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1987**

**IEC 601-2-8:
1987**

*Incorporating
Amendment No. 1*

Medical electrical equipment —

**Part 2: Particular requirements for
safety —**

**Section 2.8 Specification for
therapeutic X-ray generators —**

**(Implementation of CENELEC
HD 395.2.8 S1)**

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Committee (HCC/-) to Technical Committee HCC/76, upon which the following bodies were represented:

- Association of X-Ray Equipment Manufacturers (BEAMA Ltd)
- British Institute of Radiology
- College of Radiographers
- Department of Health and Social Security
- Hospital Physicists Association
- Royal College of Radiologists
- Society of X-ray Technology

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National foreword

This British Standard has been prepared under the direction of the Health Care Standards Committee and is identical with IEC Publication 601-2-8:1987 “*Medical electrical equipment*” Part 2 “*Particular requirements for the safety of therapeutic X-ray generators*”, prepared by Technical Committee TC 62 Electrical equipment in medical practice of the International Electrotechnical Commission (IEC). This Particular Standard amends and supplements BS 5724-1 hereinafter called the General Standard. As stated in 1.3 of the General Standard, the requirements of this Particular Standard take precedence over those of the General Standard. This Section of BS 5724 is also in agreement with Harmonization Document HD 395.2.8 S1, published by the European Committee for Electrotechnical Standardization (CENELEC).

As in the General Standard, the requirements are followed by compliance tests. The numbers of the sections and clauses in this standard refer to the related sections and clauses in the General Standard. Clauses, subclauses or figures that are additional to those of the General Standard are numbered starting from 101; the additional appendix is numbered AA, and additional items aa), bb) etc. 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.

Terminology and conventions. The text of the International Standard has been approved as suitable for publication as a British Standard without deviation. Some terminology and certain conventions are not identical with those used in British Standards. In particular, the following print types are used.

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

Explanations, advice, general statements, exceptions and references: in small roman type
Test specifications: in italic type

Terms defined in clause 2 of the General Standard, in BS 6641 and this Particular Standard: small capitals.

Wherever the page numbers are quoted, they are IEC page numbers. These are given in brackets at the foot of each page.

NOTE Appendix AA.1 is omitted since it is essentially the French alphabetical index with an English translation. Appendix AA.2 the English alphabetical index is retained but without the French translation.

Cross-references

International Standards	Corresponding British Standards
IEC Publication 601-1:1977	BS 5724 <i>Medical electrical equipment</i> Part 1:1979 <i>Specification for general safety requirements</i> (Technically equivalent)
IEC Publication 788:1984	BS 6641:1985 <i>Glossary of medical radiology terms</i> (Identical)

There is no corresponding British Standard to IEC Publication 407:1973 “*Radiation protection in medical X-ray equipment 10kV to 400kV*”, which is partially superseded by this Particular Standard. The general requirements of IEC 407 are being replaced by IEC Publication 601-1- . . . “*Complement to Part 1: General requirements for protection against ionizing radiation from diagnostic X-ray equipment*”. The requirements of IEC 407 relating to specific equipments are being replaced by requirements incorporated in Particular Standards. The latest draft of IEC 601-1 is document IEC 62B(Secretariat)91. It is expected that a British Standard corresponding to IEC 601-1- . . . will be prepared when the IEC standard is published.

Document ICRP 33 referred to in this Particular Standard is prepared by the International Commission for Radiological Protection, Clifton Avenue, Sutton, Surrey, SM2 5PU, and is available from Pergamon Press Ltd, Headington Hill Hall, Oxford OX3 0BW.

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 to vi, pages 1 to 22, 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.

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 GENERATORS that operate with NOMINAL X-RAY TUBE VOLTAGES from 10 kV to 400 kV inclusive when connected to alternating current SUPPLY MAINS.

1.2 Object

Replacement:

The object of this Particular Standard is to establish the particular requirements for safety including the requirements 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 refers to, and is to be read in conjunction with IEC Publication 601-1 (1977): Safety of Medical Electrical Equipment, Part 1: General Requirements and its Amendment No. 1 (1984). For brevity Part 1 is referred to in this Particular Standard either as the “General Standard” or as the “General Requirement(s)”.

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 clause or sub-clause in this Particular Standard, the clause or sub-clause of the General Standard applies without modification.

Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied to therapeutic X-RAY GENERATORS, a statement to that effect is given in this Particular Standard.

1.3.102 Superseded IEC Standard

This Standard deals with some aspects of therapeutic X-RAY EQUIPMENT, particularly of therapeutic X-RAY GENERATORS and sub-assemblies thereof, that were covered by IEC Publication 407 (1973): Radiation Protection in Medical X-ray Equipment 10 kV to 400 kV.

Within its scope, this Particular Standard supersedes the corresponding requirements of IEC Publication 407.

1.4 Environmental conditions

a) *Transport and storage*

Item 2) a)

Replacement:

a) an ambient temperature between -20°C and $+70^{\circ}\text{C}$ [see Item v)] of Sub-clause 6.1 of the General Standard regarding marking of the packing).

b) Operation

2) Power supply

Item a) A SUPPLY MAINS having:

Replacement of the sixth dash:

— a frequency which does not deviate more than 1 % from the nominal value for all frequencies.

Replacement of the second paragraph in small print:

An alternating voltage is considered in practice to be sinusoidal if any instantaneous value of the waveform concerned differs from the instantaneous value of the ideal waveform at the same moment by no more than ± 2 % of the peak value of the ideal waveform.

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 Type tests and routine tests

a) Type tests

Addition:

The tests described in this Particular Standard are type tests, which are to be carried out under controlled conditions, usually prevailing only in test laboratories.

4.7 Supply and test voltages, type of current, nature of supply, frequency

Additional item:

aa) For all tests for the measurement of AIR KERMA and AIR KERMA RATE in air for compliance with requirements on LEAKAGE RADIATION and STRAY RADIATION it is assumed that the SUPPLY MAINS used for the test is delivering its output at its NOMINAL VALUES.

4.10 Moisture pre-conditioning treatment

Addition (see Sub-clause 1.3.101):

This test shall be applied only to those parts of therapeutic X-RAY GENERATORS likely to be influenced by the climatic conditions that are simulated by the test.

Where it is not practicable to treat a therapeutic X-RAY GENERATOR as a whole, the treatment may be given sequentially to separate parts.

Also, where testing cannot be carried out without dismantling or reassembling, a period longer than that required in the General Standard may elapse between treatment and testing.

5 Classification

This clause of the General Standard applies except as follows:

5.1 Replacement:

Therapeutic X-RAY GENERATORS shall be classified as CLASS I EQUIPMENT.