



SLOVENSKI STANDARD

SIST EN 60601-2-7:1998

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SIST HD 395.2.7 S1:1998

Medicinska električna oprema - 2-7. del: Posebne varnostne zahteve za visokonapetostne napajalnike generatorjev diagnostičnih rentgenskih žarkov (IEC 60601-2-7:1998)

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)

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

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

Ta slovenski standard je istoveten z: EN 60601-2-7:1998

ICS:

11.040.50 Radiografska oprema Radiographic equipment

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NORME EUROPÉENNE
EUROPÄISCHE NORM

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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)

<https://standards.iteh.ai/catalog/standards/sist/e913dd46-ba15-4ed3-972c-33f38738aeb7/sist-en-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.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Czech Republic, 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 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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INTERNATIONAL STANDARD

IEC 60601-2-7

Second edition
1998-02

Medical electrical equipment –

Part 2-7:

Particular requirements for the safety of high-voltage generators of diagnostic

X-ray generators

(standards.iteh.ai)

Appareils électromédicaux –

SIST EN 60601-2-7:1998

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Partie 2-7:

Règles particulières de sécurité pour générateurs radiographiques de groupes radiogènes de diagnostic

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –
Part 2-7: Particular requirements for the safety of
high-voltage generators of diagnostic X-ray generators

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 co-operation 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 international 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 60601-2-7 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 1987, and constitutes a technical revision. The text of this standard is based on the following documents:

FDIS	Report on voting
62B/329/FDIS	62B/334/RVD

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

Annexes AA and BB form an integral part of this standard.

Annex CC is for information only.

In this standard, the following print types are used:

- requirements, compliance with which can be tested and definitions: roman type;
- explanations, advice, notes, general statements and exceptions: smaller type;
- *test specifications: italic type*;
- TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR IN IEC 60788: SMALL CAPITALS.

A bilingual version of this standard may be issued at a later date.

MEDICAL ELECTRICAL EQUIPMENT – Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators

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.

"Addition" means that the text of this 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 standard.

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

Where there is no corresponding section, clause or subclause in this standard, the section, clause or subclause 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, a statement to that effect is given in this standard.

A requirement of this standard replacing or modifying requirements of the General Standard takes precedence over the original requirements concerned.

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.

1.3.101 Related International Standards

This standard requires HIGH-VOLTAGE GENERATORS, or subassemblies thereof, to comply with the applicable requirements of IEC 60601-1-3.

NOTE – IEC 60601-1-3 contains the following:

"In the following IEC standards, requirements that relate to medical diagnostic X-RAY EQUIPMENT are superseded by the requirements in this Collateral Standard:

IEC 60407: 1973, *Radiation protection in medical X-ray equipment 10 kV to 400 kV*

IEC 60407A: 1975, *First supplement to IEC 60407.*"

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

IEC 60417P:1997, *Graphical symbols for use on equipment: Index, survey and compilation of the single sheets – Fifteenth supplement*

IEC 60601-2-15:1988, *Medical electrical equipment – Part 2: Particular requirements for the safety of capacitor discharge X-ray generators*

IEC 60601-2-28:1993, *Medical electrical equipment – Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis*

IEC 60601-2-32:1994, *Medical electrical equipment – Part 2: Particular requirements for the safety of associated equipment of X-ray equipment*

IEC 60613:1989, *Electrical, thermal and loading characteristics of rotating anode X-ray tubes for medical diagnosis*

IEC 60664-1:1992, *Insulation coordination for equipment within low-voltage systems – Part 1: Principles, requirements and tests*

IEC 60788: 1984, *Medical radiology – Terminology*

ISO 497:1973, *Guide to the choice of series of preferred numbers and of series containing more rounded values of preferred numbers*

ISO 3665:1976, *Photography – Intra-oral dental radiographic film – Specifications*

ISO 7000:1989, *Graphical symbols for use on equipment – Index and synopsis*

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Addition before 2.1:

In this standard, terms printed in SMALL CAPITALS are used in accordance with their definitions in the General Standard or in IEC 60788.

NOTE – Attention is drawn to the fact that, in cases where the concept addressed is not strongly confined to the definition given in one of the publications listed above, a corresponding term is printed in lower case letters.

An index of defined terms used in this standard is given in annex AA.

Associated conditions qualifying the usage of certain terms are given in 2.101.

aa) In this standard unless otherwise indicated:

- values of X-RAY TUBE VOLTAGE refer to peak values, transients being disregarded;
- values of X-RAY TUBE CURRENT refer to average values.

bb) The electric power in the high-voltage circuit mentioned in 6.8.2 a) 3) and 6.8.2 a) 4) is calculated according to the formula:

$$P = f U I$$

where

P is the electric power;

f is the factor depending on the waveform of the X-RAY TUBE VOLTAGE, selected as below and is

a) 0,74 for ONE-PEAK HIGH-VOLTAGE GENERATORS and TWO-PEAK HIGH-VOLTAGE GENERATORS, or

b) 0,95 for SIX-PEAK HIGH-VOLTAGE GENERATORS, or

c) 1,00 for TWELVE-PEAK HIGH-VOLTAGE GENERATORS and CONSTANT POTENTIAL HIGH-VOLTAGE GENERATORS; or

d) for other HIGH-VOLTAGE GENERATORS, the most appropriate value, 0,74, 0,95 or 1,00, chosen according to the waveform of the X-RAY TUBE VOLTAGE, with a statement of the value selected;

U is the X-RAY TUBE VOLTAGE;

I is the X-RAY TUBE CURRENT.

Addition:

2.101 Qualifying conditions for defined terms

2.101.1 Operating conditions for NOMINAL X-RAY TUBE VOLTAGE

NOMINAL X-RAY TUBE VOLTAGE is defined in IEC 60788 (rm-36-03) as the highest permitted X-RAY TUBE VOLTAGE for specific operating conditions. In this standard, if specific operating conditions are not stated, it is to be assumed that the value referenced is unconditional and is thus the highest X-RAY TUBE VOLTAGE permitted for NORMAL USE of the item under consideration. Such a value cannot be higher, but is sometimes lower, than values permitted for certain separate subassemblies or parts of the item.

2.101.2 PERCENTAGE RIPPLE in CONSTANT POTENTIAL HIGH-VOLTAGE GENERATORS

Unless otherwise stated, it is to be assumed that for a HIGH-VOLTAGE GENERATOR to be regarded as a CONSTANT POTENTIAL HIGH-VOLTAGE GENERATOR, the PERCENTAGE RIPPLE of its output voltage (under the relevant conditions) does not exceed 4.

2.101.3 RADIATION QUANTITY for NOMINAL SHORTEST IRRADIATION TIME

The definition of NOMINAL SHORTEST IRRADIATION TIME refers to a required constancy of a RADIATION QUANTITY. In this standard the RADIATION QUANTITY concerned is AIR KERMA.

2.101.4 IRRADIATION TIME

Generally the IRRADIATION TIME is measured in terms of LOADING TIME as the time interval between:

- the instant that the X-RAY TUBE VOLTAGE has risen for the first time to a value of 75 % of the peak value; and
- the instant at which it finally drops below the same value.

For systems in which LOADING is controlled by electronic switching of the high voltage, using a grid in an electronic tube or in the X-RAY TUBE, the LOADING TIME may be determined as the time interval between the instant when the TIMING DEVICE generates the signal to start the IRRADIATION and the instant when it generates the signal to terminate the IRRADIATION.

For systems in which LOADING is controlled by simultaneous switching in the primaries of both the high-voltage circuit and the heating supply for the filament of the X-RAY TUBE, the LOADING time shall be determined as the time interval between the instant when the X-RAY TUBE CURRENT first rises above 25 % of its maximum value and the instant when it finally falls below the same value.

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, to any connected X-RAY TUBE ASSEMBLY, a voltage greater than the NOMINAL X-RAY TUBE VOLTAGE for the X-RAY TUBE ASSEMBLY concerned.

5 Classification

This clause of the General Standard applies except as follows:

5.1 Replacement:

HIGH-VOLTAGE GENERATORS shall be CLASS I EQUIPMENT or INTERNALLY POWERED EQUIPMENT.

5.6 Replacement:

Unless otherwise specified, HIGH-VOLTAGE GENERATORS or subassemblies thereof shall be classified as suitable for continuous connection to the SUPPLY MAINS in the STAND-BY STATE and for specified LOADINGS; see also 6.1 m) and 6.8.101.

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

- g) Connection to the supply

Addition:

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

- h) Supply frequency

Addition:

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

- j) Power input

Addition:

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 permissible value for APPARENT RESISTANCE OF SUPPLY MAINS, in ohms;
- 5) the characteristics of OVER-CURRENT RELEASES required in the SUPPLY MAINS.