

Medical electrical equipment —

Part 2-7: Particular requirements for safety — Specification for high voltage generators of diagnostic X-ray generators

The European Standard EN 60601-2-7:1998 has the status of a
British Standard

ICS 11.040.50

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ISBN 0 580 29947 3

Amendments issued since publication

Amd. No.	Date	Comments

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National foreword

This British Standard is the English language version of EN 60601-2-7:1998. It is identical with IEC 60601-2-7:1998. It supersedes BS 5724-2.7:1987 which is withdrawn. 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.

As in the general standard, the requirements are followed by compliance tests. The numbers of the section 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.

“Additional” means that the text of this standard is additional to the requirement of the general standard.

The UK participation in its preparation was entrusted to Technical Committee CH/71, Diagnostic imaging equipment and accessories, 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 international or European publications referred to in this document 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. 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 clause 2 of the general standard or in BS 6641: SMALL CAPITALS.

For the purpose of this British Standard, any references to IEC page numbers in the text should be ignored.

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 iv, the EN title page, pages 2 to 28 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, radiodiagnostic X-ray generator, high-voltage generators, safety requirements, protection against electric shock, protection against mechanical hazard, radiation protection, fire protection, environmental conditions

English version

Medical electrical equipment
Part 2-7: Particular requirements for the safety of
high-voltage generators of diagnostic X-ray generators

(IEC 60601-2-7:1998)

Appareils électromédicaux
Partie 2-7: Règles particulières de sécurité pour
générateurs radiographiques de groupes
radiogènes de diagnostic
(CEI 60601-2-7:1998)

Medizinische elektrische Geräte
Teil 2-7: Besondere Festlegungen für die
Sicherheit von Röntgengeneratoren von
diagnostischen Röntgenstrahlenerzeugern
(IEC 60601-2-7:1998)

This European Standard was approved by CENELEC on 1998-04-01. 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.

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CENELEC

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

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Foreword

The text of document 62B/329/FDIS, future edition 2 of IEC 60601-2-7, prepared by SC 62B, Diagnostic imaging equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-7 on 1998-04-01.

This European Standard supersedes HD 395.2.7 S1:1989.

The following dates were 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) 1999-01-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2001-01-01

Endorsement notice

The text of the International Standard IEC 60601-2-7:1998 was approved by CENELEC as a European Standard without any modification.

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Section 1. General

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

1.1 Scope

Replacement:

This Particular Standard applies to HIGH-VOLTAGE GENERATORS of medical diagnostic X-RAY GENERATORS and to their subassemblies including the following:

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

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

This standard excludes

- CAPACITOR DISCHARGE HIGH-VOLTAGE GENERATORS (these are covered by IEC 60601-2-15),
- HIGH-VOLTAGE GENERATORS for mammography,
- HIGH-VOLTAGE GENERATORS for RECONSTRUCTIVE TOMOGRAPHY.

1.2 Object

Replacement:

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

NOTE 1 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.

NOTE 2 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 3 The safety philosophy on which this standard is based is described in the introduction to the General Standard and in IEC 60513.

NOTE 4 Concerning RADIOLOGICAL PROTECTION it has been assumed in the preparation of this standard that MANUFACTURERS and USERS do accept the general principles of the ICRP as stated in ICRP 60, 1990, paragraph 112,¹⁾ namely:

- a) "No practice involving exposures to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes. (The justification of a practice.)
- b) In relation to any particular source within a practice, the magnitude of individual doses, the number of people exposed, and the likelihood of incurring exposures where these are not certain to be received should all be kept as low as reasonably achievable, economic and social factors being taken into account. This procedure should be constrained by restrictions on the doses to individuals (dose constraints), or the risks to individuals in the case of potential exposures (risk constraints), so as to limit the inequity likely to result from the inherent economic and social judgements. (The optimisation of protection.)
- c) The exposure of individuals resulting from the combination of all the relevant practices should be subject to dose limits, or to some control of risk in the case of potential exposures. These are aimed at ensuring that no individual is exposed to radiation risks that are judged to be unacceptable from these practices in any normal circumstances. Not all sources are susceptible of control by action at the source and it is necessary to specify the sources to be included as relevant before selecting a dose limit. (Individual dose and risk limits)."

NOTE 5 Most of the requirements on X-RAY EQUIPMENT and its subassemblies for protection against IONIZING RADIATION are given in the Collateral Standard IEC 60601-1-3.

This standard does, however, deal with some aspects of RADIOLOGICAL PROTECTION, mainly those that depend upon the supply, control and indication of electrical energy from the HIGH-VOLTAGE GENERATOR.

NOTE 6 It is recognized that many of the judgements necessary to follow the ICRP general principles have to be made by the USER and not by the MANUFACTURER of the EQUIPMENT.

1.3 Particular Standards

Addition:

This Particular Standard, hereinafter referred to as "this standard", amends and supplements a set of IEC publications, hereinafter referred to as "General Standard", consisting of IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*, its amendments 1 (1991) and 2 (1995), and all Collateral Standards. The numbering of sections, clauses and subclauses of this standard corresponds to 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 standard.

¹⁾ ICRP Publication 60: Recommendations of the International Commission on Radiological Protection (*Annals of the ICRP* Vol. 21 No 1-3, 1990). Published by Pergamon Press.