength and a is related to the geometrical radius of the transducer and is given by $a = \sqrt{(BCSA_o/\pi)}$). For ka less than 40, Factor = (2.90 - 0.0386 ka).

For many of the transducers dealt with in this report the values of BNR will be similar to those calculated in the measurement plane of interest. From Table 15, values for BNR for the transducers DE-12 (AL-3), BL-3, AL-3 and BL-1 are 4.27, 4.29, 7.28 and 6.22.

7.2 Moving the measurement plane away from a 'hot-spot'

87(Benwell)1 describes a procedure for ensuring that the measurement planes chosen for the raster scans are sufficiently distant from the position of the axial maximum (peak-rms) to render its influence insignificant. Table 15 gives the results for four transducers, detailing values of the BCSA(TNO) at the position of the maximum, compared to values interpolated or extrapolated from the linear regression through the four defined measurement planes. In all cases, the contraction in the value of BCSA(TNO) is small, typically a few per cent. Of particular interest are the results for the 3 MHz AL-3 transducer (ka = 176), where the value of BNR(TNO) at the axial maximum is equal to 7.4. The contraction of the TNO (75%) area in this case is equal to 3.8% and is large enough to be significant.

As a general statement, if BNR(TNO) < 6, the fact that a raster measurement plane is at the axial maximum will have only a small effect on the derived BCSA(TNO) value. If this is the case, the raster scan performed at this position could potentially be included in the linear regression, removing the requirement for measurements at one of the other raster planes.

The transducers included in Table 15 are all of geometrical diameter 25 mm or greater. For smaller transducers (Ø < 15 mm) the values for BNR(TNO) are typically less than 3.

Table 15 Table showing the effect of measurements of BCSA(z) at the position of the axial maximum ($z = z_p$). Directly measured values BCSA(z_p) are compared with those obtained from the linear regression through the measurement planes defined in 87(Benwell)1 (BCSA$_e$(z_p)).

Transducer	ka	z_p (mm)	BCSA(z_p) (mm^2)	BNR(TNO) $z = z_p$	BCSA$_e$ (z_p) (mm^2)	Differ -ence
DE-12 AL-3 3 MHz	176	46	223	4.55	226	-1.3 %
BL-3 3 MHz	151	131	213.4	4.78	218.5	-2.4%
AL-3 3 MHz	176	20	248.3	7.4	258.2	-3.8%
BL-1 1 MHz	50.3	3	233.8	6.22	239	-2.2%

7.3 Rationalisation with existing standards

Table 16 represents a comparison between values of ERA determined from measurements in compliance with FDA [5] and values determined from the new procedures. For the purposes of Table 16 these distinct values are identified as ERA(FDA) and ERA(IEC). Also presented in Table 16 are values for BCSA$_0$ determined from the linear regression and values for d, ka and Factor evaluated in the way described in the previous Section.

Included in Table 16 are transducers that have been diagnosed as working normally as well as defective transducers. Generally, as with transducers operating normally, values of BCSA(z) derived for defective transducers exhibit a linear relationship with z. From Table 4, it may be seen that uncertainties in BCSA$_0$ due to the linear regression are similar for defective and normal transducers. However, some care needs to be exercised in interpreting the values of ERA for defective transducers; although the intercept value retains a significance, there must be an uncertainty in the correct value of Factor to use. However, for collimated beams and a linear dependence of BCSA(z) with z, a factor close to 1.333 should still be appropriate.

It is possible to draw some general conclusions from the results shown in Table 16. For the 1 MHz transducer BS-1, the ERA(IEC) exceeds ERA(FDA) by 12%. More generally, the FDA definition yields values for the ERA which are typically 27% higher than the ERA determined from the new procedures. There is considerable variation within this group of transducers, with differences being as small as 9% and as high as 37%.

An important consequence of this difference is that invoking the new methods of measurement will result in values of effective intensity increasing by 25% or possibly more. However, this statement needs to be qualified to some extent. Clearly, a crucial aspect of the calculation of ERA(IEC) lies in the value of Factor used to convert BCSA$_0$ to ERA(IEC) and this is the subject of the report produced by the PTB. Part of the program of calculations was to evaluate ERA using the FDA definition and these calculations suggest that the procedure defined by the FDA actually overestimates the value of the ERA by 10% to 30%. This therefore accounts for part of the difference in the two methods of determination of the effective radiating area.

Table 16 Tabulation of values of ERA(FDA), ERA(IEC) and $BCSA_o$ for some of the transducers studied. The final column represents the % difference between the two effective radiating area values and has been calculated using the expression

$$\text{Difference} = \frac{[\ \text{ERA(FDA)} - \text{ERA(IEC)}\ ]}{\text{ERA(FDA)}} \times 100\%.$$

Note:- Factor is the quantity required to convert $BCSA_o$ derived from the IEC measurement procedure to ERA(IEC).

Transducer details	$BCSA_o$ (mm^2)	ka	Factor	ERA (IEC) mm^2	ERA (FDA) mm^2	Difference (%)
DE-08 3 MHz 28 mm	234.6	110	1.354	318	367.2	13.5%
DE-04 AL-1 28 mm *	284.1	60.5	1.354	384.7	220.7	-74%
BL-3 3 MHz 24 mm	193.1	110	1.354	261.5	397.7	34%
BL-1 1 MHz 24 mm	232.5	40.1	1.354	314.8	344.3	9%
AS-3 3 MHz 13 mm	27.0	37.3	1.46	39.5	57.4	31%
AL-3 3 MHz 28 mm	226.3	108	1.354	311	407.5	24%
CS-3 3 MHz 10 mm	25.85	36.5	1.49	38.6	60.8	37%
BS-1 1 MHz 16 mm +	25.1	13.2	2.39	60	53.4	-12%
BS-3 3 MHz 16 mm	38.1	48.7	1.354	51.6	87.2	41%
DE-128 BL-1 1 MHz 24 mm°	264.1	42.8	1.354	358	467.6	24%

* - 'hot-spot' transducer, axial maximum at 29 mm (see Section 6.1).
° - non-87(Benwell)1 scan plane areas used.
+ - measurements made at planes defined by the position of the last-axial maximum (25 mm). Raster scans were performed at distances of 5, 11.5, 18 and 25 mm.

8. MEASUREMENT UNCERTAINTY

Sources of uncertainty and their estimates for the measurement of BCSA(z) in any plane z are presented in Table 17.

Table 17 Sources of uncertainty for the measurements of BCSA(z). The Table provides typical values of the systematic uncertainty expressed as semi-ranges.

Source of uncertainty	Estimate
random (95% confidence level)	± 3% - 4%
noise	± 0.8%
truncation of raster scan	± 0.6%
system nonlinearity	± 0.8%
spatial-averaging	± 1.5%
resolution	± 1%
transducer stability	± 1%
total systematic uncertainty (95% confidence level)	± 2.8%
overall uncertainty (95% confidence level)	± 4% - 5%

The resolution uncertainty has been derived from 100 measurement points contributing to the BCSA value with no interpolation applied. For measurements on some transducers, a systematic drift in the transducer output was noted during the course of the raster scan. This was estimated by comparing on-axis signal levels for v^2 at the beginning and end of the raster scan. Typical changes, involving both increasing and decreasing transducer output power during the raster scan, were 2% to 7%. For some transducers, such as BS-3, the output exhibited a systematic increase during the scan of typically 3% and this would be expected to contribute to the systematic uncertainty in BCSA(z) measurement.

For the determination of $BCSA_o$, typical uncertainties in the intercept of the linear regression are ± 2.5% to ± 5%. However, where the linear regression is poor, as in the example of the transducer BS-1 highlighted in Section 4.2, the uncertainty is as high as ± 18%. The total systematic uncertainty for the measurement of $BCSA_o$ is estimated to be typically between ± 5% and ± 7%.

For diametrical scans, sources of systematic uncertainty are similar to those presented in Table 17. The random uncertainties, which now include the spread in values produced by diametrical scans of different orientation, are typically between ± 5% and ± 7% for eight equally spaced diametrical scans.

The total measurement uncertainty for the determination of BCSA(z) from diametrical scans is estimated to be in the range ± 6% to ± 8%. Total measurement uncertainties for determination of $BCSA_o$ are estimated to be between ± 7% and ± 9% when expressed at the 95% confidence level.

9. CONCLUSIONS

The accuracy of measurements of BCSA(z) and $BCSA_o$ derived from raster scans has been studied and typical overall values assessed at ± 4% to ± 6% (95% confidence level). The studies have indicated the importance of a number of factors in specifying the details of the raster scan.

The first is the need to specify the raster scan area. To ensure that the truncation error is less than 1%, the dynamic range of the scan, which may be defined as the level at the edge of the raster scan relative to the peak value in the scan, should be greater than 30 dB.

For certain transducers, the positions of the raster scan planes was found to have a significant effect on the extrapolation process for determining $BCSA_o$. For transducers of last-axial maximum position, N, greater than 50 mm, the variation of BCSA(z) with separation, z, exhibited a linear dependence. For some transducers for which N < 50 mm, strong curvature was noted, particularly for a 1 MHz Ø = 16 mm transducer, leading to large uncertainties in the extrapolated value of $BCSA_o$. Redefining the positions of the scan planes relative to N, improves the linearity but still results in significant uncertainty as much of the curvature appears well within the near-field. These problems are particularly acute for divergent transducers, or for transducers of ka product < 30. Due to the nonlinear variation of BCSA(z) with z for these transducers, it may in some instances be more appropriate to adopt a simplified measurement method based on a single measurement close to the transducer face. This simpler method of measurement could be triggered by a certain minimum value of ka or when the error in the intercept of the linear regression exceeded a certain level. A 10% level could be used as typical uncertainties for good linear regressions are better than 5%.

The method of $BCSA_o$ determination involves a linear regression from raster scans at four measurement planes. One objective of this project was to develop methods of measurements that would be less time-consuming. In this respect, simplified methods, based on single measurements at z = 5 mm, exhibit good agreement with values derived from measurements in four planes, providing N > 50 mm. The agreement is due to the collimated nature of the acoustic beams.

Values of BCSA(z) have been shown to be insensitive to the raster scan step-size used, with square grids as coarse as 20 x 20 being shown to yield consistent results. Reliable values require at least 80 measurement points contributing to BCSA(z).

The requirement for moving the measurement planes closer to the transducer, and away from the divergent transducer far-field was additionally confirmed by the need to avoid problems caused by directional characteristics of the hydrophone. This could, in some circumstances, lead to significant differences in BCSA measurements made using pvdf and ceramic hydrophones. For measurements in well collimated beams, differences between BCSA measurements made using these particular hydrophone types were small, typically a few per cent.

The effect of violating the IEC criterion [6] dealing with maximum hydrophone size has been studied. Measurements made on a 3 MHz therapy transducer of diameter 28 mm using hydrophones of effective diameter 0.6 mm, 1.0 mm and 4.0 mm have revealed agreement to within 2% for measurements of BCSA(z) - even in situations where the criterion has been violated by a factor of 26.

With a view to developing rapid measurement techniques suitable for routine testing, values of BCSA and $BCSA_0$ obtained using reference raster scans and diametrical beam plots have been shown to be in good agreement.

The contraction in the BCSA(z) at the position of the axial peak has been shown to be less than a few per cent. For transducers exhibiting 'hot-spots', the relative change in BCSA(z) is still small, the maximum value observed being 11% for a beam nonuniformity ratio of approximately 20. The value of the beam nonuniformity ratio is very sensitive to the position of a 'hot-spot', and a value of 8 has been ascribed to the demarcation of what constitutes 'normal' and 'hot-spot' transducers.

10. ACKNOWLEDGEMENTS

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