

Medical electrical equipment —

Part 2: Particular requirements for safety —

Section 2.7 Specification for high-voltage generators of diagnostic X-ray generators —

(Implementation of CENELEC HD 395.2.7 S1)

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Committees responsible for this British Standard

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- 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
- Hospital Physicists' Association
- 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 601-2-7:1987 “*Medical electrical equipment*” Part 2 “*Particular requirements for the safety of high-voltage generators of diagnostic 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 395.2.7 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, sub-clauses or figures that are additional to those of the General Standard are numbered starting from 101; additional appendices are lettered AA, BB, etc., 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, sub-clause or specified paragraph of the General Standard is replaced by the text of this standard.

“Amendment” means that the clause, sub-clause 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 in this Particular Standard: small capitals.

Cross-references

International Standard	Corresponding British Standard
IEC 417G:1985	BS 6217:1987 <i>Guide to graphical symbols for use on electrical equipment</i> (Identical)
IEC 601-1:1977 [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 613:1978	BS 6058:1981 <i>Method of specifying and verifying the characteristics of rotating anode X-ray tubes and X-ray tube assemblies used in medical diagnosis</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)

International Standard	Corresponding British Standard
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)
ISO 497:1973	BS 2045:1965 <i>Preferred numbers</i> (Technically equivalent)

There are no corresponding British Standards to IEC Publication 407:1973 “*Radiation protection in medical X-ray equipment 10 kV to 400 kV*” or to IEC Publication 407A:1975 “First supplement to Publication 407 (1973): Sub-clause 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 specific 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.

There is no corresponding British Standard to ISO 3665:1976 “*Photography — Intra-oral dental radiographic film — Specification*”. The Technical Committee has reviewed the provisions of ISO 3665, to which reference is made in the text, and has decided that they are acceptable for use in conjunction with this standard.

ICRP Publication 26 referred to in the text 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 48, 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 HIGH-VOLTAGE GENERATORS of medical diagnostic X-RAY GENERATORS that operate between 10 kV and 400 kV and in which the electric energy for LOADING an X-RAY TUBE is derived from alternating current SUPPLY MAINS without an essential element of energy storage within the equipment.

NOTE An essential element of energy storage is considered not to exist if the energy for LOADING at the LOADING FACTORS defining the NOMINAL ELECTRIC POWER is delivered from the SUPPLY MAINS during LOADING.

This Particular Standard applies to:

- dental HIGH-VOLTAGE GENERATORS;
- sub-assemblies of HIGH-VOLTAGE GENERATORS;
- HIGH-VOLTAGE GENERATORS that are integrated with an X-RAY TUBE ASSEMBLY;
- HIGH-VOLTAGE GENERATORS of radiotherapy treatment simulators.

In this Particular Standard, references to equipment “specified for dental applications” apply only to equipment with NOMINAL X-RAY TUBE VOLTAGES not exceeding 125 kV. For equipment operating above 125 kV the other requirements of this Particular Standard apply without regard to whether dental applications are specified.

Where necessary, requirements for X-RAY GENERATORS are given but only where these concern the functioning of the associated HIGH-VOLTAGE GENERATOR.

This Particular Standard excludes

- equipment for RECONSTRUCTIVE TOMOGRAPHY;
- equipment that is battery operated.

Rationale. — Requirements to be observed for the equipment excluded from the scope have not been sufficiently investigated. In order not to delay the issue of this Particular Standard such equipment is excluded for the time being.

Consideration of those requirements may later allow them to be given as an addendum to this Particular Standard; otherwise they will be dealt with in stand-alone Particular Standards of Part 2 of Publication 601.

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, linearity, constancy 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 HIGH-VOLTAGE 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 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.

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 electrical energy from the 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 (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 HIGH-VOLTAGE GENERATORS, a statement to that effect is given in this Particular Standard.

1.3.102 *Related International Standards*

This Particular Standard requires HIGH-VOLTAGE GENERATORS, or sub-assemblies thereof, to comply with the applicable requirements of the Collateral Standard: General Requirements for the Protection against Ionizing Radiation (*under consideration*).

Attention is drawn to the existence of the following IEC Publications:

IEC Publication 417G: Graphical Symbols for Use on Equipment. Index, Survey and Compilation of the Single Sheets (1985)

IEC Publication 613: Electrical, Thermal and Loading Characteristics of Rotating Anode X-ray Tubes for Medical Diagnosis (1978)

IEC Publication 637: Marking of and Accompanying Documents for X-ray Tubes and X-ray Tube Assemblies for Medical Use (1979)

IEC Publication 664A: Insulation Co-ordination within Low-voltage Systems including Clearances and Creepage Distances for Equipment. First Supplement (1981)

ISO Standard 497: Guide to the choice of series of preferred numbers and of series containing more rounded values of preferred numbers (1973)

ISO Standard 3665: Photography — Intra-oral dental radiographic film — Specifications (1976)

1.3.103 *Superseded IEC standards*

This Particular Standard deals with some aspects of X-RAY EQUIPMENT, particularly of HIGH-VOLTAGE GENERATORS and sub-assemblies thereof, that were covered by:

IEC Publication 407: Radiation Protection in Medical X-ray Equipment 10 kV to 400 kV, and (1973)

IEC Publication 407 A: First Supplement to Publication 407 (1973): Sub-clause **7.5.5**: Equipment for Dental Radiography. (1975)

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,

b) *Operation*

2) Power supply

Item a)

Replacement:

A SUPPLY MAINS having:

- a RATED voltage not exceeding:
 - 250 V single-phase or 500 V three-phase for HIGH-VOLTAGE GENERATORS with a rated apparent power input of up to 4 kVA,
 - 500 V for all other HIGH-VOLTAGE GENERATORS with the restriction that the voltage to earth within the MAINS PART shall not exceed 300 V;
- a sufficiently low internal impedance.

The internal impedance of a SUPPLY MAINS is to be considered sufficiently low for the operation of a HIGH-VOLTAGE GENERATOR if the value of the APPARENT RESISTANCE OF SUPPLY MAINS does not exceed:

- the appropriate reference value according to Table 101,
- or the value specified according to Item j) 4) of Sub-clause 6.1 whichever is the greater.
- voltage fluctuations not exceeding $\pm 10\%$ of the nominal voltage, except momentary fluctuations (of duration less than 1 s for example) at irregular intervals such as those caused by operation of X-RAY GENERATORS or similar equipment.

Momentary fluctuations caused by the HIGH-VOLTAGE GENERATOR itself are to be disregarded in any determination of whether the voltage fluctuations are within the limits given in the preceding paragraph.

- a practically sinusoidal waveform;
- practical symmetry in the case of a three-phase system;
- a frequency of not more than 1 kHz;
- a frequency deviating not more than 1 % from the nominal value.

A supply derived from a local electric power generator is considered suitable only if it is approved as such by the manufacturer of the HIGH-VOLTAGE GENERATOR.

If a nominal voltage is claimed for a mains power supply system, it is assumed that there is no voltage of a higher value between any of the conductors of the system or between any of these conductors and earth.

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 $\pm 2\%$ of the peak value of the ideal waveform.

A three-phase SUPPLY MAINS is considered to have a practical symmetry if it delivers symmetrical voltages and produces, when loaded symmetrically, symmetrical currents.

Symmetrical voltages are considered to exist, if, when determined according to Fortescue's theorem¹⁾, neither the magnitude of the negative sequence voltages nor the magnitude of the zero sequence voltages exceeds 2 % of the magnitude of the positive sequence voltages.

Symmetrical currents are considered to exist if, when determined according to Fortescue's theorem, neither the magnitude of the negative sequence currents, nor the magnitude of the zero sequence currents exceeds 5 % of the magnitude of the positive sequence currents.

The requirements of this Particular Standard are based upon the assumption that three-phase systems have a symmetrical configuration of the MAINS VOLTAGE with respect to earth and include a neutral conductor, and that single-phase systems are derived from such three-phase systems. Where the supply system is not earthed at the source it is assumed that adequate measures have been provided to detect, limit and remedy any disturbance of symmetry within a reasonably short time.

A HIGH-VOLTAGE GENERATOR is considered to comply with the requirements of this Standard only if its specified NOMINAL ELECTRIC POWER can be demonstrated at an APPARENT RESISTANCE OF SUPPLY MAINS having a value not less than the relevant reference value in Table 101 or not less than the APPARENT RESISTANCE OF SUPPLY MAINS specified according to Item j) 4) of Sub-clause 6.1, whichever is the greater.

¹⁾ C.L. Fortescue, Method of symmetrical coordinates applied to the solution of poly-phase networks, Trans. AIEE. vol. 37, pp. 1027–1140, 1918.

Table 101 — Reference values for the APPARENT RESISTANCE OF SUPPLY MAINS

Waveform of high voltage	NOMINAL ELECTRICAL POWER according to Item a) 4) of Sub-clause 6.8.2 kW	MAINS VOLTAGE						
		480 V	440 V	415 V	380 V	240 V	220 V	120 V
		APPARENT RESISTANCE OF SUPPLY MAINS Ω						
one peak	0.5					0.95	0.80	
	1.0	2.4	2.0	1.79	1.5	0.60	0.50	0.15
	2.0	1.6	1.3	1.19	1.0	0.40	0.34	0.10
	4.0	1.0	0.80	0.72	0.6	0.24	0.20	0.06
	8.0	0.50	0.40	0.36	0.3	0.12	0.10	0.032
	10.0	0.40	0.34	0.30	0.25			
	16.0	0.24	0.20	0.18	0.15			
two peak	4.0	1.6	1.3	1.19	1.0	0.40	0.34	0.10
	8.0	1.0	0.80	0.72	0.60	0.24	0.20	0.06
	10.0	0.80	0.67	0.60	0.50	0.18	0.15	0.045
	16.0	0.50	0.40	0.36	0.30	0.12	0.10	0.032
	20.0	0.40	0.34	0.30	0.25			
	32.0	0.24	0.20	0.18	0.15			
six peak twelve peak and up to constant potential	50.0	0.16	0.14	0.12	0.10			
	16.0	0.83	0.65	0.60	0.50	0.19	0.16	0.045
	20.0	0.64	0.50	0.48	0.40	0.14	0.12	0.035
	32.0	0.40	0.34	0.30	0.25			
	40.0	0.32	0.27	0.24	0.20			
	50.0	0.24	0.20	0.18	0.15			
	75.0	0.16	0.14	0.12	0.10			
	100	0.12	0.10	0.09	0.08			
	150	0.08	0.07	0.06	0.05			

For this purpose, the APPARENT RESISTANCE OF SUPPLY MAINS R is determined according to the formula:

$$R = \frac{U_0 - U_1}{I_1}$$

where:

U_0 is the no-load MAINS VOLTAGE

U_1 is the MAINS VOLTAGE under load

I_1 is the mains current under load

A single resistive load shall be applied. The MAINS VOLTAGE shall be measured between phase and neutral or, if applicable, between phase and phase and in a three-phase system between each two phases.

The APPARENT RESISTANCE OF SUPPLY MAINS shall be measured by applying a single resistive load of a value corresponding approximately to the NOMINAL ELECTRIC POWER specified according to Item a) 4) of Sub-clause 6.8.2, but not more than 30 kW. The overall uncertainty of the determination of the APPARENT RESISTANCE OF SUPPLY MAINS shall not exceed 10 %.

Reference values for the APPARENT RESISTANCE OF SUPPLY MAINS for MAINS VOLTAGES not included in Table 101 may be interpolated and shall be calculated on the basis that the reference value is proportional to the square of the MAINS VOLTAGE.

If values of NOMINAL ELECTRIC POWER between those given in Table 101 are specified, it shall be possible to fulfil all requirements applying for the next lower value of NOMINAL ELECTRIC POWER given in Table 101 with the APPARENT RESISTANCE OF SUPPLY MAINS given for that lower value.

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:

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

For these terms, the alphabetic index refers to the standards mentioned.

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

3 General requirements

This clause of the General Standard applies except as follows:

3.1 Addition:

HIGH-VOLTAGE GENERATORS shall be designed so as not to deliver in NORMAL USE a voltage to the X-RAY TUBE greater than the NOMINAL X-RAY TUBE VOLTAGE or the LIMITED X-RAY TUBE VOLTAGE.

As far as the requirements of sub-clauses 50.101 to 50.103 are concerned, a HIGH-VOLTAGE GENERATOR or a sub-assembly thereof is in compliance with this Standard if the X-RAY GENERATOR or a sub-assembly thereof is in compliance with this Standard if the X-RAY GENERATOR can pass all relevant tests of Sub-clauses 50.104 to 50.114.

Additional sub-clauses:

3.101 Conventional meanings of electrical quantities

In this Particular Standard unless otherwise indicated:

- values of high voltage refer to peak values, switching transients being disregarded,
- values of electric current in rectified high voltage circuits refer to average values.

The electric power in the high voltage circuit mentioned in Item a) 3) and a) 4) of Sub-clause 6.8.2 shall be calculated according to the formula:

$$P = UIf$$

where:

P is the electric power

U is the voltage delivered to the X-RAY TUBE

I is the X-RAY TUBE CURRENT.

For conventional generating systems the following values of the factor f shall be used:

$f = 0.74$ for ONE and TWO PEAK HIGH-VOLTAGE GENERATORS

$f = 0.95$ for SIX PEAK HIGH-VOLTAGE GENERATORS

$f = 1.0$ for TWELVE PEAK HIGH-VOLTAGE GENERATORS and CONSTANT POTENTIAL HIGH-VOLTAGE GENERATORS.

For other generating systems the most appropriate value of the factor f from the three given above shall be used to calculate the electric power to a reasonable accuracy.

The term “constant potential” is taken for the purpose of this Particular Standard to apply to a HIGH-VOLTAGE GENERATOR having a high voltage output with a PERCENTAGE RIPPLE not exceeding 4 %.

3.102 Radiation quantities

In accordance with a policy of avoiding the use of the quantity EXPOSURE and 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 to $1\ J\ kg^{-1}$.

For X-RADIATION generated at high voltages up to 400 kV, as covered by this Particular Standard, an AIR KERMA of 1 Gy corresponds to the 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 HIGH-VOLTAGE 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, which are to be carried out under controlled conditions, of the kind prevailing in test laboratories.

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

Additional Item:

aa) *For the tests to be carried out according to Sub-clauses 50.105 to 50.114 the conditions of Sub-clause 50.104 shall be maintained.*

Rationale. — Fluctuations of the supply and other environmental conditions even within the limits permissible according to Sub-clause 1.4, can influence the measurements to such an extent that the safe functioning of the HIGH-VOLTAGE GENERATOR cannot be judged when several unfavourable conditions coincide. Therefore, in order to get reasonable data to verify compliance, controlled test conditions have to be maintained.

4.10 Moisture preconditioning treatment

Addition (see: Sub-clause 1.3.101):

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

Where it is not practicable to treat a HIGH-VOLTAGE 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:*

HIGH-VOLTAGE GENERATORS shall be classified as CLASS I EQUIPMENT.

5.2 *Replacement:*

Unless otherwise specified to a higher degree of protection against electric shock, HIGH-VOLTAGE GENERATORS shall be classified as TYPE B EQUIPMENT.

5.3 *Replacement:*

Unless otherwise specified, HIGH-VOLTAGE GENERATORS are ordinary MEDICAL ELECTRICAL EQUIPMENT (enclosed equipment without protection against ingress of liquids).

5.6 *Replacement:*

Unless otherwise specified, HIGH-VOLTAGE GENERATORS or sub-assemblies thereof shall be classified as suitable for continuous connection to the SUPPLY MAINS in the STAND-BY STATE and for specified LOADINGS; see also Item m) of Sub-clause 6.1 and Sub-clause 6.8.5

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts

Addition at the beginning of the sub-clause:

HIGH-VOLTAGE GENERATORS and their constituent sub-assemblies and components shall be appropriately marked if their correlation to one another influences safety; see also Sub-clause 6.8.1.

g) *Connection to the supply*

Addition at the end, add the paragraph:

— For HIGH-VOLTAGE GENERATORS that are specified to be permanently installed, the information required in Item g) of Sub-clause 6.1 of the General Standard may be stated in the ACCOMPANYING DOCUMENTS only.

h) *Supply frequency (in hertz)*

Addition at the end, add the paragraph:

— For HIGH-VOLTAGE GENERATORS that are specified to be permanently installed, the information required in Item h) of Sub-clause 6.1 of the General Standard may be stated in the ACCOMPANYING DOCUMENTS only.

j) *Power input*

Replacement:

For HIGH-VOLTAGE GENERATORS that are specified to be permanently installed, the information may be stated in the ACCOMPANYING DOCUMENTS only.

The information on the input power shall be specified in terms of combinations of:

- 1) the RATED MAINS VOLTAGE of the X-RAY GENERATOR in volts, see Item g),
- 2) the number of phases, see Item g),
- 3) the frequency in hertz, see Item h),
- 4) the maximum APPARENT RESISTANCE OF SUPPLY MAINS in ohms,
- 5) the characteristics of OVER-CURRENT RELEASES required in the SUPPLY MAINS.

m) *Mode of operation*

Replacement:

The mode of operation — where appropriate, together with maximum permissible ratings — shall be stated in the ACCOMPANYING DOCUMENTS; see Sub-clause 6.8.5.

n) *Fuses*

Addition:

For HIGH-VOLTAGE GENERATORS that are specified to be permanently installed, this sub-clause of the General Standard does not apply; see Item j).

p) *Output*

Replacement:

This sub-clause of the General Standard does not apply.

t) *Cooling conditions*

Addition:

The cooling requirements for the safe operation of a HIGH-VOLTAGE GENERATOR, or a sub-assembly thereof, shall be indicated in the ACCOMPANYING DOCUMENTS, including as appropriate:

- the maximum heat dissipation into the surrounding air, given separately for each sub-assembly that dissipates more than 100 W and might be separately located on installation;
- the maximum heat dissipation into forced air cooling devices and the corresponding flow rate and temperature rise of the forced air stream;
- the maximum heat dissipation into a cooling medium utility and the highest permissible input temperature, minimum flow rate and pressure requirements for the utility.

Additional item:

aa) *Marking of compliance*

If, for a HIGH-VOLTAGE GENERATOR or sub-assembly thereof, compliance with this Standard is to be marked on the outside of the equipment, such marking shall be made in combination with the MODEL OR TYPE REFERENCE as follows:

...^{+) IEC 601-2-7}

...^{+) MODEL OR TYPE REFERENCE}

Marking indicating compliance of equipment, or sub-assembly thereof, with the requirements of this Standard shall be made only if compliance of the equipment, or the sub-assembly, is complete.

6.2 Marking on the inside of EQUIPMENT or EQUIPMENT parts

Item c)

Addition:

This marking does not apply to parts containing high voltage circuits of X-RAY TUBE ASSEMBLIES and of HIGH-VOLTAGE TRANSFORMER ASSEMBLIES.

6.7 Indicator lights and push-buttons

a) Colour of indicator lights

Addition in front of the last paragraph:

For HIGH-VOLTAGE GENERATORS, the colours to be used for indicator lights shall be as follows:

- the colour red shall be used exclusively to indicate that operation must not be started or an immediate action is required to terminate a hazardous state of operation, for example because maximum permitted values have been exceeded,
- the colour green shall be used at the CONTROL PANEL to indicate the state from which one further action leads to the LOADING STATE; see Item a) of Sub-clause **29.1.103**,
- the colour yellow shall be used at the CONTROL PANEL to indicate the LOADING STATE; see Item b) of Sub-clause **29.1.103**.

An indicator light need not be red when its purpose is to indicate a state that is prevented from becoming hazardous by an interlock.

Light emitting diodes (LEDs) in the red spectrum are not considered to be red indicator lights provided that:

- on any one CONTROL PANEL all indications for which no particular colour is required are given by light emitting diodes of the same colour and
- the indications for which particular colours are required are given in a clearly distinguishable way.

The colours of indicator lights are chosen according to the message to be given. Thus, the same operational state of an equipment can lead to simultaneous indications in different colours depending upon the place of indication, for example: green at the CONTROL PANEL and red at the entrance to the EXAMINATION ROOM.

6.8 ACCOMPANYING DOCUMENTS

6.8.1 General

Addition:

The ACCOMPANYING DOCUMENTS shall clearly state the identity of the HIGH-VOLTAGE GENERATOR, or sub-assembly thereof, to which they refer.

All particulars required to be marked under Sub-clause **6.1** shall also be stated in the ACCOMPANYING DOCUMENTS.

This Particular Standard contains no requirements concerning the language(s) in which ACCOMPANYING DOCUMENTS are to be provided.

Attention is drawn to the fact that ACCOMPANYING DOCUMENTS in a language other than that in which they are supplied and approved by the manufacturer of the equipment or sub-assembly need a careful check by an expert who, wherever possible, should be authorized by the manufacturer to act in that capacity.

The ACCOMPANYING DOCUMENTS shall state the language(s) in which they were originally drafted, approved or supplied by the manufacturer and shall give a reference identifying at least one original version.

6.8.2 INSTRUCTIONS FOR USE

a) General information

Addition:

Electric output data shall be stated in the INSTRUCTIONS FOR USE in terms of LOADING FACTORS as described in Items a) 1) to a) 6) of Sub-clause **6.8.2**, when the HIGH-VOLTAGE GENERATOR is loading one of the specified X-RAY TUBES or X-RAY TUBE ASSEMBLIES.

For diagnostic devices in which part of the HIGH-VOLTAGE GENERATOR is integrated with the X-RAY TUBE ASSEMBLY — for example X-RAY TUBE HEADS — the stated values shall refer to the complete device.

All values stated according to this sub-clause shall be obtainable with settings of LOADING FACTORS that are within the SPECIFIED RANGE OF COMPLIANCE.

The following combinations and data shall be stated:

- 1) For both CONTINUOUS MODE and INTERMITTENT MODE, the NOMINAL X-RAY TUBE VOLTAGE together with the highest X-RAY TUBE CURRENT obtainable from the HIGH-VOLTAGE GENERATOR when operated at its NOMINAL X-RAY TUBE VOLTAGE.
- 2) For both CONTINUOUS MODE and INTERMITTENT MODE, the highest X-RAY TUBE CURRENT together with the highest X-RAY TUBE VOLTAGE, obtainable from the HIGH-VOLTAGE GENERATOR when operating at its highest X-RAY TUBE CURRENT.
- 3) For both CONTINUOUS MODE and INTERMITTENT MODE, the X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT which result in the highest electric output power; see Sub-clause **3.101**.
- 4) The NOMINAL ELECTRIC POWER given as the highest constant electric output power in kilowatts which the HIGH-VOLTAGE GENERATOR can deliver, for a selectable LOADING TIME of 0.1 s at an X-RAY TUBE VOLTAGE of 100 kV (or, if this is not preselectable, at the value nearest to 100 kV); see Sub-clause **3.101**. NOMINAL ELECTRIC POWER shall be given together with the combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT.

Additionally, values of electric power can be given for other combinations of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT and can be qualified by reference to any special applications to which they refer.

- 5) The REFERENCE CURRENT TIME PRODUCT which is a CURRENT TIME PRODUCT not smaller than that which can be obtained in an IRRADIATION TIME of 0.1 s or if this value is not available, at the next higher available value.

The electric power for which the REFERENCE CURRENT TIME PRODUCT is given shall correspond to about, but not more than, 50 % of the NOMINAL ELECTRIC POWER, when referred to an IRRADIATION TIME of 0.1 s.

The REFERENCE CURRENT TIME PRODUCT shall be given together with the combination of X-RAY TUBE VOLTAGE, X-RAY TUBE CURRENT and IRRADIATION TIME at which it is obtainable.

Different values of REFERENCE CURRENT TIME PRODUCT may be stated for various values of X-RAY TUBE VOLTAGE.

- 6) For HIGH-VOLTAGE GENERATORS indicating precalculated or measured CURRENT TIME PRODUCT, the lowest CURRENT TIME PRODUCT or the combination(s) of LOADING FACTORS resulting in the lowest CURRENT TIME PRODUCT that is within THE SPECIFIED RANGES OF COMPLIANCE for linearity and constancy.

If the value of the lowest CURRENT TIME PRODUCT depends upon the X-RAY TUBE VOLTAGE or upon certain combinations of values of LOADING FACTORS, the lowest CURRENT TIME PRODUCT may be given as a table or curve showing the dependence.

- 7) If a HIGH-VOLTAGE GENERATOR is capable of operating at combinations of LOADING FACTORS resulting in TRUE VALUE(S) exceeding the limits for reproducibility, linearity, constancy and accuracy according to Sub-clauses **50.101** and **50.102**, the ACCOMPANYING DOCUMENTS shall contain the indication of a) SPECIFIED RANGE(S) OF COMPLIANCE over which these limits are not exceeded.

For the combinations of LOADING FACTORS resulting in TRUE VALUE(S) outside the SPECIFIED RANGE OF COMPLIANCE the relationship between these TRUE VALUE(S) and the associated combination of LOADING FACTORS shall be described in the INSTRUCTIONS FOR USE, for example in terms of correction factors in tables or curves.

8) For HIGH-VOLTAGE GENERATORS provided with AUTOMATIC CONTROL SYSTEMS controlling the IRRADIATION TIME: the NOMINAL SHORTEST IRRADIATION TIME.

The NOMINAL SHORTEST IRRADIATION TIME is determined as a time

- for which the PERCENT AVERAGE ERROR of AIR KERMA is less than 20 referred to the average AIR KERMA attained at an IRRADIATION TIME at least 50 times the specified NOMINAL SHORTEST IRRADIATION TIME when measured in accordance with Subclauses **50.107.1**, **50.107.2**, Item a) of Sub-clause **50.107.3** and Sub-clauses **50.111** to **50.114**, and
- which is no shorter than the shortest IRRADIATION TIME for which the requirements on the COEFFICIENT OF VARIATION of AIR KERMA are met in accordance with Sub-clause **50.101**.

If the NOMINAL SHORTEST IRRADIATION TIME depends upon LOADING FACTORS such as X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT, the ranges of these LOADING FACTORS for which the NOMINAL SHORTEST IRRADIATION TIME is valid shall be specified together with the latter.

6.8.3 Technical description

a) General

Addition:

The technical description shall contain information about the combination or, if necessary, the combinations of sub-assemblies and ACCESSORIES of an X-RAY GENERATOR with which compliance with the requirements of Sub-clauses **50.101** to **50.103** can be shown; see Sub-clause **50.2.102**.

NOTE Attention is drawn to the usefulness in the technical description of

- data and essential characteristics to determine the ratings of an earth leakage circuit breaker, or
- indication of the type(s) of earth leakage circuit breaker(s) which can be used in accordance with the HIGH VOLTAGE GENERATOR.

The technical description shall contain appropriate instructions for the connection of the HIGH-VOLTAGE GENERATOR or of sub-assemblies to the SUPPLY MAINS.

For HIGH-VOLTAGE GENERATORS with a high electric power input attention shall be drawn to the possible need for a separate feeder in order to avoid interference with other electrical equipment.

6.8.5 Reference to ACCOMPANYING DOCUMENTS

Addition:

Clauses and sub-clauses of this Particular Standard in which additional requirements concerning the content of ACCOMPANYING DOCUMENTS are given:

APPARENT RESISTANCE OF SUPPLY MAINS	and	1.4 b) 2) a) 6.1 j) 4)
Local rotary electric power generator		1.4 b) 2) a)
Classification		5.1
Degree of protection against electric shock		5.2
Protection against ingress of liquids		5.3
Mode of operation and specified LOADINGS		5.6
Connection to the supply	and	6.1 m)
Number of phases of SUPPLY MAINS		6.1 g)
Frequency of SUPPLY MAINS	and	6.1 j) 2)
Power input	and	6.1 h)
MAINS VOLTAGE(S)		6.1 j) 3)
OVER-CURRENT RELEASE		6.1 j)
Fuses		6.1 j) 1)
Cooling conditions		6.1 j) 5)
Identification of corresponding components		6.1 n)
Markings on equipment		6.1 t)
Original language(s) of ACCOMPANYING DOCUMENTS		6.8.1
Electric output data, combinations of LOADING FACTORS		6.8.1
	and	6.8.2 a)
SPECIFIED RANGES OF COMPLIANCE		50.1
Suitable combinations for compliance test	and	6.8.2 a) 7)
Earth leakage circuit breaker	and	50.101.1
		6.8.3 a)
	and	50.2.102
		6.8.3 a)