

Medical electrical equipment —

Part 3: Particular requirements for performance —

Section 3.26 Method for declaring parameters for ultrasonic diagnostic equipment using test objects

UDC 615.47:62-83:621.31 + 620.179.16.004.15

Confirmed December 2011

NO COPYING WITHOUT BSI PERMISSION EXCEPT AS PERMITTED BY COPYRIGHT LAW



Document Sharing Hub

Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/111, upon which the following bodies were represented:

- British Institute of Radiology
- College of Radiographers
- Department of Health
- Department of Trade and Industry (National Physical Laboratory)
- Electro-Medical Trade Association Limited
- Institute of Physical Sciences in Medicine (IPSM)
- Ministry of Defence
- Ophthalmological Society of the United Kingdom
- Scottish Health Services

This British Standard, having been prepared under the direction of the Health Care Standards Policy Committee, was published under the authority of the Board of BSI and comes into effect on 29 June 1990

© BSI 06-1999

The following BSI references relate to the work on this standard:
Committee reference HCC/111
Draft for comment 87/52777 DC

ISBN 0 580 17884 6

Amendments issued since publication

Amd. No.	Date of issue	Comments

Contents

	Page
Committees responsible	Inside front cover
Foreword	2
Section 1. General	
1 Scope and object	1
2 Definitions	1
Section 2. Preliminary test and operating conditions	
3 Preliminary test and operating conditions	3
Section 3. Declaration and measurement of parameters	
4 Performance parameters	5
5 Resolution	5
6 DEAD ZONE	6
7 SLICE THICKNESS	6
8 DEPTHS OF PENETRATION	7
9 DISPLAYED DYNAMIC RANGE	7
10 MAGNIFICATION ERRORS	7
11 REGISTRATION ERROR	8
12 ACCURACY OF THE CALLIPER	8
13 Presentation of performance parameters	10
Section 4. Requirements for TEST-OBJECTS	
14 TEST-OBJECT design	11
Appendix A Tissue-mimicking material	12
Figure 1 — Section through TEST-OBJECT CONFIGURATION 1 to determine AXIAL RESOLUTION, DEAD ZONE and DEPTHS OF PENETRATION when $2 \text{ MHz} < \text{frequency} < 8 \text{ MHz}$	13
Figure 2 — Section through the REFERENCE PLANE of TEST-OBJECT CONFIGURATION 2 to determine LATERAL RESOLUTION when $2 \text{ MHz} < \text{frequency} < 8 \text{ MHz}$	14
Figure 3 — Section in a plane perpendicular to the REFERENCE PLANE of TEST-OBJECT CONFIGURATION 3 to determine SLICE THICKNESS when $2 \text{ MHz} < \text{frequency} < 8 \text{ MHz}$	15
Figure 4 — Section through the REFERENCE PLANE of TEST-OBJECT CONFIGURATION 4 for the production of an ACOUSTIC GREY SCALE wedge when $2 \text{ MHz} < \text{frequency} < 8 \text{ MHz}$	16
Figure 5 — Section through the REFERENCE PLANE of TEST-OBJECT CONFIGURATION 5 to determine MAGNIFICATION ERROR, REGISTRATION ERROR and ACCURACY OF THE CALLIPER when $2 \text{ MHz} < \text{frequency} < 8 \text{ MHz}$	17
Table 1 — Specified values for the attenuation of sound in tissue-mimicking materials	11
Publications referred to	Inside back cover

Foreword

This Section of BS 5724 has been prepared under the direction of the Health Care Standards Policy Committee.

This British Standard complements BS 5724 “*Medical electrical equipment*” — Part 2 “*Particular requirements for safety*” — Section 2.26 “*Specification for ultrasonic medical diagnostic equipment*”¹⁾, which will be identical with the corresponding international standard being prepared by the International Electrotechnical Commission (IEC).

The Technical Committee responsible for this British Standard was unable to specify requirements for declaring performance in respect of low contrast detectability and was unable to specify a method of measuring back scatter in the tissue-mimicking material used in the TEST-OBJECTS.

In this British Standard, it is assumed that a light image is displayed on a dark background. If the displaying image is a dark image on a light background, then the term DARK THRESHOLD should be replaced throughout by LIGHT THRESHOLD.

Terms defined in this and other Parts of BS 5724 are written in capitals.

NOTE The titles of the publications referred to in this standard are listed on the inside back cover. A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 18, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

¹⁾ In preparation.

Section 1. General

1 Scope and object

1.1 Scope

This Section of BS 5724 describes the performance parameters to be stated in documents accompanying an ULTRASONIC MEDICAL DIAGNOSTIC EQUIPMENT as defined in 2.31, together with methods for evaluating its performance using specified TEST-OBJECTS.

This Section of BS 5724 does not cover Doppler effect facilities of ULTRASONIC MEDICAL DIAGNOSTIC EQUIPMENT.

1.2 Object

The object is to permit the direct comparison of ULTRASONIC MEDICAL DIAGNOSTIC EQUIPMENT of different manufacture, and to standardize methods for the determination of compliance with the manufacturer's declared performance.

2 Definitions

For the purposes of this Section of this British Standard, the following definitions apply.

2.1

accuracy of the calliper

the difference between the length or area of a feature of a TEST-OBJECT and the value determined using the calliper. The difference is expressed as a percentage of the length or area

2.2

accoustic grey scale

an area of a TEST REGION, the position of which is identified in the TEST-OBJECT documentation, that displays a wide range of grey scale levels

2.3

central magnification

letter symbols: a_{cx} and a_{cy}

ratio of the length of the image, in the OUTPUT DISPLAY PLANE, of a given feature of a TEST-OBJECT, determined when the centre of the image is located at the CENTRE OF THE FIELD OF VIEW, to the length of the given feature. The image is aligned such that the length direction is either perpendicular to (subscript x) or parallel to (subscript y) the scan line passing through its centre

2.4

centre of the field of view

a point on the centreline of the TEST-OBJECT, which is situated nearest to midway between the TEST-OBJECT SCANNING SURFACE and the MAXIMUM DEPTH OF PENETRATION

2.5

30 % dark threshold

a TEST REGION is said to be at 30 % DARK THRESHOLD when approximately 30 % of the region is at the lowest displayable grey level

2.6

70 % dark threshold

a TEST REGION is said to be at 70 % DARK THRESHOLD when approximately 70 % of the region is at the lowest displayable grey level

2.7

dead zone

the distance from the TEST-OBJECT SCANNING SURFACE to the first wire, the image of which is unequivocally displayed

2.8

displayed dynamic range

the ratio of the amplitude of the maximum echo that does not saturate the display to the minimum echo that can be distinguished in the display under stated operating conditions

2.9

field of view

that part of a TEST-OBJECT which is imaged when scanned by the ULTRASOUND IMAGING SYSTEM with the transducer held stationary against the TEST-OBJECT SCANNING SURFACE and the scanner set to the appropriate settings

2.10

fine scale echoes

echoes from bulk fine structure in the TEST-OBJECT

2.11

image region

any region in the OUTPUT DISPLAY PLANE representing an area of more than one TEST REGION

2.12

30 % light threshold

a TEST REGION is said to be at 30 % LIGHT THRESHOLD when approximately 30 % of the region is at the highest displayable grey level

2.13

70 % light threshold

a TEST REGION is said to be at 70 % LIGHT THRESHOLD when approximately 70 % of the region is at the highest displayable grey level

2.14

local magnification

letter symbols: a_{dx} and a_{dy}

the ratio of the length of the image, in the OUTPUT DISPLAY PLANE, of a given feature of a TEST-OBJECT, determined when the centre of the image is located at the point under consideration, to the length of the given feature. The image is aligned such that the length direction is either perpendicular to (subscript x) or parallel to (subscript y) the central scan line of the image

2.15 magnification error

letter symbols: V_{dx} and V_{dy} .

the difference between the CENTRAL MAGNIFICATION and the LOCAL MAGNIFICATION at a particular point in the FIELD OF VIEW for a given orientation, expressed as a percentage of the CENTRAL MAGNIFICATION

2.16 maximum depth of penetration

the maximum depth at which the images of wires within the TEST-OBJECT can be obtained

2.17 normal depth of penetration

the maximum depth in the TEST-OBJECT from which FINE SCALE ECHO information can be obtained under normal operating conditions

2.18 output display plane

the optical plane in which the displayed output image lies

2.19 radial scanning system

a scanning system which generates an essentially circular set of scan lines in a plane

NOTE Examples of radial scanning systems include rotating transducers and phased array sector scanners.

2.20 rectilinear scanning system

a scanning system which is capable of employing parallel or approximately parallel scan lines

NOTE Examples of rectilinear scanning systems include linear arrays, manual contact B-scanners and stand-alone A-mode systems. A-mode facilities linked to an imaging system would be placed in the category which defines that system. M-mode systems are considered as B-mode.

2.21 reference plane

a plane so indicated on the external structure of the TEST-OBJECT

2.22 registration error

the maximum distance between the centres of images of a wire in a TEST-OBJECT when referred to the TEST-OBJECT dimensions

NOTE REGISTRATION ERROR applies only to scanners producing composite scans in two or more distinct directions.

2.23 scan plane

a plane containing the ULTRASOUND scan lines

2.24 slice thickness

the dimension, perpendicular to the SCAN PLANE, at a stated depth, of the material of the TEST-OBJECT from which acoustic information is displayed

2.25 test-object

a device containing one or more groups of TEST-OBJECT CONFIGURATIONS immersed in a tissue-mimicking material

2.26 test-object configuration

a group of wires or inserts within a TEST-OBJECT which is used for one or more performance measurements

2.27 test-object scanning surface

a surface of the TEST-OBJECT through which the ULTRASOUND beam enters

2.28 test region

any region in the OUTPUT DISPLAY PLANE representing a specified area in the TEST-OBJECT

2.29 ultrasound

mechanical oscillation consisting of local compression, and rarefaction of the material, the frequency of which is above 20 kHz

2.30 ultrasound imaging system

a system by means of which the position of an object in the SCAN PLANE is displayed as an output image in the OUTPUT DISPLAY PLANE

2.31 ultrasonic medical diagnostic equipment

EQUIPMENT for the generation and application to PATIENTS of ULTRASOUND and intended for medical diagnostic investigation (hereafter referred to as EQUIPMENT)

Section 2. Preliminary test and operating conditions

3 Preliminary test and operating conditions

3.1 General

3.1.1 The tests shall be undertaken using TEST-OBJECTS complying with section 4.

NOTE The TEST-OBJECT should be chosen such that its enclosure fits the ultrasonic probe(s) supplied with the equipment.

3.1.2 Scans shall be repeated through slightly different orientations until the studied feature is consistently imaged on all the scans. All measurements of axial and lateral resolution on RADIAL SCANNING SYSTEMS shall be made along the line of symmetry of the sector (0° measurement) and should if possible be repeated at an angle of 30° to this line (30° measurement).

3.1.3 The tests shall be undertaken using the accessories and associated cables recommended in the ACCOMPANYING DOCUMENTS.

3.1.4 If manual gain controls are provided, they shall be used for the tests. If automatic gain control is the only method provided for the control of gain, measurements shall be made at scanning gain and this fact should be recorded.

NOTE To ensure consistency in any set of results, the tests should be carried out by a single observer under a constant and subdued lighting level.

3.2 Initial scanner setting

The EQUIPMENT shall be set up for scanning as recommended in the ACCOMPANYING DOCUMENTS.

3.3 Scanning gain

3.3.1 The scanning gain shall be set as described in 3.3.2 to 3.3.8.

3.3.2 Select initial settings according to 3.2.

3.3.3 Scan TEST-OBJECT CONFIGURATION 1 (see Figure 1) through TEST-OBJECT SCANNING SURFACE 1 in the REFERENCE PLANE.

3.3.4 Adjust all gain controls to maximize the depth of visualization of the FINE SCALE ECHOES in the OUTPUT DISPLAY PLANE.

3.3.5 Observe the average intensity level of the FINE SCALE ECHOES in the penultimate centimetre visualized.

3.3.6 Match the FINE SCALE ECHOES throughout the visualized depth to that observed in the penultimate centimetre. Begin by using the near field controls if provided and use the minimum possible adjustment of controls which affect the far gain.

3.3.7 Adjust the overall gain to bring the overall FINE SCALE ECHO intensity level to the mid-range grey scale.

3.3.8 Record the resulting position in all gain controls as the scanning gain setting.

3.4 Viewing screen settings, recording screen settings and camera settings

3.4.1 Viewing screen settings, recording screen settings and camera settings shall be established as described in 3.4.2 to 3.4.13.

NOTE The selection of scanning gain as described in 3.3 is an essential preliminary to this procedure.

3.4.2 Scan TEST-OBJECT CONFIGURATION 1 through SCANNING SURFACE 1 in the REFERENCE PLANE.

3.4.3 Using, as a convenient test structure, the visualization of the axial beam profile groups (group D), adjust all focus controls available to the user that affect the screen focus so as to obtain the sharpest presentation of the image.

3.4.4 Scan TEST-OBJECT CONFIGURATION 4 (see Figure 4) through TEST-OBJECT SCANNING SURFACE 1 in the REFERENCE PLANE.

3.4.5 Determine an echo-free IMAGE REGION. Reduce the contrast and brilliance controls to their minimum values.

3.4.6 Adjust the control until there is a just noticeable difference in screen brightness thus ensuring the display of the lowest level echoes. This procedure establishes the brilliance level.

3.4.7 Examine the image region designated as ACOUSTIC GREY SCALE in the TEST-OBJECT documentation and, by adjusting the contrast controls, maximize the length of this region over which a brightness variation is visible. This procedure establishes the contrast setting.

3.4.8 Repeat the procedure given in 3.4.6 and 3.4.7 in sequence until both the brightness and contrast setting criteria are simultaneously met.

3.4.9 If these brightness and contrast settings are significantly different from those recorded in 3.3.8 repeat the scanning gain setting by the procedure outlined in 3.3 and then from 3.4.2.

3.4.10 Record the final focus, brilliance and contrast settings. These are the viewing screen settings.

3.4.11 Repeat the procedure given in 3.4.2 and 3.4.10 for any additional viewing screens.

3.4.12 Repeat the procedure given in 3.4.2 to 3.4.10 so as to optimize any image recording system but using the recorded image in place of the viewing screen.

3.4.13 Record the final focus, brilliance and contrast settings as recording settings and, if a camera is used, include focus, aperture, shutter speed, and film type as camera settings. If the same screen is used both for viewing and recording, the monitor settings appropriate to the task in hand, i.e. viewing or recording, shall be used.

NOTE It will generally be found that a screen set for photographic recording will be too bright and have too little contrast for viewing.

3.5 Measurement gain settings

3.5.1 Select the scanning gain and viewing screen settings as described in **3.3** and **3.4**.

The measurement gain settings shall be established as described in **3.5.2** and **3.5.3**.

3.5.2 Scan the TEST-OBJECT CONFIGURATION 1 (see Figure 1) or the TEST OBJECT CONFIGURATION 2 (see Figure 2) in the REFERENCE PLANE depending on the test procedure of the parameter being measured (e.g. imaged beam profile) and select an image region at the depth of interest.

3.5.3 Reduce the overall gain of the scanner until the image region is at 70 % DARK THRESHOLD. This image region is then at the measurement gain.

3.6 Recording gain

3.6.1 Select the scanning gain and viewing screen settings as described in **3.3** and **3.4**.

The recording gain settings shall be established as described in **3.6.2** and **3.6.3**.

3.6.2 Scan the TEST-OBJECT CONFIGURATION 1 (see Figure 1) or the TEST-OBJECT CONFIGURATION 2 (see Figure 2) in the REFERENCE PLANE depending on the test procedure of the parameter being measured (e.g. imaged beam profile) and select an area of interest.

3.6.3 Reduce the overall gain of the scanner until this area of the image is between 70 % DARK THRESHOLD and 30 % DARK THRESHOLD.