
British Standard

Medical electrical equipment

Part 2. Particular requirements for safety

Section 2.1 Specification for medical electron accelerators
in the range 1 MeV to 50 MeV

Supplement 1. Revised and additional text

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Foreword

This Supplement to Section 2.1 of BS 5724 has been prepared under the direction of the Health Care Standards Policy Committee. It is technically equivalent to Amendment No. 2 to IEC Publication 601-2-1 (1981) 'Medical electrical equipment' Part 2 'Particular requirements for medical electron accelerators in the range 1 MeV to 50 MeV' Section One: 'General', Section Two: 'Radiation safety for equipment' which was published in 1990 by the International Electrotechnical Commission (IEC).

IEC 601-2-1, which was published in 1981, was not presented in the same format as other Parts of IEC 601 and, in particular, IEC 601-1, the General Standard (see foreword to BS 5724 : Section 2.1 : 1989). For convenience in using the British Standard it was decided when preparing the 1989 edition of BS 5724 : Section 2.1 to publish it with identical clause numbering to that of the first edition of the General Standard*. At the same time, the opportunity was taken to combine the technical content of IEC 601-2-1 (1981) with its Amendment No. 1 (1984).

This Supplement 1 to BS 5724 : Section 2.1 presents amendments to that standard and provides additional test procedures in Section Five where radiation safety compliance tests are required. These additional requirements similarly amend and supplement the General Standard.

The changes from the text of the General Standard are specified by the use of the following words.

'Replacement' means that the clause, subclause or specified paragraph of the General Standard is replaced by the text of this standard.

'Amendment' means that the clause, subclause or specified paragraph of the General Standard is amended as indicated by the text of this standard.

'Addition' means that the text of this standard is additional to the requirements of the General Standard.

The following print types are used in this standard:

Requirements, compliance with which can be tested, and definitions: in roman type.

Explanations, advice and general statements: in small roman type.

Test procedures: in *italic type*.

Terms defined in clause 2 of the General Standard: IN CAPITALS.

Additional information. Reference is made in the Introduction to the 'Particular Standard'. This reference is to IEC 601-2-1 (1981) which was implemented as the technically equivalent BS 5724 : Section 2.1 : 1989.

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

*Implemented as BS 5724 : Part 1 : 1979

Introduction

This amendment to the Particular Standard contains test procedures for compliance with radiation safety requirements specified in Section Five of BS 5724 : Section 2.1.

This amendment specifies test procedures given for those items of BS 5724 : Section 2.1, where a radiation safety compliance test is required.

The rules of this amendment to the Particular Standard are applicable only to compliance tests for radiation safety requirements and not for any other requirements, such as:

- Performance requirements
- Electrical and mechanical safety requirements

The test procedures are specified either as TYPE TEST or as SITE TEST (see definitions in Appendix AA). This amendment does not specify procedures or intervals for periodic tests during the working life of the accelerator.

- Notes*
1. — Requirements for tests of radiation safety of medical electron accelerators are subject to legal regulations in certain countries.
 2. — Supplementary tests may be required for equipment which is controlled by programmable devices.

SECTION ONE — GENERAL

1. Scope and object

Addition:

1.5 General aspects of test procedures

1.5.1 The test procedures described in this amendment are classified in three grades:

GRADE A

Inspection of the analysis of equipment design provided by the manufacturer as related to the specified safety provisions.

GRADE B

Visual inspection, functional test or measurement on the equipment. The test procedures are specified by this amendment to the Particular Standard. The test procedures are based only on operating states (including fault condition states) achievable without interference with the circuitry or construction of the equipment.

GRADE C

Functional test or measurement on the equipment. The test procedure shall be specified by the manufacturer in the ACCOMPANYING DOCUMENTS in accordance with the principle stated in this amendment to the Particular Standard. The test procedure may involve operating states which require interference with the circuitry or construction of the equipment. In such cases of interference, the work should be performed by the manufacturer's personnel or under the direct supervision or approval of the manufacturer's personnel.

1.5.2 Test procedures specified by the manufacturer shall include instructions on how to reset the equipment into the primary condition after the execution of the tests, and how this condition shall be verified.

1.5.3 Test procedures specified by the manufacturer shall include the test conditions (e.g. GANTRY angular position, NOMINAL ENERGY, RADIATION TYPE).

1.5.4 Test procedures specified by the manufacturer shall either:

a) generate the described fault condition

or, if not practicable

b) as near as practicable to the source of the signal that would be produced in a fault condition, simulate this signal.

The manufacturer shall demonstrate in the ACCOMPANYING DOCUMENTS by results of design analysis or experiment that the test signal accurately simulates the signal that would be produced in the fault condition.

Note. — In special cases, one test signal may simulate more than one fault condition.

2. Terminology and definitions

This clause of the General Standard applies except as follows:

Replacement:

Terms printed in capitals in this amendment are used in compliance with the definitions given in BS 5724 : Section 2.1. Additional definitions used for this amendment are given in Appendix AA.

Replace the title of Clause 6 by the following:

6. Identification, marking, documentation and test reports

Add the following new sub-clauses:

6.9 Information to be provided for the purpose of the SITE TESTS

The following radiation safety documents shall be supplied:

- ACCOMPANYING DOCUMENTS as required in BS 5724 : Section 2.1.
- Test procedure specifications of the manufacturer, as required above in Sub-clause 1.5.1 for GRADE C.
- Documentation of the manufacturer demonstrating the effectiveness of the specified tests, as required above in Sub-clause 1.5.4b).
- Report on the test conditions, test procedures, test devices and results of all TYPE TESTS required in the following Sub-clauses 29.1 to 29.4.

6.10 Report of SITE TESTS

The results of the SITE TESTS shall be recorded in a test report which, together with information mentioned in Sub-clause 6.9, forms part of the ACCOMPANYING DOCUMENTS. The test report shall comprise:

- Identification of user and site of accelerator
- Name and office of the testing personnel
- Date of the tests
- Type and fabrication number of the equipment
- Test conditions, test procedures and devices used, as far as this information cannot be derived from Sub-clauses 29.1 to 29.4 or from documents mentioned in Sub-clause 6.9.
- Environmental conditions (Sub-clause 1.4 of BS 5724 : Section 2.1).

SECTION FIVE — PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

Note — The numbering of these compliance test procedures follows exactly the numbering of Section Five of BS 5724 : Section 2.1.

29.1 Protection of the PATIENT against incorrect ABSORBED DOSE in the TREATMENT VOLUME

Supplement the clauses and subclauses of this Section Five as follows:

29.1.2 Monitoring and control of ABSORBED DOSE

29.1.2.1 DOSE MONITORING SYSTEMS

Addition to 2nd paragraph:

— *after the 1st sentence:*

SITE TEST
GRADE C

Principle: Verification of correct functioning of one DOSE MONITORING SYSTEM with generated or simulated malfunction of the other DOSE MONITORING SYSTEM and vice versa.

— *after the 2nd sentence:*

TYPE TEST
GRADE A

Principle: Design analysis to determine which elements are common to both DOSE MONITORING SYSTEMS and to show how failure of each of these elements will TERMINATE IRRADIATION.

SITE TEST

GRADE C

Principle: Verification of correct functioning of INTERLOCK terminating IRRADIATION by simulation of failure of each element.

— *after the 3rd sentence:*

SITE TEST

GRADE C

Principle: Verification of correct functioning of INTERLOCK terminating IRRADIATION by generation or simulation of failure of each available power supply.

— *after the 4th sentence:*

TYPE TEST

GRADE A

Principle: Design analysis of detector.

Addition to 3rd paragraph:

TYPE TEST

GRADE C

Principle: Verification that the DOSE MONITORING SYSTEM(S) performance stated in the ACCOMPANYING DOCUMENTS is maintained up to ABSORBED DOSE RATES of twice the maximum NOMINAL ABSORBED DOSE RATE of the MEDICAL ELECTRON ACCELERATOR in which it is used. This test may be performed with the DOSE MONITORING SYSTEM not installed in the MEDICAL ELECTRON ACCELERATOR.

Addition to 4th paragraph:

TYPE TEST

GRADE A

Principle: Design analysis of the required independence of circuit parameter changes.

29.1.2.2 RADIATION DETECTORS

Addition to 1st paragraph:

TYPE TEST

GRADE A

Principle: Design analysis of the required position of the axis-centred detector.

Addition to 2nd paragraph:

SITE TEST

GRADE C

Principle: Verification of correct functioning of the INTERLOCKS in the case of movable detectors by generation or simulation of the fault condition.

29.1.2.3 DISPLAY of number of DOSE MONITORING UNITS

Addition to 1st paragraph:

TYPE TEST

GRADE B

Procedure: Visually inspect the DISPLAYS.

Addition to 2nd paragraph:

SITE TEST

GRADE B

Procedure:

- 1) Verify readings of the DISPLAYS after INTERRUPTION and after TERMINATION.
- 2) Attempt to initiate IRRADIATION without resetting the DISPLAYS to zero.
- 3) Generate dose DISPLAYS, switch off supply mains and verify that the DISPLAYED dose information is retained for the specified period.

Addition to 3rd paragraph:

TYPE TEST

GRADE A

Principle: Design analysis of DISPLAYS, including overdose condition.

SITE TEST

GRADE B

Procedure: Visually inspect the DISPLAYS.

29.1.2.4 *Selection of number of DOSE MONITORING UNITS*

Addition:

SITE TEST

GRADE B

Procedure: Following IRRADIATION at a selected number of DOSE MONITORING UNITS attempt to initiate a second IRRADIATION without making a new selection, at one NOMINAL ENERGY for each RADIATION TYPE.

29.1.2.5 *DISPLAY of selected number of DOSE MONITORING UNITS*

Addition:

SITE TEST

GRADE B

Procedure: Select an arbitrary number of DOSE MONITORING UNITS, perform an IRRADIATION and observe functioning of the DISPLAY. Test at one NOMINAL ENERGY for each RADIATION TYPE.

29.1.2.6 *TERMINATION OF IRRADIATION by the DOSE MONITORING SYSTEM*

Addition to 1st paragraph, after the 1st sentence:

TYPE TEST

GRADE A

Principle: Design analysis of the two DOSE MONITORING SYSTEMS.

Addition to the 1st paragraph (after the 2nd sentence) and to the 2nd and 3rd paragraphs:

SITE TEST

GRADE C

Principle: Verification of correct functioning of IRRADIATION TERMINATION by each system when the other system is disabled. Test at one NOMINAL ENERGY for each RADIATION TYPE.

Addition to 4th paragraph:

TYPE TEST

GRADE A

Principle: Design analysis of the INTERLOCK circuit to ensure that the required TERMINATION OF IRRADIATION capability is verified between IRRADIATIONS.

SITE TEST

GRADE C

Principle: Verification of correct functioning of INTERLOCKS at one NOMINAL ENERGY for each RADIATION TYPE.

29.1.2.7 *Monitoring of distribution of ABSORBED DOSE*

Addition:

TYPE TEST

GRADE A

Principle: Design analysis to ensure that different parts of the RADIATION BEAM are monitored by the required detectors and to determine whether the design is in accordance with alternative *a*) or *b*).

— Referring to alternative *a*):

SITE TEST

GRADE C

Principle: Verification of correct functioning of the IRRADIATION TERMINATION when a distortion of the distribution of ABSORBED DOSE exceeding the specified limit is generated or simulated when an ABSORBED DOSE of approximately 0,4 Gy is delivered.

— Referring to alternative *b*):

TYPE TEST

GRADE A

Principle: Design analysis to ensure an overdose greater than 0,4 Gy cannot be given and that the specified overriding or resetting action is required.

SITE TEST

GRADE C

Principle: Verification of correct functioning of the INTERLOCK preventing subsequent IRRADIATIONS and that the specified overriding or resetting action is required.

29.1.3 *TIMER*

Addition:

If a TIMER is provided:

Addition to 1st and 2nd paragraphs:

SITE TEST

GRADE B

Procedure: For one NOMINAL ENERGY for each RADIATION TYPE, verify that the TIMER:

- 1) counts up during IRRADIATION;
- 2) switches on and off when IRRADIATION starts and stops;
- 3) retains its reading after IRRADIATION is INTERRUPTED or TERMINATED;
- 4) requires resetting to zero after TERMINATION OF IRRADIATION before subsequent IRRADIATION can be initiated;
- 5) TERMINATES IRRADIATION when the preselected time has elapsed.

Addition to 3rd paragraph:

TYPE TEST

GRADE A

Principle: Design analysis to ensure that the running up of the TIMER and the IRRADIATION TERMINATION capabilities are tested between IRRADIATIONS.

SITE TEST

GRADE C

Principle: Verification of correct functioning of INTERLOCKS.

Addition to 4th paragraph:

TYPE TEST

GRADE B

Principle: Inspection of TIMER graduations.

29.1.4 ABSORBED DOSE RATE

Addition to 1st paragraph:

SITE TEST

GRADE B

Procedure: Verify correct DISPLAY of the readings at one NOMINAL ENERGY for each RADIATION TYPE.

Addition to 2nd paragraph:

SITE TEST

GRADE C

Principle: Verification of correct functioning of the specified TERMINATION device.

Addition to 3rd paragraph:

TYPE TEST

GRADE A

Principle: Design analysis of maximum potential ABSORBED DOSE RATE and of electron beam current limiting device.

SITE TEST

GRADE C

Principle: Verification of correct functioning of the specified electron beam current limiting device by generation or simulation of fault condition.

29.1.5 RADIATION TYPE (X-RADIATION and ELECTRON RADIATION)

29.1.5.1 Selection of RADIATION TYPE

Addition:

TYPE TEST

GRADE A

Principle: Design analysis of the INTERLOCK circuit.

SITE TEST

GRADE B

Procedure:

- a) Attempt to initiate IRRADIATION without selecting RADIATION TYPE.
- b) and c)
 - Verify correct functioning of specified INTERLOCK.
- d) Verify correct functioning of specified INTERLOCK when a beam-modifying accessory not suitable for the RADIATION TYPE selected is fitted.