

Medical electrical equipment —

**Part 3: Particular requirements for
performance —**

**Section 3.129 Methods of declaring
functional performance characteristics
of radiotherapy simulators —**

**Supplement 1: Guide to functional
performance values**

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/81, upon which the following bodies were represented:

- Association of X-ray Equipment Manufactures (BEAMA Ltd.)
- British Institute of Radiology
- College of Radiographers
- Department of Health
- Institute of Physical Sciences in Medicine
- Institution of Electrical Engineers
- National Radiological Protection Board
- Royal College of Radiologists

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National foreword

This Supplement to Section 3.129 of BS 5724 has been prepared under the direction of the Health Care Standards Policy Committee. It is identical with IEC 1170:1993 *Radiotherapy simulators — Guidelines for functional performance characteristics* published by the International Electrotechnical Commission (IEC).

This Particular Standard, which is for use in conjunction with Section 2.129 and Section 3.129 of BS 5724, gives guidance on the values of the functional performance characteristics of radiotherapy simulators which may be declared by the manufacturer. It also gives recommendations to manufacturers for the values to be declared in accordance with BS 5724-3.129:1994.

Cross-references

International Standard	Corresponding British Standard
	BS 5724 <i>Medical electrical equipment</i>
IEC 601-1:1988	Part 1:1989 <i>General requirements for safety</i> (Identical)
IEC 977:1989	Part 3 <i>Particular requirements for performance</i> Section 3.1:Supplement 1:1990 <i>Guide to functional performance values</i> (Identical)
IEC 1168:1993	Section 3.129:1994 <i>Methods of declaring functional performance characteristics of radiotherapy simulators</i> (Identical)

Additional information. The following print types are used in this standard.

Terms defined in clause 2 of BS 5724-1: SMALL CAPITAL.

For the purposes of this British Standard, any references of IEC page numbers in the text should be ignored.

Textual error. When adopting the text of the International Standard, the textual error given below was discovered. It has been marked in the text and has been reported to IEC in a proposal to amend the text of the International Standard.

In 7.3 (page 9), line 2, “X-RAY” should be replaced by “X-RADIATION”.

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 12, 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 Introduction

The guidelines given in this report are recommendations both to MANUFACTURERS and to USERS. They provide guidance to MANUFACTURERS on the needs of radiotherapists in respect of the performance of RADIOTHERAPY SIMULATORS and they provide guidance to USERS wishing to check the MANUFACTURER'S declared performance characteristics, to carry out acceptance tests and to check periodically the performance throughout the life of the EQUIPMENT.

IEC 601-1¹⁾ is a general standard for the safety of medical electrical EQUIPMENT. It is supplemented by IEC 1168²⁾, a standard which lays down particular requirements for RADIOTHERAPY SIMULATORS. It has been issued as a disclosure standard. It is a standard which standardizes methods of declaring the RADIOTHERAPY SIMULATOR functional performance characteristics. It standardizes the TYPE TEST conditions and TYPE TEST methods to which MANUFACTURERS' declared values of functional performance relate.

A format for the presentation of functional performance values is contained in IEC 1168 as Annex A. It is repeated herein in 2.1, with the addition of a set of suggested values which reflect the need for precision in RADIOTHERAPY and the knowledge of what is reliably achievable technically. A corresponding rationale for the suggested values is presented in 2.2.

In order to check whether each individual EQUIPMENT at the time of installation performs in a manner consistent with the set of functional performance values declared by the MANUFACTURER based upon his TYPE TEST data, it is customary to perform a series of acceptance tests at the USER'S site before the EQUIPMENT is put into full medical use. Because of the limitations of time and test equipment, this series of acceptance tests is usually less extensive than the TYPE TESTS specified in the disclosure standard, IEC 1168.

During the working life of the RADIOTHERAPY SIMULATOR, periodic tests are usually conducted by the USER to check whether the functional performance of the EQUIPMENT is satisfactory. Because the available EQUIPMENT time is limited, a highly abbreviated set of test conditions is essential. Individual tests should not be repeated any more or less frequently than can be justified by experience with the particular EQUIPMENT or EQUIPMENT type. Suggested periodic tests to be performed during the working life of the RADIOTHERAPY SIMULATOR and suggested intervals between such tests are presented in 4.1. The MANUFACTURER may recommend different intervals or additional or different tests, depending on the special requirements of the RADIOTHERAPY SIMULATOR in question.

2 General, TYPE TESTS

2.1 Format of Annex A of the disclosure standard with suggested functional performance values (in brackets)

2.1.1 Introduction

The purpose of 2.1 is to provide a suggested format for the presentation of functional performance values corresponding to the standardized statements of functional performance in the disclosure standard, IEC 1168.

USERS of RADIOTHERAPY SIMULATORS may find this format useful in getting information from the MANUFACTURERS on the expected performance, in recording acceptance test values measured at the time of installation and in periodic testing of performance during the working life of the EQUIPMENT.

MANUFACTURERS may find it useful in declaring the functional performance values for their particular types of RADIOTHERAPY SIMULATORS in response to IEC 1168.

It is not suggested that a MANUFACTURER should provide information to USERS from his TYPE TEST in any greater detail than a simple declaration of these functional performance values.

As a result of extensive deliberation by Working Group 1 of IEC sub-committee 62C, a set of suggested values of functional performance was agreed upon with respect to the standardized statements of IEC 1168.

Values are designated +/- where they represent permissible deviations in more than one direction from a desired point or value. The +/- designation is not used where the tolerance represents permissible deviation in any one direction between two points or values. The abbreviations "max." and "min." are used for "maximum" and "minimum", respectively.

¹⁾ IEC 601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*, and Amendment 1, 1991.

²⁾ IEC 1168:1993, *Radiotherapy simulators — Functional performance characteristics*

2.1.2 Format of Annex A of IEC 1168

Functional performance values

MANUFACTURER:

RADIOTHERAPY SIMULATOR

Type Designation:

Date:

Location:

Clause or
subclause
of IEC 1168

4.3 X-RAY TUBE

FOCAL SPOT size

Large: mm

Small: mm

TARGET ANGLE:

..... °

ANODE SPEED:

with high speed starter: RPM
without high speed starter: RPM

NOMINAL X-RAY TUBE VOLTAGE:

..... kVp

CONTINUOUS MODE:

..... Joules

with fan:

..... Joules

INHERENT FILTRATION

..... mm Al

5 Indication of DELINEATED RADIATION FIELDS

DELINEATED RADIATION FIELD size at 100 cm.

Max. : cm x cm

Min. : cm x cm

5.1 Numerical field-indicator

Maximum difference between the numerical DELINEATED RADIATION FIELD indication and the dimensions of the DELINEATED RADIATION FIELD:

	Values declared				Values (suggested)
	min.	80 cm	100 cm	max.	
SAD					
3 cm × 3 cm to 20 cm × 20 cm	 mm	 mm	 mm	 mm	(2)
From 20 cm × 20 cm to maximum square	 %	 %	 %	 %	(1)