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

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MEDICAL ELECTRICAL EQUIPMENT
PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF CAPACITOR DISCHARGE X-RAY GENERATORS

Appareils électromédicaux
Deuxième partie: Règles particulières de sécurité pour groupes radiogènes à décharge de condensateur

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die Sicherheit von Kondensatorgeneratoren

BODY OF THE HD

The Harmonization Document consists of:

- IEC 601-2-15 (1988) ed 1; IEC/SC 62B, not appended

This Harmonization Document was approved by CENELEC on 6 December 1988.

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 1989-07-01

to publish their new harmonized national standard by or before 1990-01-01

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.

NORME INTERNATIONALE
INTERNATIONAL STANDARD

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Appareils électromédicaux

Deuxième partie: Règles particulières de sécurité pour groupes radiogènes à décharge de condensateur

Medical electrical equipment

Part 2: Particular requirements for the safety of capacitor discharge X-ray generators

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Clause

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for the safety of capacitor discharge 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.

PREFACE

This 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	Report on Voting
62B(CO)62	62B(CO)66

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

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 requirements of this Particular Standard take priority over those of the General Standard. The title of the General Standard was changed in the second edition (1988) 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.

The following IEC publications are quoted in this standard:

Publications Nos. 407 (1973): Radiation protection in medical X-ray equipment 10 kV to 400 kV.
407A (1975): First supplement: Sub-clause 7.5.5 — Equipment for dental radiography.
417 (1973): Graphical symbols for use on equipment. Index, Survey and compilation of the single sheets.
601-1 (1977): Safety of medical electrical equipment. Part 1: General requirements.
601-1 (1988): Medical electrical equipment. Part 1: General requirements for safety.
601-2-7 (1987): Medical electrical equipment. Part 2: Particular requirements for the safety of high voltage generators of diagnostic X-ray generators.
637 (1979): Marking of and accompanying documents for X-ray tubes and X-ray tube assemblies for medical use.
664 (1980): Insulation co-ordination within low-voltage systems including clearances and creepage distances for equipment.
664A (1981): First Supplement.
788 (1984): Medical radiology — Terminology.

MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for the safety of capacitor discharge 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 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.

Notes 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).

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.

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)*.

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.

* The second edition has been published in 1988.

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.

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.