

Medical electrical equipment —

Part 2: Particular requirements for safety —

Section 2.15 Specification for capacitor discharge X-ray generators —

(Implementation of CENELEC HD 395.2.15 S1)

UDC [615.47:62-83:621.31 + 615 + 849.114 + 621.313]:613.647.614.825

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/75, upon which the following bodies were represented:

- Association of X-ray Equipment Manufacturers (BEAMA Ltd)
- British Dental Association
- British Institute of Radiology
- British Society of Dental and Maxillofacial Radiology
- College of Radiographers
- Department of Health
- Institute of Physical Sciences in Medicine (Ipsm)
- Society of X-ray Technology

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 31 October 1989

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The following BSI references relate to the work on this standard:
Committee reference HCC/75
Draft for comment 85/52864 DC

ISBN 0 580 17627 4

Amendments issued since publication

Amd. No.	Date of issue	Comments
6989	April 1992	Indicated by a sideline in the margin

Contents

	Page
Committees responsible	Inside front cover
National foreword	iv
Section 1. General	
1 Scope and object	1
1.1 Scope	1
1.2 Object	1
1.3 Particular Standards	2
1.4 Environmental conditions	2
2 Terminology and definitions	2
2.12 Miscellaneous	2
3 General requirements	3
3.101 Conventional meanings of electrical quantities	3
3.102 Radiation quantities	3
4 General requirements for tests	3
4.1 Type tests and routine tests	3
4.10 Moisture pre-conditioning treatment	3
5 Classification	3
6 Identification, marking and documents	4
6.1 Marking on the outside of equipment or equipment parts	4
6.2 Marking on the inside of equipment or equipment parts	5
6.7 Indicator lights and push buttons	5
6.8 ACCOMPANYING DOCUMENTS	5
7 Power input	8
Section 2. Safety requirements	
8 Basic safety categories	8
9 Removable protective means	8
10 Special environmental conditions	8
11 Special measures with respect to safety	8
12 SINGLE FAULT CONDITION	8
Section 3. Protection against electric shock hazards	
13 General	8
14 Requirements related to classification	8
15 Limitation of voltage and/or current	8
16 Enclosures and PROTECTIVE COVERS	9
17 Insulation and PROTECTIVE IMPEDANCES	9
18 Earthing and potential equalization	9
19 Continous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	9
19.3 Allowable values	9
20 Dielectric strength	10
20.3 Values of test voltages	10
20.4 Tests	10
Section 4. Protection against mechanical hazards	
21 Mechanical strength	10
22 Moving parts	10
23 Surfaces, corners and edges	10
24 Stability and transportability	11
25 Expelled parts	11
26 Vibration and noise	11

	Page
27	Pneumatic and hydraulic power 11
28	Suspended masses 11
Section 5. Protection against hazards from unwanted or excessive radiation	
29	X-radiation 11
29.1	X-RADIATION generated by diagnostic CAPACITOR DISCHARGE X-RAY GENERATORS 11
30	Alpha, beta, gamma, neutron radiation and other particle radiation 13
31	Microwave radiation 13
32	Light radiation (including visual radiation and lasers) 13
33	Infra-red radiation 13
34	Ultra-violet radiation 13
35	Acoustical energy (including ultrasonics) 13
36	Electromagnetic compatibility 13
Section 6. Protection against hazards of explosions in medically used rooms	
37	General 13
38	Classification, marking and ACCOMPANYING DOCUMENTS of ANAESTHETIC-PROOF EQUIPMENT 13
39	Common requirements for “AP” and “APG” equipment 13
40	Requirements and tests for ANAESTHETIC-PROOF EQUIPMENT, equipment parts or components (AP) 14
41	Requirements and tests for ANAESTHETIC-PROOF CATEGORY G EQUIPMENT, equipment parts or components 14
Section 7. Protection against excessive temperatures, fire and other hazards, such as human errors	
42	Excessive temperatures 14
42.1	Addition 14
42.5	Guards 14
43	Fire prevention 14
44	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection 14
45	Pressure vessels and parts subject to pressure 14
46	Human errors 14
47	Electrostatic charges 14
48	Materials in APPLIED PARTS in contact with the body of the PATIENT 14
49	Interruption of the power supply 14
Section 8. Accuracy of operating data and protection against incorrect output	
50	Accuracy of operating data 15
50.1	Indication of electric and radiation output 15
50.101	Reproducibility of radiation output 15
50.102	Agreement between indicated and measured values of LOADING FACTORS 15
50.103	Correction for fluctuations of MAINS VOLTAGE 16
50.104	Test conditions 16
50.105	General 17
50.106	Methods of measuring LOADING FACTORS 17
50.107	Conditions for measuring AIR KERMA 18

	Page
50.108 Combination of LOADING FACTORS for the determination of COEFFICIENT OF VARIATION	19
50.109 Combination of LOADING FACTORS for the determination of PER CENT AVERAGE ERROR	19
51 Protection against incorrect output	19
Section 9. Fault conditions causing overheating and/or mechanical damage; environmental tests	
52 Fault conditions causing overheating and/or mechanical damage	20
53 Environmental tests	20
Section 10. Constructional requirements	
54 General	20
55 Enclosures and covers	20
56 Components and general assembly	20
56.8 Indicators	20
56.11 Switches	20
57 MAINS PARTS, components and layout	20
57.1 Separation from the SUPPLY MAINS	20
57.9 Mains supply transformers and MEDICAL ISOLATING TRANSFORMERS	21
57.10 CREEPAGE DISTANCES and AIR CLEARANCES	21
58 PROTECTIVE EARTH TERMINALS	21
59 Construction and layout	21
59.4 Oil containers	21
Appendix AA Terminology	22
Appendix AA.2 Alphabetical index of English terms	22
Informative annex to HD 395.2.15 S1	
Figure 101 — TOTAL FILTRATION for the measurement of AIR KERMA	18
Table 101 — Permissible PER CENT AVERAGE ERROR of LOADING FACTORS	16
Publications referred to	Inside back cover

National foreword

This British Standard has been prepared under the direction of the Health Care Standards Policy Committee and is identical with IEC Publication 601-2-15:1988 “*Medical electrical equipment*” Part 2 “*Particular requirements for the safety of capacitor discharge 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 395.2.15 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 lettered AA. 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 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 procedures: in italic type.

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

NOTE Appendix AA 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 Standard	Corresponding British Standard
IEC 417G:1985	BS 6217:1981 <i>Guide to graphical symbols for use on electrical equipment</i> (Identical)
IEC 601-1:1977 ^a [as amended by Amendment No. 1(1984)]	BS 5724 <i>Medical electrical equipment</i> Part 1:1979 <i>Specification for general safety requirements</i> (Technically equivalent)
IEC 601-2-7:1987	Part 2 <i>Particular requirements for safety</i> Section 2.7:1987 <i>Specification for high-voltage generators of diagnostic X-ray generators</i> (Identical)
IEC 637:1979	BS 6059:1981 <i>Specification for essential data to be supplied with X-ray tubes and X-ray tube assemblies for medical use</i> (Identical)

^a The 1977 edition of IEC 601-1 has been superseded by IEC 601-1:1988 and the corresponding British Standard for this revision is BS 5724-1:1989.

International Standard	Corresponding British Standard
IEC 664:1980	PD 6499:1981 <i>Guide to insulation co-ordination within low-voltage systems including clearances and creepage distances for equipment</i> (Identical)
IEC 664A:1981	PD 6499:1981 <i>Guide to insulation co-ordination within low-voltage systems including clearances and creepage distances for equipment</i> [Identical to Amendment No. 1 (1987)]
IEC 788:1984	BS 6641:1985 <i>Glossary of medical radiology terms</i> (Identical)

There are no corresponding British Standards to IEC 407:1973 “*Radiation protection in medical X-ray equipment 10 kV to 400 kV*” or to IEC 407A:1975 “*First supplement to Publication 407 (1973): Subclause 7.5.5: Equipment for dental radiography*”, which are partially superseded by this Particular Standard. The general requirements of IEC 407 and IEC 407A 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 and IEC 407A relating to particular equipments are being replaced by requirements incorporated in Particular Standards. IEC 601-1-.. is referred to in this Particular Standard as “*the Collateral Standard: General Requirements for the Protection against Ionizing Radiation (under consideration)*”, the latest draft of which 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.

ICRP Publication 26 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 24, 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 CAPACITOR DISCHARGE X-RAY GENERATORS operating in INTERMITTENT MODE for medical RADIOGRAPHY, in which the electrical energy for LOADING of the X-RAY TUBE is completely or mainly capacitively stored at, and switched in, the high-voltage circuit.

This Particular Standard is confined to those devices which are MEDICAL ELECTRICAL EQUIPMENT and in which

- the storage capacitor is in the high-voltage circuit and has a specified capacitance not exceeding 2 μF ,
- the INITIAL X-RAY TUBE VOLTAGE is between 40 kV and 150 kV,
- an overcurrent protection, if provided, would not require a rating exceeding that which corresponds to an apparent power of 3 kVA,
- LOADING of the X-RAY TUBE is controlled in the high-voltage circuit.

This Particular Standard does not exclude CAPACITOR DISCHARGE X-RAY GENERATORS that are capable of operation in CONTINUOUS MODE for DIRECT RADIOSCOPY or INDIRECT RADIOSCOPY. However, for this mode of operation the device will have to comply with the relevant requirements for diagnostic HIGH-VOLTAGE GENERATORS and diagnostic X-RAY EQUIPMENT (see Sub-clause 1.3.102).

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements to ensure safety and to specify methods for demonstrating compliance with those requirements.

Requirements for reproducibility and accuracy are given because of their relationship to the quality and quantity of the IONIZING RADIATION produced and are confined to those considered necessary for safety.

Rationale. — Both the levels for compliance and the tests prescribed to determine compliance reflect the fact that the safety of CAPACITOR DISCHARGE X-RAY GENERATORS is not sensitive to small differences in levels of performance. The combinations of LOADING FACTORS specified for the tests are therefore limited in number but are chosen from experience as being appropriate in most cases. It is considered important to standardize the choice of combinations of LOADING FACTORS so that comparison can be made between tests performed in different places on different occasions. However, combinations other than those specified could be of equal technical validity.

NOTE 1 The safety philosophy on which this Particular Standard is based is described in the Introduction to the General Standard (see Sub-clause 1.3.101).

NOTE 2 With respect to protection against IONIZING RADIATION, this Particular Standard deals with indirect aspects of safety, namely those that depend upon the supply and control of electric energy from the CAPACITOR DISCHARGE HIGH-VOLTAGE GENERATOR. Direct requirements for protection against IONIZING RADIATION are given in the Collateral Standard referenced in Sub-clause 1.3.102.

NOTE 3 Concerning RADIOLOGICAL PROTECTION, it has been assumed in the preparation of this Particular Standard that USERS of medical diagnostic X-RAY EQUIPMENT will accept the basic recommendations of the International Commission on Radiological Protection (ICRP), as stated in ICRP Publication 26, 1977, paragraph 12, namely:

- “a) no practice shall be adopted unless its introduction produces a positive net benefit;
- b) all exposures shall be kept as low as reasonably achievable, economic and social factors being taken into account; and
- c) the dose equivalent to individuals shall not exceed the limits recommended for the appropriate circumstances by the Commission.”

It is recognized that many of the judgements necessary to follow these recommendations have to be made by the USER and not by the manufacturer of the equipment.

1.3 Particular Standards

Additional sub-clauses:

1.3.101 *Relation to the General Standard*

This Particular Standard refers to IEC Publication 601-1 (First edition, 1977): Safety of medical electrical equipment, Part 1: General requirements, and its Amendment No. 1 (1984)¹⁾.

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 CAPACITOR DISCHARGE X-RAY GENERATORS, a statement to that effect is given in this Particular Standard.

1.3.102 *Related International Standards*

This Particular Standard requires CAPACITOR DISCHARGE X-RAY GENERATORS, or sub-assemblies thereof, to comply with the applicable requirements of the Collateral Standard: General requirements for protection against ionizing radiation (under consideration) and of the Particular Standard:

IEC Publication 601-2-7 (1986): Medical electrical equipment Part 2: Particular requirements for the safety of high voltage generators of diagnostic X-ray generators (see also the Scope, Sub-clause 1.1).

Attention is also drawn to the IEC publications listed in the Preface.

1.3.103 *Superseded IEC Standards*

This Standard deals with some aspects of X-RAY EQUIPMENT, particularly of CAPACITOR DISCHARGE X-RAY GENERATORS and sub-assemblies thereof, that were covered by IEC Publications 407 and 407A.

Within its scope, this Particular Standard supersedes the corresponding requirements of IEC Publications 407 and 407A.

1.4 Environmental conditions

- a) Transport and storage

Item 2) a)

Replacement:

an ambient temperature between – 20 °C and + 70 °C.

2 Terminology and definitions

This clause of the General Standard applies, except as follows:

Addition:

In this Particular Standard, terms printed in capital letters are used as defined in IEC Publications 601-1 and 788 and Sub-clause 2.12.

For these terms and for the adjectives “specific” and “specified”, the alphabetical index refers to the standards mentioned; see Appendix AA.

2.12 Miscellaneous

Additional definition:

2.12.101 *Specified range of compliance*

For RADIOLOGICAL EQUIPMENT for which information on the behaviour of functional parameters is required in a standard, range or set of ranges over which the reproducibility, linearity, constancy or accuracy of such parameters is within limits described in the standard.

¹⁾ The second edition has been published in 1988.

3 General requirements

This clause of the General Standard applies, except as follows:

Additional sub-clauses:

3.101 Conventional meanings of electrical quantities

In this Particular Standard, unless otherwise indicated,

- values of X-RAY TUBE VOLTAGE refer to the maximum value at the initial stage of the LOADING of the X-RAY TUBE;
- values of electric current in the high-voltage circuit refer to the maximum value of the X-RAY TUBE CURRENT during the initial stage of the LOADING of the X-RAY TUBE.

3.102 RADIATION quantities

In accordance with a policy of avoiding the use of the quantity EXPOSURE with its unit the coulomb per kilogram (C.kg^{-1}) and its earlier unit the röntgen (R), the quantity AIR KERMA is used in this Particular Standard with its unit the gray (Gy). 1 Gy corresponds approximately to 1 J.kg^{-1} .

For X-RADIATION generated by high voltages up to 150 kV, covered by this Particular Standard, an AIR KERMA of 1 Gy corresponds to an EXPOSURE $X = 29.7 \text{ mC.kg}^{-1}$ or $X = 115 \text{ R}$.

All values of AIR KERMA given in this Particular Standard are followed by an indication of the corresponding approximate value of EXPOSURE in röntgen, reading: ($X = \dots \text{ R}$).

4 General requirements for tests

This clause of the General Standard applies, except as follows:

Addition:

Safety tests to be carried out after installation of a CAPACITOR DISCHARGE X-RAY GENERATOR, or after putting it into use, are under consideration.

4.1 Type tests and routine tests

a) *Type tests*

Addition:

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

4.10 Moisture pre-conditioning treatment

Addition (see Sub-clause 1.3.101):

This test shall be applied only to those parts of CAPACITOR DISCHARGE 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 CAPACITOR DISCHARGE 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:

CAPACITOR DISCHARGE X-RAY GENERATORS energized from an external power source shall be classified as CLASS I EQUIPMENT.

5.2 Replacement:

Unless otherwise specified to a higher degree of protection against electric shock, CAPACITOR DISCHARGE X-RAY GENERATORS shall be classified as TYPE B EQUIPMENT.

5.3 Replacement:

Unless otherwise specified, CAPACITOR DISCHARGE X-RAY GENERATORS are ordinary MEDICAL ELECTRICAL EQUIPMENT (enclosed equipment without protection against the ingress of liquids).

5.6 Replacement:

Unless otherwise specified, CAPACITOR DISCHARGE X-RAY GENERATORS shall be classified as suitable for continuous connection to the SUPPLY MAINS in the STAND-BY STATE and for specified LOADINGS in INTERMITTENT MODE (see also Sub-clause 6.8.5).