Irish Standard
I.S. EN 60601-2-8:2015&A1:2016

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

I.S. EN 60601-2-8:2015&A1:2016

Incorporating amendments/corrigenda/National Annexes issued since publication:

EN 60601-2-8:2015/A1:2016

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This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):

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National Foreword

I.S. EN 60601-2-8:2015&A1:2016 is the adopted Irish version of the European Document EN 60601-2-8:2015, 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

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-8:2015/A1

January 2016

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English Version

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 (IEC 60601-2-8:2010/A1:2015)

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/A1:2015)

Medizinische elektrische Geräte - Teil 2-8: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Therapie-Röntgeneinrichtungen im Bereich von 10 kV bis 1 MV (IEC 60601-2-8:2010/A1:2015)

This amendment A1 modifies the European Standard EN 60601-2-8:2015; it was approved by CENELEC on 2015-11-03. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment 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 CEN-CENELEC Management Centre or to any CENELEC member.

This amendment 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 CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

European foreword

The text of document 62C/593/CDV, future IEC 60601-2-8:2010/A1, prepared by SC 62C "Equipment for radiotherapy, nuclear medicine and radiation dosimetry", of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-8:2015/A1:2016.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2016-08-03
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-11-03

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s), see informative Annex ZZ, included in EN 60601-2-8:2015.

Endorsement notice

The text of the International Standard IEC 60601-2-8:2010/A1:2015 was approved by CENELEC as a European Standard without any modification.

In the Bibliography of EN 60601-2-8:2015, replace the existing reference to IEC 60601-2-17 by the following:

IEC 60601-2-17:2013	NOTE	Harmonized as EN 60601-2-17:2015 (not modified).

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-8

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English Version

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 (IEC 60601-2-8:2010)

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)

Medizinische elektrische Geräte - Teil 2-8: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Therapie-Röntgeneinrichtungen im Bereich von 10 kV bis 1 MV (IEC 60601-2-8:2010)

This European Standard was approved by CENELEC on 2015-04-14. 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.

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CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

The text of document 62C/499/FDIS, future edition 2 of IEC 60601-2-8, prepared by SC 62C, "Equipment for radiotherapy, nuclear medicine and radiation dosimetry", of IEC TC 62, "Electrical equipment in medical practice", was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-8:2015.

The following dates are 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)	2016-01-14
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2018-04-14

This document supersedes EN 60601-2-8:1997.

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This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 60601-2-8:2010 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

IEC 60601-2-17 NOTE Harmonized as EN 60601-2-17.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Annex ZA of EN 60601-1:2006 applies with the following exceptions:

Publication	Year	Title	EN/HD	Year
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	EN 61217	-
ISO/IEC Guide 98-3	2008	Uncertainty of measurement - Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)	-	-

Annex ZZ
(informative)

Coverage of Essential Requirements of EU Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and within its scope the Standard covers all relevant essential requirements given in Annex I of EU Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

NOTE Presumption of conformity with Essential Requirements 13.1 to 13.6 should depend on the manufacturer confirming the accuracy of the accompanying documents in all relevant languages.

WARNING: Other requirements and other EU Directives can be applied to the products falling within the scope of this standard.

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

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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

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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

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of 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, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). 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. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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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*