SLOVENSKI STANDARD
SIST HD 395.2.7 S1:1998

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Medical electrical equipment - Part 2: Particular requirements for the safety of high -voltage generators of diagnostic X-ray generators (IEC 60601-2-7:1987)

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

Medizinische elektrische Geräte -- Teil 2: Besondere Festlegungen für die Sicherheit von Röntgengeneratoren von diagnostischen Röntgenstrahlenerzeugern

Appareils électromédicaux -- Partie 2: Règles particulières de sécurité pour générateurs radiologiques de groupes radiogènes de diagnostic

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CENELEC
Rue Bréderode 2, Bte 5 - 1000 BRUXELLES
Tél.: (+32.2)519 68 71 - Télex: 26257 Cenlec b
Fax: (+32.2)519 68 19 - Télétex: 206 2210097 CENCEL

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MEDICAL ELECTRICAL EQUIPMENT
PART 2:
PARTICULAR REQUIREMENTS FOR THE SAFETY OF HIGH-VOLTAGE GENERATORS OF DIAGNOSTIC X-RAY GENERATORS

Appareils électromédicaux
Deuxième partie:
Règles particulières de sécurité pour générateurs radiologiques de groupes radiogènes de diagnostic

Medizinische elektrische Geräte
Teil 2:
Besondere Festlegungen für die Sicherheit von Röntgengeneratoren von diagnostischen Röntgenstrahlenerzeugern

BODY OF THE HD

The Harmonization Document consists of:

- IEC 601-2-7 (1987) ed 1; IEC/SC 62B, not appended

This Harmonization Document was approved by CENELEC on 1988-06-28.

The English and French versions of this Harmonization Document are provided by the text of the IEC publication and the German version is the official translation of the IEC text.

According to the CENELEC Internal Regulations the CENELEC member National Committees are bound:

to announce the existence of this Harmonization Document at national level by or before 1989-01-01

to publish their new harmonized national standard by or before 1989-07-01

to withdraw all conflicting national standards by or before 1992-01-01.

Harmonized national standards are listed on the HD information sheet, which is available from the CENELEC National Committees or from the CENELEC Central Secretariat.

The CENELEC National Committees are the national electrotechnical committees of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxemburg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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Appareils électromédicaux

Deuxième partie: Règles particulières de sécurité pour générateurs radiologiques de groupes radiogènes de diagnostic

Medical electrical equipment

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

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT

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

FOREWORD

1) The formal decisions or agreements of the IEC on technical matters, prepared by Technical Committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.

2) They have the form of recommendations for international use and they are accepted by the National Committees in that sense.

3) In order to promote international unification, the IEC expresses the wish that all National Committees should adopt the text of the IEC recommendation for their national rules in so far as national conditions will permit. Any divergence between the IEC recommendation and the corresponding national rules should, as far as possible, be clearly indicated in the latter.

4) The IEC has not laid down any procedure concerning marking as an indication of approval and has no responsibility when an item of equipment is declared to comply with one of its recommendations.

PREFACE

This Particular Standard has been prepared by Sub-Committee 62B: X-Ray Equipment Operating up to 400 kV and Accessories, of IEC Technical Committee No. 62: Electrical Equipment in Medical Practice.

The text of this standard is based upon the following documents:

Six Months' Rule	Reports on Voting	Two Months' Procedure	Report on Voting
62B(CO)50 62B(CO)59	62B(CO)54 62B(CO)63	62B(CO)58	62B(CO)61

Further information can be found in the relevant Reports on Voting indicated in the table above.

This Particular Standard amends and supplements IEC Publication 601-1 (first edition 1977): Safety of Medical Electrical Equipment. Part 1: General Requirements, hereinafter referred to as the General Standard. The title of the General Standard will be changed in the next edition to read: Medical Electrical Equipment, Part 1: General Requirements for Safety. This change is anticipated in the title of this Particular Standard.

The numbering of sections, clauses and sub-clauses of this Particular Standard corresponds with that of the General Standard.

Sub-clauses or figures which 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.

In this standard, the following print types are used:

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

— explanations, advice, introductions, general statements, exceptions and references: in smaller type;

— *test specifications: in italic type;*

— TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD, IN IEC PUBLICATION 788 OR IN THIS PARTICULAR STANDARD: SMALL CAPITALS.

MEDICAL ELECTRICAL EQUIPMENT

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

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SECTION ONE — 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.

Notes 1. – The safety philosophy on which this Particular Standard is based is described in the Introduction to the General Standard.

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.

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: (1985)	Graphical Symbols for Use on Equipment. Index, Survey and Compilation of the Single Sheets
IEC Publication 613: (1978)	Electrical, Thermal and Loading Characteristics of Rotating Anode X-ray Tubes for Medical Diagnosis

IEC Publication 637: (1979)	Marking of and Accompanying Documents for X-ray Tubes and X-ray Tube Assemblies for Medical Use
IEC Publication 664A: (1981)	Insulation Co-ordination within Low-voltage Systems including Clearances and Creepage Distances for Equipment. First Supplement
ISO Standard 497: (1973)	Guide to the choice of series of preferred numbers and of series containing more rounded values of preferred numbers
ISO Standard 3665: (1976)	Photography — Intra-oral dental radiographic film — Specifications

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: (1973)	Radiation Protection in Medical X-ray Equipment 10 kV to 400 kV, and
IEC Publication 407 A: (1975)	First Supplement to Publication 407 (1973): Sub-clause 7.5.5: Equipment for Dental Radiography.

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 ±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.

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			
	50.0	0.16	0.14	0.12	0.10			
six peak twelve peak and up to constant potential	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			

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 ±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 theorem[1]*, 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.

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.

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