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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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

PRICE CODE
CODE PRIX

W

ICS 11.040.50

ISBN 978-2-88912-238-7

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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 –

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

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:

201.4.101 Conventional meaning of electrical quantities

In this particular standard, unless otherwise indicated, values of X-RAY TUBE VOLTAGE refer to peak values.

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.1 TYPE TESTS

Addition:

201.5.1.101 Test grades

Three grades of TYPE TEST and two of SITE TEST procedures are SPECIFIED in 201.10 of this particular standard; their requirements are as follows:

– TYPE TEST grade A: an analysis of ME EQUIPMENT design, as related to the SPECIFIED radiation safety provisions, which shall result in a statement included in the technical description, regarding the working principles or constructional means by which the requirement is fulfilled;

– TYPE TEST/SITE TEST grade B: visual inspection or functional test or measurement of the ME EQUIPMENT. The test shall be in accordance with the procedure SPECIFIED in this particular standard and shall be based on operating states, including fault condition states, which are achievable only without interference with the circuitry or construction of the ME EQUIPMENT;

– TYPE TEST/SITE TEST grade C: functional test or measurement of the ME EQUIPMENT. The test shall be in accordance with the principle SPECIFIED in this particular standard. The SITE TEST procedure shall be included in the technical description. When the procedure involves operating states that require interference with the circuitry or the construction of the ME EQUIPMENT, the test should be performed by, or under the direct supervision of, the MANUFACTURER or the MANUFACTURER'S agent.

Table 201.101 summarises the data required in the technical description to support Clause 201.10 SITE TEST compliance.

201.5.4 Other conditions

Addition:

aa) The ACCOMPANYING DOCUMENTS shall include

1) statements resulting from TYPE TESTS: grade A;
2) details of and results from TYPE TESTS: grade B and grade C;
3) SPECIFIC procedures and test conditions for SITE TESTS grade C;
4) instructions on how to generate a described fault condition or, if not practicable, how to generate a test signal as close as practicable to the source of the signal that would have generated it, with a statement confirming that the test signal simulates the one that would be produced in a particular fault condition;

   NOTE In some cases, one test signal may simulate more than one fault condition.

5) instructions on how to reset the ME EQUIPMENT for NORMAL USE after the completion of the SITE TEST and how to verify this condition.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

NOTE The person responsible for the SITE TESTS should record the results in a report which should be included with the ACCOMPANYING DOCUMENTS; in addition, the SITE TEST report should contain at least the following: name and address of the RESPONSIBLE ORGANIZATION site; MODEL OR TYPE REFERENCE of the equipment; name, status and employment address of all personnel taking part in the tests, and date of their participation; environmental and power supply conditions; the actual conditions, when test conditions, procedures or devices differ from those given by the MANUFACTURER, or where the information cannot be derived from this particular standard.

Table 201.101 – Data required in the technical description to support Clause 201.10 SITE and TYPE TEST compliance

Compliance subclause	Statement regarding data from TYPE TESTS grade A	Details of, and results from, TYPE TESTS or SITE TESTS grade B	Details of ,and results from, TYPE TEST grade C	SPECIFIC procedures and test conditions for SITE TESTS grade C
201.10.1.2.101		₸		
201.10.1.2.102		₸		
201.10.1.2.103.1	₸			
201.10.1.2.103.2		₸		
201.10.1.2.104		₸		
201.10.1.2.105.1	₸			₸
201.10.1.2.105.2	₸			₸
201.10.1.2.105.3	₸			₸
201.10.1.2.105.4	₸			₸
201.10.1.2.105.5	₸			
201.10.1.2.105.6	₸	₸		
201.10.1.2.105.7	₸			
201.10.1.2.105.8	₸			
201.10.1.2.106	₸	₸		
201.10.1.2.107	₸	₸		
201.10.1.2.108	₸			
201.10.1.2.109.1	₸			₸
201.10.1.2.109.2		₸		
201.10.1.2.109.3		₸ ₸		
201.10.1.2.109.4	b), d)	d)		a), b), c)
201.10.1.2.109.5		a), b), c), d), e), f)		
201.10.1.2.109.6	a), c)			a), b), c)
201.10.1.2.109.7	₸			₸
201.10.1.2.110.1	₸			
201.10.1.2.110.2.1	₸			₸
201.10.1.2.110.2.2	₸			₸
201.10.1.2.110.2.3	₸			₸
201.10.1.2.110.3.1	₸			₸
201.10.1.2.110.3.2	₸	₸		
201.10.1.2.110.3.3	₸			₸
201.10.1.2.110.4	₸			₸
201.10.1.2.110.5	₸			₸
201.10.1.2.110.6	₸			₸
201.10.1.2.110.7.1	₸			
201.10.1.2.110.7.2	₸			

Compliance subclause	Statement regarding data from TYPE TESTS grade A	Details of, and results from, TYPE TESTS or SITE TESTS grade B	Details of ,and results from, TYPE TEST grade C	SPECIFIC procedures and test conditions for SITE TESTS grade C
201.10.1.2.111.1	∓			
201.10.1.2.111.2	∓	∓		
201.10.1.2.111.3	∓	∓		
201.10.1.2.111.4	∓	∓		
201.10.1.2.111.5	∓			
201.10.1.2.111.6	∓	∓		
201.10.1.2.111.7	∓			
201.10.1.2.112.1				∓
201.10.1.2.112.2				∓
201.10.1.2.112.3				∓
NOTE ∓ requirement of subclause having no other identification.				

201.5.5 Supply voltages, type of current, nature of supply, frequency

Addition:

aa) For all tests for the measurement of AIR KERMA and AIR KERMA RATE in air for compliance with requirements on LEAKAGE RADIATION and stray radiation it is assumed that the SUPPLY MAINS used for the test is delivering its output at its nominal values.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2.2 Identification

Addition:

X-RAY TUBES and X-RAY TUBE HOUSING/assemblies shall be supplied to the RESPONSIBLE ORGANIZATION together with ACCOMPANYING DOCUMENTS.

Any information given on the X-RAY TUBE HOUSING shall not differ from that also given in the ACCOMPANYING DOCUMENTS and shall indicate accurately the data applying to the X-RAY TUBE assembled in the X-RAY TUBE HOUSING. It shall be the responsibility of the organization assembling the X-RAY TUBE into the X-RAY TUBE HOUSING to ensure that this information is accurate, and make such changes as may be necessary in the event of X-RAY TUBE replacement. See also 201.10.1.2.105.8.

X-RAY TUBES shall carry the following markings (not applicable to X-RAY TUBE ASSEMBLIES intended for BRACHYTHERAPY):

- name or trademark of the MANUFACTURER;
- MODEL OR TYPE REFERENCE;

- individual identification.

The above markings may be given in the form of a combined designation explained in the ACCOMPANYING DOCUMENTS.

X-RAY TUBE HOUSINGS shall carry the following markings (not applicable to X-RAY TUBE ASSEMBLIES intended for BRACHYTHERAPY):

– name or trademark of MANUFACTURER or supplier;
– type and SERIAL NUMBER of X-RAY TUBE HOUSING;
– maximum permissible voltage of X-RAY TUBE HOUSING.

X-RAY TUBE ASSEMBLIES shall carry the following markings (not applicable to X-RAY TUBE ASSEMBLIES intended for BRACHYTHERAPY):

– name or trademark of MANUFACTURER or supplier;
– type and SERIAL NUMBER of X-RAY TUBE;
– maximum permissible X-RAY TUBE VOLTAGE;
– nominal value of the permanent FILTRATION of the X-RAY TUBE ASSEMBLY in quality equivalent FILTRATION;
– position of FOCAL SPOT.

X-RAY TUBE ASSEMBLIES intended for BRACHYTHERAPY shall carry the following markings:

– type and SERIAL NUMBER of X-RAY TUBE ASSEMBLY;

The ACCOMPANYING DOCUMENTS of X-RAY TUBE ASSEMBLIES intended for BRACHYTHERAPY shall state:

– maximum permissible X-RAY TUBE VOLTAGE;
– nominal value of the permanent FILTRATION of the X-RAY TUBE ASSEMBLY in quality equivalent FILTRATION;
– position of FOCAL SPOT relative to the outside of the X-RAY TUBE ASSEMBLY.

NOTE Since X-RAY TUBE ASSEMBLIES intended for BRACHYTHERAPY are small and the X-RAY TUBE and the X-RAY TUBE HOUSING are of an integral design not intended to be serviced in the field it would be impractical and unnecessary to mark the tube and the housing separately.

The nominal value of the permanent FILTRATION in the SPECIFIED range of operating voltages shall be indicated in the form of quality equivalent FILTRATION as follows:

– in thickness of aluminium for therapeutic X-RAY TUBES for operation at voltages within the range from 10 kV up to and including 150 kV;
– exceptionally, in thickness of beryllium or another substance, e.g. molybdenum, for therapeutic X-RAY TUBES when the tube window is composed substantially of beryllium or this other substance;
– in thickness of copper for therapeutic X-RAY TUBES for operation at voltages within the range from 150 kV up to and including 1 MV.

Where there is a significant variation in permanent FILTRATION of the X-RAY TUBE over the entire range of voltages, this variation should be stated in the ACCOMPANYING DOCUMENTS.

In cases where, for convenience, permanent FILTRATION is indicated in thickness of other material, e.g. iron, the quality equivalent FILTRATION of aluminium or copper according to the operating range of voltages shall also be given.

201.7.2.6 Connection to the SUPPLY MAINS

Addition:

For therapeutic X-RAY EQUIPMENT that is SPECIFIED to be permanently installed, the information required in subclause 7.2.6 of the general standard need only be stated in the ACCOMPANYING DOCUMENTS.

201.7.2.7 Electrical input power from the SUPPLY MAINS

Addition:

For therapeutic X-RAY EQUIPMENT that is SPECIFIED to be permanently installed, the information required in subclause 7.2.7 of the general standard need only be stated in the ACCOMPANYING DOCUMENTS.

If compliance with this standard is to be marked on the outside of the X-RAY EQUIPMENT, such marking shall be made in combination with the MODEL OR TYPE REFERENCE as follows:

MODEL OR TYPE REFERENCE IEC 60601-2-8:2010

Marking indicating compliance of equipment, or subassembly thereof, with the requirements of this standard shall be made only if compliance of the ME EQUIPMENT or the subassembly is complete.

201.7.4 Marking of controls and instruments

Additional subclause:

201.7.4.101 Provision of scales and indications for moving parts

Each scaled DISPLAY of any value of a parameter relating to X-RADIATION output that is provided on the TREATMENT CONTROL PANEL shall have only one scale in a unit of only one kind and/or its decimal subdivisions.

Except for ME EQUIPMENT intended to be used as BRACHYTHERAPY devices, the following shall be provided:

a) a mechanical scale, or a numerical indication, for each available movement;

b) a LIGHT FIELD indication of the X-ray field, where an adjustable BEAM APPLICATOR is provided;

c) a mechanical scale, or a numerical indication, of the RADIATION SOURCE TO SKIN DISTANCE.

The designation, direction of increasing value and zero position of all movements shall comply with IEC 61217.

NOTE Since X-RAY TUBE ASSEMBLIES intended for BRACHYTHERAPY are placed inside the PATIENT or very close to the skin of the PATIENT the provisions required by this subclause are not relevant for this type of devices.

Compliance is checked by inspection.

201.7.8.1 Colours of indicator lights

Addition:

NOTE Subclauses 201.10.1.2.105.6 and 201.10.1.2.111 of this particular standard, and 7.8 and 15.4.4 of the general standard, deal with indicators and indicator lights.

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.1 General

Addition: