

Medical electrical equipment —

Part 2: Particular requirements for safety —

Section 2.8 Specification for therapeutic X-ray equipment operating in the range 10 kV to 1 MV

The European Standard EN 60601-2-8:1997 including EN 60601-2-8/A1:1997 has the status of a British Standard

ICS 11.040.50

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on 15 May 1998

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Amendments issued since publication

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National foreword

This British Standard is the English language version of EN 60601-2-8:1997. It is identical with IEC 60601-2-8:1987 including IEC 60601-2-8/A1:1997 (both of which have now been adopted by CENELEC). It supersedes BS 5724-2.8:1987 which is withdrawn. Corrigendum No. 1 has been produced to correct errors introduced in interpreting the IEC amendment instructions. Subclauses **50.1.101** to **50.104.3** have been renumbered as Subclauses **29.103.1** to **29.108.3** and the term “X-RAY GENERATOR” has been replaced by “X-RAY EQUIPMENT”.

The UK participation in its preparation was entrusted to Technical Committee CH/81, Radiotherapy equipment, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

From 1 January 1997, all IEC publications have the number 60000 added to the old number. For instance, IEC 27-1 has been renumbered as IEC 60027-1. For a period of time during the change over from one numbering system to the other, publications may contain identifiers from both systems.

Cross-references

Attention is drawn to the fact that CEN and CENELEC standards normally include an annex which lists normative references to international publications with their corresponding European publications. The British Standards which implement these international or European publications may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

Additional information

Subclauses, figures or tables that are additional to those of BS 5724-1 (the General Standard) are numbered starting from 101; additional annexes are lettered AA, etc. and additional items aa), bb), etc. Annex AA is for information only. Annex BB forms an integral part of this standard.

The following print types are used in this standard.

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

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

Test procedures: in *italic* type.

Terms defined in this Particular Standard which have been listed in Annex AA and defined in clause 2, or in the General Standard and its Collateral Standards or in BS 6641: SMALL CAPITALS.

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, the EN title page, pages 2 to 34, 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.

Descriptors: Medical electrical equipment, X-ray equipment, therapeutic X-ray generators, safety requirements, protection against electric shock, protection against mechanical hazard, radiation protection, fire protection, environmental conditions

English version

Medical electrical equipment
Part 2: Particular requirements for the safety of therapeutic
X-ray equipment operating in the range 10 kV to 1 MV

(includes amendment A1:1997)
(IEC 60601-2-8:1987 + A1:1997)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité pour
les équipements à rayonnement X de thérapie
fonctionnant dans la gamme de 10 kV à 1 MV
(inclut l'amendement A1:1997)
(CEI 60601-2-8:1987 + A1:1997)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die
Sicherheit von Therapie-Röntgeneinrichtungen
im Betriebsbereich von 10 kV bis 1 MV
(enthält Änderung A1:1997)
(IEC 60601-2-8:1987 + A1:1997)

This European Standard was approved by CENELEC on 1997-07-01; amendment A1 was approved by CENELEC on 1997-07-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B-1050 Brussels

Foreword

The text of the International Standard IEC 60601-2-8:1987, prepared by SC 62B, Diagnostic imaging equipment, of IEC TC 62, Electrical equipment in medical practice, was approved by CENELEC as HD 395.2.8 S1:1988 on 1988-06-28.

This Harmonization Document was submitted to the formal vote for conversion into a European Standard and was approved by CENELEC as EN 60601-2-8 on 1997-07-01.

The following date was fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1998-06-01

Subclauses, tables and figures which are additional to those in part 1 are numbered starting from 101.

Annexes which are additional to those in part 1 are lettered AA, BB, etc. and additional items aa), bb), etc.

Foreword to EN 60601-2-8:1997/A1: 1997

The text of document 82C/186/FDIS, future amendment 1 to IEC 60601-2-8:1987, prepared by SC 62C, Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as amendment A1 to EN 60601-2-8:1987 on 1997-07-01.

The following dates were fixed:

- latest date by which the amendment has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1998-06-01
- latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 1998-06-01

Annexes designated “normative” are part of the body of the standard.

Annexes designated “informative” are given for information only.

In this standard, Annex BB and Annex ZA are normative and Annex AA and Annex ZB are informative. Annex ZA and Annex ZB have been added by CENELEC.

Endorsement notice

The text of amendment 1:1997 to the International Standard IEC 60601-2-8:1987 was approved by CENELEC as an amendment to the European Standard without any modification.

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Foreword

- 1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international cooperation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
- 3) The documents produced have the form of recommendations for internal use and are published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.
- 4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
- 5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
- 6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60601-2-8 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this standard is based on the following documents:

Six Months' Rule	Report on voting
62B(CO)49	62B(CO) 64

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

Subclauses, figures or tables that are additional to those of the General Standard are numbered starting from 101; additional annexes are lettered AA, etc., and additional items aa), bb) etc.

Annex AA is for information only.

Annex BB forms an integral part of this standard.

In this Particular Standard, the following print types are used:

- requirements, compliance with which can be tested, and definitions, in roman type;
- explanations, advice, general statements and exceptions: in small roman type;
- TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN LISTED IN ANNEX AA AND DEFINED IN CLAUSE 2, OR IN THE GENERAL STANDARD 60601-1 AND ITS COLLATERAL STANDARDS OR IN IEC 60788: SMALL CAPITALS.

Introduction

The use of X-RAY EQUIPMENT for RADIOTHERAPY purposes may expose the PATIENT to danger if the EQUIPMENT fails to deliver the required dose to the PATIENT, or if the EQUIPMENT design does not satisfy standards of electrical and mechanical safety. The EQUIPMENT may also cause danger to persons in the vicinity if the EQUIPMENT itself fails to contain the RADIATION adequately and/or if there are inadequacies in the design of the TREATMENT ROOM.

This Particular Standard establishes requirements to be complied with by the MANUFACTURERS in the design and construction of therapeutic X-RAY EQUIPMENT. Clause 29 contains limits beyond which INTERLOCKS prevent, INTERRUPT or TERMINATE IRRADIATION in order to avoid an unsafe condition.

Clause 29 does not attempt to define optimum performance requirements. Its purpose is to identify those features of design that are regarded, at the present time, as essential for the safe operation of such EQUIPMENT. It places limits on the degradation of EQUIPMENT performance beyond which it can be presumed that a fault condition exists, e.g. a component failure, and where an INTERLOCK then operates to prevent continued operation of the equipment.

It should be understood that, before installation, a MANUFACTURER can provide a Compliance Certificate relating only to TYPE TESTS: data available from SITE TESTS should be incorporated in the ACCOMPANYING DOCUMENTS, in the form of a SITE TEST report, by those who test the EQUIPMENT at installation.

Section 1. General

1 Scope and object

This clause of the General Standard applies except as follows:

1.1 Scope

Addition:

This Particular Standard applies to therapeutic X-RAY EQUIPMENT with NOMINAL X-RAY TUBE VOLTAGES in the range 10 kV to 1 MV when connected to alternating current SUPPLY MAINS.

1.2 Object

Replacement:

This Particular Standard establishes requirements for the safety of therapeutic X-RAY EQUIPMENT including the requirement for accuracy and reproducibility of performance to the extent that these are related to RADIATION QUALITY and the quantity of IONIZING RADIATION produced and thus must be considered as aspects of safety.

An object of this Particular Standard is to present the general functional requirements of the demand for safety, rather than any particular technological means of implementation.

1.3 Particular Standards

Additional sub-clauses:

1.3.101 Relation to the General Standard

This Particular Standard shall be read in conjunction with IEC 60601-1 (1988) and its amendments 1 (1991) and 2 (1995).

As in the General Standard, the requirements of this Particular Standard are followed by compliance tests.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds with that of the General Standard. The changes to the text of the General Standard are SPECIFIED by the use of the following words:

“Replacement” means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

“Addition” means that the text of this Particular Standard is additional to the requirements of the General Standard.

“Amendment” means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

The term “this Standard” is used to make reference to the General Standard and this Particular Standard taken together.

A requirement of this Particular Standard replacing or modifying requirements of the General Standard takes precedence over the corresponding General Requirement(s).

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification. Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard. Unless otherwise stated, all clauses of the General Standard shall apply.

1.3.103 IEC 61217

This standard defines the designation of EQUIPMENT movements, the marking of scales, their zero positions and the direction of movements with increasing values.

1.5 Collateral Standards

1.5.101 IEC 60601-1-1

This Collateral Standard does not apply.

1.5.102 IEC 60601-1-2

ELECTROMAGNETIC COMPATIBILITY (EMC) — Requirements and tests: see clause 36.

1.5.103 IEC 60601-1-3

This Collateral Standard does not apply.

1.5.104 IEC 60601-1-4

NOTE The Collateral Standard IEC 60601-1-4 and/or a future amendment to the General Standard, with a consequent amendment to this Particular Standard, will provide a comprehensive treatment of all safety aspects of PROGRAMMABLE ELECTRONIC SYSTEMS used in therapeutic X-RAY EQUIPMENT.

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Addition:

In this Particular Standard, terms in capital letters are used as defined in:

- the General Standard
- IEC Publication 788 (1984): Medical Radiology — Terminology

An index of these terms, referring to the standards mentioned is given in Appendix AA.

3 General requirements

This clause of the General Standard applies except as follows:

Additional sub-clause:

3.101 Conventional meaning of electrical quantities

In this Particular Standard unless otherwise indicated, values of X-RAY TUBE VOLTAGE refer to peak values.

4 General requirements for tests

This clause of the General Standard applies except as follows:

4.1 Tests

4.1.101 Test grades

Three grades of TYPE TEST and two of SITE TEST procedures are SPECIFIED in clause 29 of this Particular Standard; their requirements are as follows:

- TYPE TEST grade A: An analysis of EQUIPMENT design, as related to the SPECIFIED RADIATION safety provisions, which shall result in a statement included in the technical description, regarding the working principles or constructional means by which the requirement is fulfilled.

- TYPE TEST/SITE TEST grade B: Visual inspection or functional test or measurement of the EQUIPMENT. The test shall be in accordance with the procedure SPECIFIED in this Particular Standard and shall be based on operating states, including fault condition states, which are achievable only without interference with the circuitry or construction of the EQUIPMENT.

- TYPE TEST/SITE TEST grade C: Functional test or measurement of the EQUIPMENT. The test shall be in accordance with the principle SPECIFIED in this Particular Standard. The SITE TEST procedure shall be included in the technical description; when the procedure involves operating states that require interference with the circuitry or the construction of the EQUIPMENT, the test should be performed by, or under the direct supervision of, the MANUFACTURER or his agent.

4.6 Other conditions

Addition:

aa) SITE TEST information shall be provided in the technical description and shall include

- 1) statements resulting from TYPE TESTS: grade A;
 - 2) details of and results from TYPE TESTS: grade B and grade C;
 - 3) SPECIFIC procedures and test conditions for SITE TESTS grade C;
 - 4) instructions on how to generate a described fault condition or, if not practicable, how to generate a test signal as close as practicable to the source of the signal that would have generated it, with a statement confirming that the test signal simulates the one that would be produced in a particular fault condition;
- NOTE In some cases, one test signal may simulate more than one fault condition.
- 5) instructions on how to reset the EQUIPMENT for NORMAL USE after the completion of the SITE TEST and how to verify this condition.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

NOTE The person responsible for the SITE TESTS should record the results in a report which should be included with the ACCOMPANYING DOCUMENTS; in addition, the SITE TEST report should contain at least the following:

- name and address of the USER site;
- MODEL OR TYPE REFERENCE NUMBER and SERIAL NUMBER of the EQUIPMENT;
- name, status and employment address of all personnel taking part in the test, and date of their participation;
- environmental and power supply conditions;