IEC 60601-2-8

Edition 2.0 2010-11

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV

Appareils électromédicaux –
Partie 2-8: Exigences particulières pour la sécurité de base et les performances essentielles des équipements à rayonnement X de thérapie fonctionnant dans la gamme de 10 kV à 1 MV

IEC 60601-2-8:2010

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV

FOREWORD

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International Standard IEC 60601-2-8 has been prepared by IEC subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition of IEC 60601-2-8. This edition constitutes a technical revision which brings this standard in line with the third edition of IEC 60601-1 and its collateral standards.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62C/499/FDIS	62C/505/RVD

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

A list of all parts of the IEC 60601 series, published under the general title *MEDICAL ELECTRICAL EQUIPMENT*, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

X-RAY EQUIPMENT for RADIOTHERAPY purposes is used for TELETHERAPY, where the RADIATION SOURCE is far from the tissues to the treated (usually more than 50 cm), and also for BRACHYTHERAPY, where the RADIATION SOURCE is positioned within or adjacent to the tissue to be treated. This particular standard covers X-RAY EQUIPMENT for both TELETHERAPY and BRACHYTHERAPY.

The use of X-RAY EQUIPMENT for RADIOTHERAPY purposes may expose the PATIENT to danger if the equipment fails to deliver the required dose to the PATIENT, or if the equipment design does not satisfy standards of electrical and mechanical safety. The equipment may also cause danger to persons in the vicinity if the equipment itself fails to contain the radiation adequately and/or if there are inadequacies in the design of the TREATMENT ROOM.

This particular standard establishes requirements to be complied with by the MANUFACTURERS in the design and construction of therapeutic X-RAY EQUIPMENT. Subclause 201.10.1 contains limits beyond which INTERLOCKS prevent, INTERRUPT or TERMINATE IRRADIATION in order to avoid an unsafe condition.

Subclause 201.10.1 does not attempt to define optimum performance requirements. Its purpose is to identify those features of design that are regarded, at the present time, as essential for the safe operation of such equipment. It places limits on the degradation of equipment performance beyond which it can be presumed that a fault condition exists, e.g. a component failure, and where an INTERLOCK then operates to prevent continued operation of the equipment.

It should be understood that, before installation, a MANUFACTURER can provide a compliance certificate relating only to TYPE TESTS: data available from SITE TESTS should be incorporated in the ACCOMPANYING DOCUMENTS, in the form of a SITE TEST report, by those who test the equipment at installation.

MEDICAL ELECTRICAL EQUIPMENT –

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201.1 Scope, object and related standards

Clause 1 of the general standard[1)] applies, except as follows:

201.1.1 Scope

Replacement:

This international standard applies to the basic safety and essential performance of therapeutic X-RAY EQUIPMENT with NOMINAL X-RAY TUBE VOLTAGES in the range 10 kV to 1 MV when connected to alternating current SUPPLY MAINS, hereafter referred to as ME EQUIPMENT.

NOTE This standard covers TELETHERAPY and BRACHYTHERAPY.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular basic safety and essential performance requirements for therapeutic X-RAY EQUIPMENT. It includes the requirements for accuracy and reproducibility of performance to the extent that these are related to radiation quality and the quantity of ionizing radiation produced and thus must be considered as aspects of safety.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-3 and IEC 60601-1-10[2)] do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

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1) The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

2) IEC 60601-1-10, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other basic safety and essential performance requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). 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 or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

Clause 2 of the general standard applies, except as follows:

Addition:

IEC TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC 60601-2-1:2009, *Medical electrical equipment – Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV*

IEC 61217, *Radiotherapy equipment – Coordinates, movements and scales*

ISO/IEC Guide 98-3:2008, *Uncertainty of measurement – Part 3: Guide to the expression of uncertainty in measurement* (GUM:1995)

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC TR 60788:2004 apply, except as follows.

NOTE An index of defined terms is found beginning on page 33.

Addition:

201.3.201
BRACHYTHERAPY
RADIOTHERAPY using one or more RADIATION SOURCES with the RADIATION SOURCE/sources inside or close to the TARGET VOLUME

NOTE BRACHYTHERAPY techniques include INTERSTITIAL, INTRACAVITARY, SUPERFICIAL or INTRALUMINAL RADIOTHERAPY.

201.3.202
INTERSTITIAL RADIOTHERAPY
RADIOTHERAPY with RADIATION SOURCES inserted within the TARGET VOLUME

201.2.203
INTRACAVITARY RADIOTHERAPY
RADIOTHERAPY in which one or more RADIATION SOURCES, with or without SOURCE APPLICATORS, are introduced into a body cavity through a natural or artificial opening

201.3.204
INTRALUMINAL RADIOTHERAPY
RADIOTHERAPY in which one or more RADIATION SOURCES, with or without SOURCE APPLICATORS, are introduced into a body lumen such as a blood vessel, air way, or the gastrointestinal tract

201.3.205
SOURCE APPLICATOR
<BRACHYTHERAPY> device to bring one or more RADIATION SOURCES into the intended positions

NOTE A SOURCE APPLICATOR may include protective shielding.

201.3.206
TELERADIOTHERAPY
TELETHERAPY
RADIOTHERAPY with a large RADIATION SOURCE TO SKIN DISTANCE, usually not less than 50 cm

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

Additional subclause: